THROUGH THE LOOKING GLASS: RETURN TO PPV

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

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Wednesday, June 6, 2012

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

The Committee met, pursuant to notice, at 10:31 a.m., in Room 334, Cannon House Office Building, Hon. Jeff Miller [Chairman of the Committee] presiding.

Present: Representatives Miller, Lamborn, Roe, Flores, Johnson, Denham, Runyan, Brown, Reyes, Michaud, McNerney, Donnelly, Walz, and Barrow.

OPENING STATEMENT OF CHAIRMAN JEFF MILLER

The CHAIRMAN. Good morning, everybody. This hearing will come to order.

Before I begin, I want to note today's important place in the history of this Nation. It is the anniversary of the allied invasion of Normandy better known as D Day.

Nearly 160,000 troops bravely fought for and obtained a foothold in Europe that would prove pivotal to our victory. Many of these troops gave the ultimate sacrifice and to the veterans who took part, we say thank you.

This Committee will always remember the efforts of those who were there and we will work to ensure that we fulfill our obligations to them and all veterans.

I want to welcome everybody to this hearing this morning entitled Through the Looking Glass: Return to PPV. We are returning to our examination of VA's pharmaceutical prime vendor contract after the hearing we held back in February.

The PPV contract is the largest contract at VA valued around $4 billion. When executed correctly, the just in time delivery system of the PPV contract ensures that pharmaceuticals are delivered to VA's medical facilities in a timely fashion and at a competitive price.

As the February hearing revealed, an important aspect of the PPV contract was not executed correctly for a long period of time. A subsequent information request to VA spurred by a subpoena that was authorized by this Committee confirmed this suspicion.

When a needed pharmaceutical is either not available due to a supply shortage or not available through the PPV, federal acquisition regulations outline a clear path towards acquiring the pharmaceutical through an open market purchase.

The open market process provides protections through due diligence, competition, and a contract. The actions of purchasing officials at VA willfully ignores these protections and were, in fact, illegal.

In February, the illegal purchases were described as the routine way of doing business and according to the testimony we heard, no one within VA was held accountable.

Now that VA has had even more time to consider the actions of its employees, it is my hope that the illegal purchases are no longer occurring and that the many employees involved in this throughout the VA have been held accountable. The problem is neither of those outcomes appears to have been achieved.

While VA may boast about a reduction in unauthorized purchases of pharmaceuticals, this hearing is going to reveal that they still occur despite new training and policies throughout the entire department.

The VA also identified employees who made unauthorized commitments and the disciplinary course of action was letters of counseling where appropriate. Not much of a disciplinary action given the egregious violations that have been identified.

As VA will point out, there are ways outlined in federal acquisition regulation to review and ratify unauthorized commitments. The guidelines for ratification are clear. And I caution against anybody oversimplifying and misusing the ratification process as a way of dismissing the hundreds of thousands of unauthorized commitments made by VA employees.

I am further disappointed to know that there was strong push back from many within the department in implementing the new procedures intended to minimize the illegal purchasing of pharmaceuticals.

The illegal purchasing of pharmaceuticals does not help veterans. It is just another example of VA wishing to take the easy route instead of doing what is right and required as outlined in law, regulation, and VA policy.

Despite VA's new policies and procedures and occasional counseling letters, I remained very concerned that there will be employees who continue trying to find some type of work-around and that supervisors will not hold these employees or themselves accountable for their actions. The precedent of not holding anyone accountable is a bad one to continue to follow.

The fact is VA knew they were heading down a slippery slope with regards to pharmaceutical purchases back in the 1990s, yet it appears that minimal effort was made to address this until this Committee put its oversight spotlight on it over a decade later.

Many of those that did try to call attention to the problem were dismissed by their peers and even their supervisors for trying to do the right thing.

We already know the problems that exist. What we need to know now is not only the detailed action that has been taken to fix them but also how it will prevent these same problems from occurring again in the future.

It is my hope going forward that when VA identifies a problem just like this one, it is forthcoming with this Committee and Congress.

We look forward to working to fix them together. Receiving VA's testimony less than 24 hours before this hearing, however, does not help us in this effort.

With that, I yield to the gentle lady from Florida, the ranking member, Ms. Brown.

[The statement of Chairman Miller appears in the Appendix]

OPENING STATEMENT OF HON. CORRINE BROWN, ACTING RANKING DEMOCRATIC MEMBER

Ms. BROWN. Thank you, Mr. Chairman, and thank you for holding these hearings.

Before I begin, let me just say one of the most profound experiences that I have ever had in my life was going to Normandy and visiting the visitors center which I would recommend anyone if they have an opportunity to go to see the contributions that the men made to this country, not just to this country, but to the world. It was profound.

And I want to thank Mr. Obey who was Chairman of the appropriations during that time and Mr. Murtha who made it happen.

And for years when the families would visit Normandy, it was not a facility there for them to go and have a moment. And I can tell you the visitors center that is run by our Park Service in Normandy is something that the American people would be extremely proud of.

But back to this hearing. Like I said before, thank you for having it.

We just had one February the 1st, but today we are going to examine what steps the Department of Veterans Affairs have taken to correct problems identified in the pharmaceutical prime vendor, PPV, contract since the Committee February the 1st, 2012 hearing.

The hearing will also address concerns regarding the PPV contracts that have come to light since the hearing including accountability.

I believe it is important to hold follow-up hearings to examine if VA is making progress, but also to ensure that the recommendations that are implemented are effective, efficient, and being monitored for these purposes.

The recent IG audit shows that the VA fast pay system consistently provides payment within 48 hours to the PPV from the prime vendor shipment of the order. VA was paying the accurate amount for accurate goods received. VA was processing payment to the PPV in accordance to the law, regulations, and current terms of the PPV contract. VA was reimbursing by other government agencies in a timely and accurate fashion. All very positive steps.

However, the audit report determined that the VA did not have reliable controls to ensure timely corrections of improper payments. This is not a new issue for VA. Lack of management control and not following established process procedure is a common theme in many former reports as well.

The VA has proven that when determined to make correction action, they can successfully implement measures to do so. I do not understand why the VA has to wait for a hearing or the IG audit report for them to take these measures.

Additionally, I would like to hear from VA what action it took with about how the National Acquisition Center PPV contracting officer who did not execute his responsibility properly for several months effectively stopped the process put in place. Was this individual recommended to provide additional training removed from his post?

Finally, I am looking forward to hearing from VA on progress made since the last hearing to prevent unauthorized purchases through the PPV contract and how the new agreement differs from the previous contract because I understand that the same company got the contract.

I want to thank you and I yield back the balance of my time.

[The statement of Ms. Brown appears in the Appendix]

The CHAIRMAN. Thank you very much.

And the first panel at the table this morning, we are going to hear testimony from the Honorable W. Scott Gould, deputy secretary of Veterans Affairs. He is accompanied by Mr. John Gingrich, chief of staff; Philip Matkovsky, assistant deputy under secretary for Health for Administrative Operations; Mr. Glenn Haggstrom, executive director of the Office of Acquisitions, Logistics, and Construction; Mr. Jan Frye, deputy assistant secretary for the Office of Acquisition and Logistics; Steven Thomas, director of the National Contracting Service at the National Acquisition Center; and Michael Valentino, chief consultant of the Pharmacy Benefits Management Services.

All of the individuals that I have just identified, I would like to ask if you would rise because I intend to swear you in. If you would raise your right hand.

[Witnesses sworn.]

The CHAIRMAN. Thank you.

Deputy Secretary Gould, your complete written statement as customary in this Committee will be made a part of the official hearing record and you are recognized for five minutes. Thank you.

TESTIMONY OF THE HONORABLE W. SCOTT GOULD, DEPUTY SECRETARY OF VETERANS AFFAIRS, U.S. DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY: JOHN R. GINGRICH, CHIEF OF STAFF, U.S. DEPARTMENT OF VETERANS AFFAIRS; PHILIP MATKOVSKY, ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH FOR ADMINISTRATIVE OPERATIONS, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; GLENN D. HAGGSTROM, EXECUTIVE DIRECTOR, OFFICE OF ACQUISITIONS, LOGISTICS, AND CONSTRUCTION, U.S. DEPARTMENT OF VETERANS AFFAIRS; JAN R. FRYE, DEPUTY ASSISTANT SECRETARY, OFFICE OF ACQUISITION AND LOGISTICS, U.S. DEPARTMENT OF VETERANS AFFAIRS; STEVEN A. THOMAS, DIRECTOR, NATIONAL CONTRACTING SERVICE, NATIONAL ACQUISITION CENTER, U.S. DEPARTMENT OF VETERANS AFFAIRS; MICHAEL VALENTINO, CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT SERVICES, U.S. DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF W. SCOTT GOULD

Mr. GOULD. Chairman Miller, thank you for that courtesy.

And Ranking Member Brown and Members of the Committee, thank you for the opportunity to appear before you here today to discuss VA's pharmaceutical prime vendor program and our very measurable progress towards improving internal controls since we first put corrective actions in place in November.

Thank you for introducing the fellow panel members. I would also like to add seated behind me are Mr. Craig Robinson from the National Acquisition Center and Phillipa Anderson from VA's Office of General Counsel.

The subject of today's hearing concerns the management and administration of the pharmaceutical prime vendor contract. But before we dive into the subject of pharmaceutical contracting, I would like to say that pharmacy is an essential part of our health care operations.

Pharmacy personnel filled 137 million prescriptions last year alone. They won the J.D. Power customer satisfaction best of the best rating for the last three years in a row and they have held administrative costs per prescription filled basically level for a decade.

I believe it is fair to say that they have set a pharmacy and clinical benchmark in the industry and that is widely recognized.

Now, returning to the pharmaceutical prime vendor contract or PPV as we know it, the PPV provides warehouse and shipping services for pharmaceuticals and related medical products to every VA location across the U.S. and around the world.

The company that provides these services is McKesson. Working with VA, McKesson fulfills over a half million line items of activity per month.

Last year, the month of September, VA discovered that about 70,000 of these transactions were unauthorized commitments. This means that the commitments to purchase items, excuse me, from the contract were not accomplished in compliance with all applicable law and regulation.

The scope of the problem and the corrective actions taken by VA in November of 2011 were reported in testimony before this Committee, as Ms. Brown pointed out, in February of this year. Since then, we have taken continued action including the following.

We changed—made changes to the portal that prohibit unauthorized purchases directly through this venue.

We have increased management oversight of ordering officer activities by both automated and manual processes.

We have improved training for ordering officers and other VA personnel.

We have escalated actions to hold noncompliant personnel accountable including extensive counseling, focused retraining for 81 individuals, entry of counseling letters in personnel files for 15 personnel which we all know affects their opportunity for promotion, suspension of 48 hours of ordering responsibilities for two ordering officers, and in one case resignation in lieu of termination.

In addition, VA has reduced the total number of employees authorized to make commitments on the PPV from nearly 2,000 to less than 1,000.

We have also expanded the number of drugs available on the contract markedly.

We have completed competition of a contract under new and more restrictive terms that was awarded in April of 2012 and will go into effect in August of this year.

I might point out that we believe that contract will save an additional $150 million a year, and we are in the process of ratifying all transactions under the FAR to ensure that the vendor acted in good faith and that the goods were provided and fair value received by VA.

Front-line employees continue to respond well to this new direction and oversight. In fact, these actions have already achieved a dramatic reduction of unauthorized commitments from 70,000 line items per month to less than 450 line items per month. That is 450 out of a half million transactions.

The overall trend continues downward and we are working hard to change practices that existed at VA for over 17 years. And we will achieve our goal of full compliance with the FAR.

Throughout this process, the discussion that we are about to have about the contract and its administration, we have been working to make sure that our overriding operational goal is met which is to provide safe, timely deliverables of pharmaceuticals to our veterans where and when they are needed.

Mr. Chairman, my colleagues and I thank you for your continued interest in our progress on the PPV contract and we are prepared to answer your questions.

[The statement of W. Scott Gould appears in the Appendix]

The CHAIRMAN. Thank you very much.

Are you aware that VA has continued to purchase thousands of pharmaceuticals even though the practice was said to have stopped in November of last year and one of the ways VA has done this is by ordering drugs through a third party with whom VA has no relationship?

And it appears, and, Ms. Brown, you asked me about the little drawing that I laid on everybody's desk, this is one of the work-

arounds that we have found. The veteran asked VA for a drug. It appears that VA orders the drug through a third party who then goes to McKesson. And then, of course, the order is drop shipped directly to the veteran. VA never verifies that the drug is safe, accurate, or where it comes from.

So is that a common practice within VA to go to a third party to order from McKesson?

Mr. GOULD. Mr. Chairman, we are a Fortune 10 company with 300,000 employees and $130 billion a year budget. The chart in my written testimony shows a dramatic decrease in the number of unauthorized commitments from over 70,000 to less than 450.

In my view as a senior manager in the private sector and as chief operating officer of VA, I believe this is clear unequivocal evidence that we get it, that change is happening, and our employees are responding.

The CHAIRMAN. First of all, you are not a Fortune 10 company. You are a government agency.

Mr. GOULD. With the equivalent size of a Fortune 10 company, that is correct, sir.

The CHAIRMAN. My question is, has or does VA use a third-party company to order through to bypass laws, rules, and regulations to order from McKesson?

Mr. GOULD. Mr. Chairman, I would like Michael Valentino to address that issue.

Mr. VALENTINO. Thank you.

What you are referring to is a drop shipment provision or sometimes called a pass-through provision which is part of the pharmaceutical prime vendor contract. It is a—it can be a legitimate process for moving heavy, bulky products from the manufacturer to the VA site. I can give you an example.

IV fluids are essentially water. If you try to move them from the manufacturer to the prime vendor to the VA, you add a lot of expense. So we have set up in collaboration with the National Acquisition Center a process where we place the order with the prime vendor. The prime vendor places the order with the manufacturer. That product is then shipped directly to our facilities and the payment goes through the prime vendor.

The CHAIRMAN. So the order goes to the prime vendor or goes to the third party?

Mr. VALENTINO. In this situation, it is my understanding that the order goes to the prime vendor.

The CHAIRMAN. Why would the third party be necessary and who is that third party?

Mr. VALENTINO. Well, in this situation, the third party is the manufacturer. So we order it from the prime vendor. The prime vendor sends that notification to the manufacturer who then ships it to our location.

The CHAIRMAN. Okay. First of all, I do not believe that IVs are considered pharmaceuticals. They may be, but I do not believe they are.

I am talking specifically about pharmaceutical drugs going to a third party and going back door to the prime vendor. Why would you need to do that?

Mr. VALENTINO. Well, there are other situations——

The CHAIRMAN. No. Specifically regarding drugs.

Mr. VALENTINO. Yeah. Yeah. I will address that.

The FDA for a variety of reasons usually based on safety has identified a small number of drugs that can only be ordered through specialty distributors or through their own facilities. Those drugs cannot come into the possession of the prime vendor.

So these are drugs typically on VA contract. There is a federal supply schedule contract for those. And we have worked that issue with the National Acquisition Center where, again, we follow the same procedure as with the IVs but for a pharmaceutical product.

So we will order it from the pharmaceutical prime vendor. They will notify the manufacturer or the specialty distributor. They will ship that product back to us and they will——

The CHAIRMAN. And it is your testimony that that is exactly the way it occurs?

Mr. VALENTINO. To the best of my knowledge, that is the exact way that it occurs for those specialty distribution drugs.

Now, it is true there could be situations where those procedures have not been followed. Perhaps there is a situation where it is a non-contract drug that we have arranged to be drop shipped and we have not followed appropriate procedures.

We believe that in March, that may have occurred ten times out of 500,000 line items. We are in the process of investigating that trying to find out exactly what happened. We do not know at this point.

The CHAIRMAN. Mr. Gingrich, who is Mel Noel; do you know?

Mr. GINGRICH. No, sir.

The CHAIRMAN. Does anybody at the table know who Melbourne Noel is?

Mr. VALENTINO. Yes, I do. Mel Noel is a VA attorney with the Office of General Counsel.

The CHAIRMAN. If somebody in the Office of General Counsel wrote a memo, would you expect that to be a truthful memo and would you trust the validity of the recommendation by somebody like Mr. Noel?

Mr. VALENTINO. Are you asking me, sir, or——

The CHAIRMAN. I am asking anybody that wants to answer, but I will direct it to you, sir.

Ms. BROWN. Mr. Chairman, did he see the memo?

Mr. GINGRICH. I have not seen the memo.

The CHAIRMAN. Okay. Ms. Brown, let me go ahead and thank VA very much for providing us all of this information. As the Members of this Committee know, we did, in fact, vote to issue a subpoena to the VA. We ended up not submitting the subpoena to the VA with the agreement that VA—Ms. Brown, I am answering your question—with the understanding that they would provide information to us.

One of the things that was provided to us, Ms. Brown, was a memo and this goes to show the Committee how far back this problem goes. This is not just this Administration. This is not just the previous Administration. This goes back to a previous Administration before that one.

But there was a memo that was written by a group of people including Mr. Noel. There are three attorneys on this memo that ba-

sically say the current—this was the contract that we were talking about—the current pharmaceutical prime vendor solicitation includes an open market item provision that was found to be unobjectionable by the 025 NAC and although we warned them that including open market items was risky and pushing the envelope.

Additionally it says that representatives ordering from a PPV or a med surge distributor should still comply with FAR 13.2 actions at or below the micro purchase threshold.

So what I am trying to lay out for the Committee is that this goes back a considerable length of time. And it is interesting that nothing was done until this issue was raised. And all of a sudden, a precipitous drop occurred even though the activity had been going on for well over a decade.

And we hear people minimizing by saying that there were only ten purchases out of 500,000 purchases. I can promise you that we will show information today that will prove that that is not true, that veterans' health has been put at risk, that there have been incidents whereby the VA did not comply with Trade Agreement requirements, and that there were drugs that were, in fact, purchased that we do not know where they came from.

And with that, Ms. Brown, you are recognized.

Ms. BROWN. Thank you, Mr. Chairman.

Mr. GOULD. Mr. Chairman, may I respond briefly to that——

Ms. BROWN. Yes, please.

Mr. GOULD. —please? Thank you, Ms. Brown.

First of all, Mr. Chairman, if you do have any information that would be helpful to us in establishing accountability or further understanding this issue, we are open to it. To the best of my knowledge, you have not communicated that to the VA.

The CHAIRMAN. Will the gentleman yield?

Ms. BROWN. This is my turn.

The CHAIRMAN. Will the gentleman——

Mr. GOULD. If I may just and I just——

Ms. BROWN. I would like for him to finish his statement.

Mr. GOULD. I think there is an—there is certainly a duty—there is a duty to share that information——

The CHAIRMAN. The Chairman takes the chair back.

Mr. GOULD. This is——

The CHAIRMAN. The Chairman takes the chair back. Mr. Gould——

Mr. GOULD. Mr. Chairman——

The CHAIRMAN. No, ma'am. The Chairman takes the chair back.

You provided this information to me. Your office provided this information.

Ms. BROWN. This is bullshit.

The CHAIRMAN. Do not try to imply that I am trying to bring something to you that you are not aware of. The people behind you sitting behind you, sir, gave us this information. It came from your office.

Mr. GOULD. Mr. Chairman, we provided over 40,000 emails at the Committee's request. I assume that you have been through the bulk of them and may now have some issues that you want to raise

with us. I hope that is a two-way process and that we have an opportunity to defend ourselves in this process.

No one on this Committee is here—no one on this panel is here to mislead this Committee in any way. And I am not aware what—what is the date of that document that you are sharing?

The CHAIRMAN. 1998, sir.

Ms. BROWN. Bullshit.

Mr. GOULD. 1998. Well, none of us here——

The CHAIRMAN. Excuse me. Mr. Gould——

Mr. GOULD. —none of us on this panel were——

The CHAIRMAN. —would you excuse me just a minute? I would like the lady's words taken down. Will you please read back exactly what the ranking member just said?

Ms. BROWN. Yes, do that.

The CHAIRMAN. The Committee will stand in recess.

Ms. BROWN. Yes. I apologize, I apologize that we are here on a witch hunt.

I apologize for saying bullshit and apologize that we are here on a witch hunt when we should be doing the veterans' business. Yes, I apologize.

The CHAIRMAN. Thank you very much.

I would like for the record, though, that that information be provided as quickly as possible to this Committee.

Mr. Gould, you may continue.

Mr. GOULD. Thank you, Mr. Chairman.

I am sorry. I was under the impression that Ms. Brown was about to have the floor. Is that——

Ms. BROWN. I yield my time to you. Do I still have time? Okay. I yield my time to you to respond, sir.

Mr. GOULD. Thank you, ma'am.

Ma'am, I would just say that this team identified the problem. We took decisive action. What you see is evidence of strong, positive results reducing from over 70,000 unauthorized commitments to less than 450.

We believe we are on the right track and that we are handling it in the right way with a tiered approach to training, counseling, and, frankly, sanctions that we have taken. And that has been a part of the reason for our very substantial progress over the last five months.

Ms. BROWN. Sir, I have another concern which is going the other way. You have gone from 2,000 to 1,000 people that have the authorization to issue these pharmaceuticals.

I want to make sure that the veterans receive their medication in a timely fashion. And you all do a good job in this particular area. And I am concerned that—first of all, the question was whether or not the veterans ask for the medication.

Is that the procedure?

I would think that physicians write the prescriptions and then they order it from the pharmaceuticals. But help me with this process because something must be missing here because I do not think that veterans directly go to the pharmaceuticals and request any medication.

Mr. GOULD. No, ma'am. That——

Ms. BROWN. Help me with the procedure. Help me. What is going on in the process? I need to understand. I must be missing something here.

Mr. GOULD. So our number one goal is to make sure that veterans who need medicine get it promptly. And the whole idea behind the PPV contract is that it is delivered in basically 24 hours under a watchful eye of physicians and pharmacists who make sure that the right drugs according to our formulary are delivered promptly.

I would invite Mr. Matkovsky and Mr. Valentino to describe how that process looks at the bedside and then leads to the purchase and finally the delivery of the drugs to the veteran.

Ms. BROWN. Thank you, sir.

Mr. VALENTINO. You are exactly right. When a patient elects to receive care from VA, they are assigned a primary care provider who evaluates them and their medical conditions, decides on a course of therapy.

If that therapy involves pharmaceuticals, they write a prescription. That prescription is reviewed by a pharmacist. That data is entered into our electronic medical record and the prescription is provided to the veteran.

Now, in between writing the prescription and having it provided, there is the ordering process and the things that we are talking about today.

Ms. BROWN. Yes, sir.

Mr. MATKOVSKY. Sorry. We did, in fact, introduce greater rigor in the ordering process, so there are specific ordering officials. The number of people who had the authority to order was reduced.

Ms. BROWN. From 2,000 to 1,000?

Mr. MATKOVSKY. Under 1,000, yes.

Ms. BROWN. Under 1,000. Did that slow down the delivery to the veteran?

Mr. MATKOVSKY. It required us to change our work patterns to make sure that folks were dedicated to this activity as opposed to performing this among other duties. It changed the way we staffed it and it required us to have additional resources to staff that function.

In addition, we added contracting officer representatives with explicit delegation of authority to review the invoicing process. Again, an additional resource required to review that more formally.

So a reduction in the staff, an increased focus on the staff performing this function in lieu of any other functions, and then an additional supervisory activity for contracting officer representatives.

Ms. BROWN. Thank you.

And I yield back.

The CHAIRMAN. Mr. Frye, if you would, explain to us how a proper supervisor would screen a purchasing order.

Mr. FRYE. Well, again, I am not in the pharmaceutical business, but I go back to my experience of nearly 30 years in supervisory positions.

I think it is as simple as this and I will add that we looked at the way VHA was doing it at the Washington Hospital. I sent my staff out to—and they spent an entire day with the pharmaceutical

personnel. And the system worked very well and it was very simple.

An ordering officer prepared an order and the supervisor of that ordering officer looked at the order to make sure that there were not drugs on it that were not authorized and then the supervisor authorized the order of those drugs.

So I think it is really a pretty simple thing from my viewpoint and based on what my staff told me. And I was very complimentary of VHA in the Washington Hospital situation.

The CHAIRMAN. If you would, to Ms. Brown's point, I think she is referring possibly to the warrants being removed from—I think that is what she was driving at.

But emails that were received by this Committee from VA, you were noted as attempting to remove warrants from about 2,000 contracting officers who were not acting in accordance with the law.

And I want to know how many of those 2,000 contracting officers actually lost their warrants.

Mr. FRYE. This is an ongoing process. We have been at it for about two and a half years. Back in 2007, the rules changed for contracting officers. Contracting officers have to be certified in accordance with the federal acquisition certification contracting.

They are certified at three levels and in order to be certified, you have to have educational credentials. You have to have certain training and certain experience.

So as we looked at VHA's contracting officers, we found that there were quite a number of them that did not qualify to be contracting officers.

I would add that most of these were not in the pharmaceutical arena, however. Most of these were in the prosthetics arena.

We still have not accomplished the withdrawal of all of those folks who we do not deem to be totally qualified. However, we have got a plan in place and we plan to have them removed from their positions and——

The CHAIRMAN. My question——

Mr. FRYE. —repurposed in other ways by the end of the fiscal year.

The CHAIRMAN. If I could, my question was, how many of those 2,000 that you recommended have actually lost their warrants?

Mr. FRYE. I think last I knew, and Mr. Matkovsky might be able to shed some more light on it, I think we are down to about 1,700.

The CHAIRMAN. Okay. Dr. Roe.

Mr. ROE. I thank the gentleman for yielding.

I am trying to get my arms around exactly a couple things here.

One, why did it take 17 years to bring this to light?

I mean, it seems to me like that the procedures that you are implementing now protects everybody. It protects the patient. It protects the VA. It protects the system. It protects everybody in the system.

Why did it take 17 years to do this, Mr. Gould?

Mr. GOULD. Sir, the hardest problem in a large organization is to find something that is not a problem from the operational perspective. So what we saw was superb cost control, delivery within

24 hours, high-quality drugs going to the veterans where and when they needed them, the right place at the right time.

So when this finally was raised to our attention——

Mr. ROE. Let me interrupt you. How would you know that there are high-quality drugs going to veterans when you clearly—right here we clearly—the Trade Agreement Act clearly states that you cannot get drugs in certain countries because we do not have any way to know and, yet, those drugs are being shipped, because I have got some emails here that say they have been, to veterans? So how would you know?

Mr. GOULD. Well, we have terms and conditions in our contract that require compliance with all of those elements.

Mr. ROE. But that was not happening, though. My point is——

Mr. GOULD. I would like to ask Glenn Haggstrom to respond to your question directly——

Mr. ROE. Okay.

Mr. GOULD. —because it clearly was not the case that we were in violation of the Trade Act Agreement.

Mr. ROE. Well, I have got some emails here that said you are from you all.

Mr. GOULD. And through this group of expert panel—I do not know where you got your emails. Again, sir, if there is anything that would help us do our job better, please disclose and let us know.

Mr. ROE. We will definitely.

Mr. GOULD. But we reviewed 16—we reviewed 17 contracts for that, 16 of the 17, I believe, if my memory serves——

Mr. ROE. So if there is a drug that has been sent to a veteran through this process that was produced in India which is not part of the Trade Agreement, maybe we should change that act. I mean, I am not saying we should not. And maybe those drugs are safe. The point is you would not know it.

Mr. HAGGSTROM. Mr. Roe, I think when we discussed this the last time and in our work with McKesson, there is two issues at hand here. One is a Trade Agreement Act which when we do a contract in the government, if that contract has a life cycle value of over $203,000, the Trade Agreement Act clauses kick in.

I think what Mike Valentino explained at our last panel was also there is an issue of even though a country may—we may not have a Trade Agreement Act with the country, that does not mean that that country does not have laboratories that have been certified by the FDA to make drugs in compliance with our processes.

So that while we may not purchase drugs with a Trade Agreement Act country through a contract, we may still obtain those drugs——

Mr. ROE. But how do you know that?

Mr. HAGGSTROM. I would have to ask Mr. Valentino.

Mr. ROE. I mean, you can say that, but how do you know you did that?

Mr. VALENTINO. As we heard from McKesson at the last hearing, they were the drugs directly from the manufacturer or the manufacturer's authorized distributor. And they only purchase drugs that are manufactured in FDA approved manufacturing plants.

So when we were ordering these non-contract drugs through McKesson, these are the very same drugs that they are providing to a CVS——

Mr. ROE. So this little drawing is inaccurate where someone would—I as a doctor would write a prescription for this patient down here, this veteran, and VA would then go over here to the—a non-contract company which would then send it back to McKesson. That is not the way it works?

Mr. VALENTINO. I cannot——

Mr. GOULD. Share a copy with us, it would——

Mr. ROE. It may be wrong.

Mr. GOULD. —very helpful.

Mr. ROE. I mean, this could be in error here.

Mr. VALENTINO. I think one of the hard——

Ms. BROWN. Mr. Chairman, he has not seen it. Okay. Thank you. If you want to question him——

Mr. ROE. Excuse me, but reclaiming my time. Anyway, if that is the way, maybe we are understanding it wrong. And then while you are looking at that——

Mr. GOULD. Mr. Roe, I would just point out that the drugs that we have for our veterans are as safe or safer than the drugs that are received all across America. And if there is a question here that you may have with the larger pharmaceutical system——

Mr. ROE. No, no, no, that is not it. I mean, my question is, again, your internal controls, how do you know that this is, because of what you said about how McKesson did? Okay. Then we will go into that later.

Mr. GOULD. Well, actually, we have got an answer for you here.

Mr. ROE. Okay.

Mr. VALENTINO. So this looks to me as if it were a diagram outlining the drop ship issue which we addressed earlier. If this were what we are talking about, the arrow would be from VA to McKesson.

Mr. ROE. So if I write a prescription to this veteran down here and it is not in that particular formulary that you have, it does not do this then? You are telling me this is wrong?

Mr. VALENTINO. This does not—this describes the drop ship issue, not——

Mr. ROE. That is what I am speaking of. If I write a prescription for a drug that is not in the formulary, not in the VA formulary, then what happens to it?

Mr. VALENTINO. Well, just because the drug is not on the VA formulary does not mean that McKesson does not stock it. They stock virtually everything, formulary or not formulary, and we ordered it primarily through them. It just was not in conformance with the FAR. It was a non-contract purchase.

But McKesson purchases drugs directly from the manufacturer, drugs that are FDA approved for use in this country, drugs that are manufactured in FDA approved plants. They do not procure private products from the gray market or secondary market.

So they have an assurance that the drugs that they are buying and putting on their shelves to distribute to VA and other organizations, Walmart, Costco, CVS are high-quality drugs.

Mr. ROE. Okay. We will have a chance.

I yield back. Thank you.

The CHAIRMAN. Mr. Walz.

Mr. WALZ. Well, thank you, Mr. Chairman.

And thank you all for being here.

I, too, like Dr. Roe, I am just trying to get my mind wrapped around everything.

Deputy Secretary Gould, what is the purpose of PPV in your opinion?

Mr. GOULD. Sir, it is to get the right drugs in the right place within 24 hours that our physicians and pharmacists in the field want to get for a particular veteran. So it is health care, it is quality, and it is getting it there quickly.

Mr. WALZ. But with a recognition that you cut back on the number of people who were able to do that? Is it your opinion that it was being used in times that it was not necessarily doing that?

Mr. GOULD. My sense is that with the new processes, training, and technology that we have, we can accomplish that same mission to the same standard with fewer people.

So what we are trying to do is bring into balance our overriding operational need, make sure veterans get the right drug at the right time, but make sure that we are being as efficient as we can and also responding to the requirements of the FAR so that we can avoid this problem in the future.

Mr. WALZ. Well, that is the way I see it. Our mission here, obviously it is patient-centric. What is best for the patient is what is best in this case.

Mr. GOULD. Yes.

Mr. WALZ. Making sure safety is adhered to is the questions that were being asked, a cost-benefit analysis to see if we can do it in the most cost-effective manner to the taxpayer——

Mr. GOULD. Yes.

Mr. WALZ. —while addressing some of those market fluctuations, drug shortages, and those types of things.

Mr. GOULD. That is correct.

Mr. WALZ. And we can do that in the manner. Is it fair though that the Committee's concern that this was operating outside of accepted practice, that the potential for abuse was here? Is it safe to say that?

Mr. GOULD. We are concerned about the fact that there were unauthorized commitments being made in the system and that is why together with training, focus on personnel and accountability, new systems, new business process, procedures, and management oversight, we have been able to lower that from 70,000 down to under 450. So we are on track and we are doing the right thing. And we continue to go at our goal of zero unauthorized commitments.

Mr. WALZ. And I certainly appreciate that. I guess I am concerned. I am hearing things and a Committee that is usually not very contentious, you can certainly obviously feel it in the air.

My concern is I have not seen any of these emails. I do not know them. Some of this was delivered yesterday apparently and they are going through discs to try and get them here. It is very hard to ask about this.

Is there a legitimate question on safety concerns or does it go back to your previous answer that the broader pharmaceutical

market and how they work is very similar to how it is working in VA?

I am concerned with Dr. Roe's question that was there potential for unsafe drugs getting in veterans' hands.

Mr. GOULD. And, Mr. Walz, to the best of my knowledge, we have a safe veteran-focused system. You have got some of our leading experts at the panel here today.

And I would just like Mike Valentino and others at the table to weigh in on that issue. We think we are the benchmark in the industry for pharmacy and clinical practice and we will stand by that.

Mr. VALENTINO. I would say that I have no concerns about the safety of our drug supply because of the way we order drugs now and the way we have ordered them in the past.

But I would point out that despite rigorous FDA review and approval, drugs do get into the marketplace that ultimately after they are in wide use are found to be problematic and are withdrawn from the market due to safety reasons. So I will make that distinction.

I am not concerned over the safety of our products because of the way we order them, but from time to time, and we know the drugs that I am talking about, they get out on the market, they cause harm, and they are withdrawn.

Mr. WALZ. I got this yesterday, the most requested, top five most purchased items, cost, and all of that.

Are the drugs being requested predominantly on PPV drugs that are not in the formulary as was previously asked or are at times they are on the formulary and they just went around to do it this way?

Mr. VALENTINO. It is a combination. Sometimes these are drugs that are on the formulary. A very common example is a generic drug where we have attempted to put a contract in place and we have not been successful. We had not gotten sufficient bids to do that. So this could be a very common formulary drug for which we do not have a contract and we would have to order it through another mechanism.

Mr. WALZ. You may not have the data and, Deputy Secretary Gould, you may not have this in there, but is the VA's purchase of drugs more cost effective than say Medicare? Is the VA's purchase of drugs more cost effective than a private sector insurer hospital, if you could?

Mr. VALENTINO. VA has some of the lowest drug prices available anywhere. This would even include other countries where they do index pricing. So——

Mr. WALZ. Is PPV part of the reason that it is cheaper?

Mr. VALENTINO. It is part of the reason. It is not the primary reason. The primary reason is because of the agreements we have with the manufacturers because we will guarantee a certain amount of utilization.

Mr. WALZ. So we should try and utilize those as often as possible, right, because our argument has always been that negotiations on drug prices at Medicare would be a way to lower health care costs? Do you think VA proves that to be true?

Mr. VALENTINO. I think we have a very robust system. We have an extremely good track record of keeping our costs very low and providing high-quality services.

Mr. WALZ. My final question, and I know I have run over time just a minute, do we ever get drugs cheaper by going PPV than we would off of a negotiated contract or is it always going to be more?

Mr. VALENTINO. Well, let me answer that two ways. We always want to follow the procurement hierarchy which is national contract, FSS on down as we have heard.

Yes, there have been times when we have been able to—when the price that we paid for a drug through a non-contract purchase was cheaper than through the procurement hierarchy. That is not why we want to do it. That is just sort of an incidental impact of what we do. But we believe in the hierarchy and we try to follow the hierarchy.

Mr. WALZ. I will yield back, Mr. Chairman. Thank you for the extra time.

The CHAIRMAN. Thank you, Mr. Walz.

Very quickly and I am just trying to get a handle.

And also, Mr. Walz, I would let you know we have been getting data dumps by disc for about three months from VA. And we have made all of that information as we got it available to the minority staff. So, you know, it has been coming in your direction.

There is a memo from November 7th, 2011, the PPV integrated product team. And I am trying to figure out. On the last page, there was open discussion and it says that L. Schwartz asked if TAA compliance was part of the McKesson PPV contract. And the answer was TAA compliance is required for contract items but not open market.

Could you explain the difference and why TAA compliance is not required?

Mr. HAGGSTROM. Mr. Chairman, I think as we talked earlier, TAA compliance kicks in when the value of the contract exceeds $203,000. Below $203,000, the Trade Agreements Act does not have an effect on our a contract for the Federal Government.

The CHAIRMAN. So if the contract was less than that——

Mr. HAGGSTROM. For an open market contract less than $203,000, the Trade Agreement Act would not be applicable.

The CHAIRMAN. Okay. Mr. Runyan.

Mr. RUNYAN. Thank you, Mr. Chairman.

I just want to touch on one thing I think we bring up every time we have a hearing like this. And I think coming, Secretary Gould, from your boss, Secretary Shinseki, is accountability.

And we talk about it all the time and you just brought it up, brought an example up where you had contracting officers that were not qualified to be a contracting officer.

Where is the accountability? Where is the teeth of people motivated fearful of losing their position?

I mean, you stated earlier that training, counseling, sanctions. I mean, I know sometimes people are going to lose their jobs. And I think a lot of times we shy away. And I think the secretary agrees with the statement that people need to do their job or bad things are going to happen to them.

I know in my life, fear is a hell of a motivator and then having consequences to your actions a lot of times keep people doing the right thing.

I mean, when you say the word sanctions, can you elaborate on that a little bit? What are the teeth? I mean, I know we deal with it, but the teeth of how we are actually going to get people to do what they are supposed to do?

Mr. GOULD. Right. And accountability and discipline are the hallmark of a great organization.

Mr. RUNYAN. Well, that's inherent in an individual. But from a leader perspective, you have got to——

Mr. GOULD. Absolutely. So we started first with the principle of fairness. So you go to somebody and just fire them out of the blue for something they have been doing for 17 years, I do not think we would agree that that would be fair.

So we started by sitting down and training every individual and making sure we had the right policy in place, coming to terms with the fact that we had not been able to come into compliance. And we knew we had to change our policies and train our people to do it.

So we began with the training and then we escalated through that. Meanwhile, the numbers start to come down immediately, 70,000 all the way down to less than 450. That is the journey we have been on the last five months. Something is working.

And now what we did is we walked through counseling, individual counseling. If you do this, this will be the consequence. We had over a dozen counseling letters entered into people's files. That affects their promotion, their paycheck, their families.

We also suspended two individuals for a 48-hour period, saying, look, if you do that, you are going to lose the right to do it in our organization.

And, finally, an individual decided to retire in lieu of being dismissed.

So what—that, I believe, strikes the right balance between career teeth. If you continue to do this, bad things will happen and responsibility and that responsibility to fairness, to teach, to train, to coach as you have seen in your career many times is essential to maintain trust with employees and senior management.

And that is what we think we have achieved together here over the last five months. The numbers have gone from 70,000 to less than 450. We think that is evidence of dramatic change. It means our field folks are getting it and we did not have to fire 300 of them to make that happen.

Mr. RUNYAN. No. And I agree getting the right people in place, but I think also is not becoming complacent in the downturn to 450. Obviously you said it before. You want zero and that is the goal because at the end of the day, we are talking about taxpayer dollars at the end of the day. And——

Mr. GOULD. Mr. Matkovsky is very, very close to this, done a superb job, and I would like him to add to the—to my response.

Mr. MATKOVSKY. The discussion about warrants and the removal of warrants, in the field, all pharmacy staff who had previously had contracting officer warrants have had those warrants pulled back. The same is true for our logistics staff in the field.

So any hospital staff who were logisticians, not contracting series had their warrants pulled back. As Mr. Frye alluded, the only remainder are the prosthetics staff and we are on a plan to complete the transition of those warrants to contracting.

We think that is part of imposing discipline, that those who are trained, educated, are in the contracting officer job series are going to be those that we entrust to have a contracting officer's warrant.

In addition to that, week in, week out, there is management attention, month in, month out, there is management attention and scrutiny to the actions of our staff be they ordering officials or contracting officers' representatives. Repeat memos from leadership, repeat communications to pay attention, that this is something that both on the contracting side and the health care administration side, we are jointly committed to this.

I think we have struck that tone that you have addressed of organizational discipline and commitment.

Mr. RUNYAN. And my time is expired, but I think when you look at it, we have just scratched the surface. And you have got to continue to press across the board and not allow—I would respectively say to have your organization in line so we do not have to drag you up here and do this to you all the time.

So thank you. I yield back.

Mr. GOULD. You have that commitment and we are on the case here. And we think that is the reason why we have seen such dramatic change over the last five months.

Mr. RUNYAN. Thank you.

The CHAIRMAN. Mr. Gould, are all purchases TAA required authorized or not?

You may have in the last hearing said that all purchases that VA made were TAA compliant. Is that——

Mr. GOULD. Comply with the law and that has the $203,000 limit.

The CHAIRMAN. Okay. So that opens up a question then. So if it is less than that, it does not have to be?

Mr. GOULD. Well, when Congress passed that law, the decision was $203,000 and we do abide by that.

The CHAIRMAN. So if it is less than $203,000, it may not be TAA compliant?

Mr. GOULD. It is not required to be TAA compliant below $203,000.

The CHAIRMAN. So it could not be TAA required, right?

Mr. GOULD. Right. Yes.

The CHAIRMAN. I know the law says it does not have to be.

Mr. GOULD. Correct.

The CHAIRMAN. But it could be? Under $230,000 or $203,000, it could be?

Mr. GOULD. Two hundred and three, it could be.

The CHAIRMAN. Okay.

Mr. GOULD. Yes.

The CHAIRMAN. Could VA stack those contracts at less than $203,000 on top of each other in order to circumvent the law?

Mr. GOULD. It is an interesting hypothetical. I think the over—the paramount drive that we have as an organization is when there is a need, we go out to contract for it. We go out to get it done.

So waiting or delaying to be able to bundle or aggregate contracts so they reach above $203,000 seems far fetched to me, but let me see if there is anybody else on the team that has——

The CHAIRMAN. I apologize. I am going the other direction. I am wondering if there is ever a time where they would be a split contract, that it could be a $5 million contract, $1 million, whatever the number is, but that it is segmented or split into smaller segments and if that happens, what happens to the TAA compliance requirement?

Mr. GOULD. Philip.

Mr. MATKOVSKY. So you are asking us would there be a concerted action to split a transaction so it falls below the 203?

The CHAIRMAN. Has it occurred.

Mr. MATKOVSKY. We do not believe it has occurred, sir.

The CHAIRMAN. And I do not have an email from 1998 that says that happened, but——

Mr. MATKOVSKY. Sir, you know, again, you know, the overriding drive here, this is a just in time medication inventory system. I really do not have any knowledge of somebody willfully splitting transactions to occur below.

The CHAIRMAN. Mr. Michaud.

Mr. MICHAUD. Thank you very much, Mr. Chairman, and I want to follow that same vein of thinking as far as TAA on the open market.

You said you did not think it occurs. Could you provide the Committee with what in the instance of the drugs and where they came from, can you provide the Committee with that information that fall underneath the 203?

Mr. GOULD. Sir, we would certainly be willing to look into that and see if it is possible to do and deliver that to the Committee.

Mr. MICHAUD. Now, if it goes through, and there will be the same question for McKesson, I mean, if it has to go through McKesson or whoever, it seems to me there must be a record of that occurring.

And I would like to know how many contracts are out there, what drugs, where they came from that might be below that $203,000, if you can provide that for the Committee.

My other question is, is dealing with the drug shortage, has that affected the VA supply for the open market purchasing at all?

Mr. GOULD. Mr. Michaud, this is—obviously we are part of a broader system that does have periodic shortages from time to time.

Michael, would you care to comment on that?

Mr. VALENTINO. Yes. That is absolutely correct. As I am sure a lot of Members know, drug shortages are occurring with increasing frequency and for a longer duration. There are a lot of factors leading to those drug shortages which we probably do not need to go into.

But VA is impacted just as every other organization in the country and beyond is impacted. So we have developed a number of ways that we can mitigate the impact on the veterans.

So, for example, a lot of our chronic medications we dispense in three-month supplies. There have been times when we have had to reduce that to one-month supplies. There have been extreme situa-

tions where we have had to switch patients from one drug to another.

But I do not think you can say that the change in our procedures has been a direct contributing factor or really exacerbated that in any significant way. At least with the information that we have, we believe that not to be the case.

Mr. MICHAUD. Moving forward since you have given the award out, do you foresee under any circumstances where the VA would allow to make open market purchasing through the PPV?

Mr. HAGGSTROM. No, sir, we do not. We have worked very closely with McKesson who was the successful awardee of the follow-on pharmacy prime vendor contract. We have taken the experiences that we have dealt with these last many years and we have asked McKesson to engineer out of the system the opportunity to do that.

I believe when you will hear McKesson testify, in looking through their testimony, they have implemented what they call a restrict and notify component that will automatically remove non-contract items from the order in the new contract and notify the pharmacy that it has done so.

Mr. MICHAUD. Thank you.

My last question, and we were just handed this document. I think it was a lot of the information which I have not seen either coming from different memos that you provided the Committee.

But—and I do not know if the chair might want to add in—on the very last page, on December 2011, the second paragraph up says Mel, which I assume is Mel Noel, specifically noted that VA should ask McKesson to offer these TAA noncompliant drugs like Stesavin on its fast pay list.

Are you aware of that happening? And this is just something that was handed out this morning. Have you ever asked McKesson to do something that—to provide drugs that are not TAA compliant?

Mr. GOULD. Mr. Michaud, I think there would be a real value in us seeing that document and be able to give you a careful answer. I think Steve Thomas might be able to share a little bit of light on that here.

Mr. THOMAS. Yes. I can tell you on the new contract, we have something called whack-based generics and those will not—will be compliant with the TAA. And that is going to take a lot of work on the part of McKesson because they are not used to doing this to make sure that the drugs that they distribute to us are in accordance with TAA.

They are not accustomed to doing that because the other pharmacies in the United States will get products from India and from China so they are—they have a concerted effort right now to assure us that we will not be getting—we will be getting drugs that are compliant.

Mr. MICHAUD. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Thomas, does that mean that McKesson may have been providing drugs that were not TAA compliant that, in fact, came from countries that we do not want them coming from?

Mr. THOMAS. Again, I would refer to what Mike Valentino said. In spite of the fact that some products come from other countries like India and China, they are still FDA approved facilities.

So when I get my prescriptions filled or possibly when you get your prescriptions filled, you may get product from India and China. It is the government that is restricted to not getting products from non-TAA agreement countries.

The CHAIRMAN. Thank you.

Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman.

Secretary Gould, according to the VA's ratification policy and acquisition regulations for each illegal purchase, the VA must produce records, documents, statements of facts, explanations, a description of work, an estimated and agreed upon price, a citation of the appropriation, the name of the individual responsible for the unauthorized commitment, and more.

Are you stating today that you have done this for each and every one of the hundreds of thousands of illegal purchases made?

Mr. GOULD. No, we are not. That process is still underway. It involves review by VHA, by OALC, and by general counsel.

And for the folks that are listening into this and veterans especially listening to this process, I just want to describe at a general level what ratification means.

Mr. JOHNSON. We are going to get into that.

Mr. GOULD. We have an unauthorized commitment and what we want to be sure is we want to be sure that we got good value, we actually received those drugs, and that——

Mr. JOHNSON. Mr. Gould, I do not mean to interrupt you, but I have got limited time and I have got a number of questions. So you have answered that one.

Mr. GOULD. It is a VA——

Mr. JOHNSON. The VA can only—Mr. Gould, reclaiming my time, I do not want to go any further into this.

Mr. GOULD. Yes, sir. I understand.

Mr. JOHNSON. The VA can only ratify a purchase made by an unauthorized individual if it has not been paid for. Since the VA's fast pay system pays within 24 to 48 hours, the VA has been paying for a product before they confirm that they have received it. Therefore, it cannot be ratified.

Since we know the fast pay system paid for items before VA confirmed that they received these items, how did you ratify these purchases or how do you ratify these purchases?

Mr. GOULD. First of all, we have very strong general counsel that has rendered an opinion that we, in fact, can ratify that. As I described to you a moment ago, the process is still underway.

Our contract is based on fast pay. What that means is our veterans and taxpayers enjoy a substantial discount for prompt pay of services that we provide. The vast majority of them, over 99 percent, there is no question about——

Mr. JOHNSON. So you are saying that you ratify them after they have been paid for?

Mr. GOULD. That is correct by definition.

Mr. JOHNSON. But you cannot do that by your own policy.

Mr. GOULD. Sir, that is not correct. That is not correct. So we have a process for ratification after payment. It is essentially a cure for this process. It is stated under the FAR and the VAR. We are following that to the letter of the law and we are in the process of doing that now.

Mr. JOHNSON. Okay. Legal precedent notes that ratification can only occur where the person ratifying the agreement has knowledge of the material facts pertaining to the agreement as a rare occurrence. VA's decade and a half long abuse is not a rare occurrence of institutional ratification.

Did VA ever conduct a detailed investigation into this issue and, if so, why has Congress never been informed?

Mr. GOULD. First I would argue strongly that this is a very rare event in VA. As I have tried to stress to the Committee today, a half a million line item events per month of which today less than 450 fall into the category that we are discussing. It is a rare event.

Mr. JOHNSON. Back to the question. Did VA conduct an investigation? Has VA ever conducted an investigation?

Mr. HAGGSTROM. Yes, sir. I believe an investigation had—the ratification authority within the department rests with our heads of contracting activities that has been delegated.

Mr. JOHNSON. Has VA ever conducted an investigation?

Mr. HAGGSTROM. VHA is in the process right now of reviewing these unauthorized commitments, gathering the information on who, what, when, where, and how and the cost. And we are in the process right now of reviewing——

Mr. JOHNSON. So the investigation is ongoing?

Mr. HAGGSTROM. It is ongoing, sir.

Mr. JOHNSON. Okay. All right. So if the VA did not investigate, they could not know all of the material facts. Therefore——

Mr. GOULD. Sir, I would also point out the IG——

Mr. JOHNSON. —the purchases cannot be ratified?

Mr. GOULD. —is also conducting an investigation now.

Mr. JOHNSON. Okay. So the investigation is ongoing and by your own policy, it requires that the person doing the ratification knows the material facts. The fact that the investigation—you cannot know the material facts until the investigation is completed. The ratification cannot be done. Is that not correct?

Mr. GOULD. Philip, would you care to add to this?

Mr. MATKOVSKY. I will add just a little bit.

So, Mr. Chairman, I know you are aware of the FAR's seven components in a ratification action, so I am not going to go through the litany of them.

In the process as we have applied it, and we would be happy to share these documents with you after the fact, it is a contracting officer who is reviewing every single line item for the month in which the transactions were committed.

In that line item, we have the individual who had committed the order. We have the item that was ordered, the quantity that was ordered, the unit price, the extended price, and any mitigating circumstance that may have resulted in the unauthorized commitment.

The FAR also requires us to actually explain how we would intend to avoid this in the future as well. That is part of the action that we are engaged in.

That CO who performs that analysis, the program requests the ratification. That goes through a review. It then goes up through our head of contracting activity. Because of the scrutiny of this process, sir, we have requested that that go through OALC, through the senior procurement executive, as well as to general counsel to ensure that we have dotted all the Is.

Mr. JOHNSON. Well, Mr. Chairman, my time has expired, but what is clear to me is that the VA's argument of ratification is inaccurate and not in accordance with normal laws and regulations and it appears that they are attempting to redefine ratification to suit this particular purpose.

And with that, I yield back.

Mr. GOULD. Mr. Chairman, I strongly disagree with that statement. I think that the facts that we put forward here show that we know what the law is. We are abiding by it step by step. We defined that we are in the middle of a process with three principal players.

And at the bottom of this, at the end of the day is the notion that McKesson, a private sector company, provided us with a good we asked for. And that pill or pharmaceutical was taken and used for a veteran. No one at this table is disputing that that happened.

So I believe that it is fair for them to be in a position where they might like to be paid. And so we are going through that process to ratify. It is a legal process to cure and we are in that process now. And we believe that it is likely that these individual unauthorized events will be ratified.

The CHAIRMAN. Are you contending that all of the issues that are being involve—that ratification is involved and now McKesson has not been paid?

Mr. GOULD. No. As Mr. Johnson pointed a moment ago, we are obligated under contract to pay them.

The CHAIRMAN. I am sorry. But you made a statement that would lead somebody that may be listening on the webcast that McKesson has not been paid. That is kind of the issue in the ratification question that Mr. Johnson has raised and I have raised with the fast pay system.

I guess my question is, if you can ratify anything, which it appears that that is what may be occurring, what is the FAR and the VAR even for?

Mr. GOULD. Well, go to a simple example. Let's assume for a moment that one of these transactions is not ratified. McKesson has already received payment. How would we deal with that?

The answer is we would reconcile payment in the next round. This is a long-term relationship with a company. If we find a problem, we will be able to deal with that accordingly.

The CHAIRMAN. But under the fast pay system, they are paid, bam. Within 48 hours, they are paid.

Mr. GOULD. And we receive a discount immediately within 48 hours.

The CHAIRMAN. But they are paid. So, I mean——

Mr. GOULD. That is correct.

The CHAIRMAN. —it is not that McKesson is not getting paid. And I think everybody here agrees that the veteran needs to get their medication and the vendor needs to be paid.

Mr. GOULD. Yes.

The CHAIRMAN. I think the thing that we are most focused on is why for 17 years up until actually November of last year, I mean, your own charts show a drastic drop from $14 million to under $2 million and it gradually goes down. I would point out that your chart shows a tick up in April in cost. I do not know what the bump is. It is not large, but, I mean, it kind of bounced off the bottom.

I am just trying to figure out why it sounds like you can ratify anything and kind of wipe the slate clean for the last however many years. Is that kind of what you are doing through the ratification process? If not, why are you doing it?

Mr. GOULD. We are doing a number of things. And I will ask Philip to chime in.

First and most important, we are striving to improve how we use this contract mechanism and we have shown evidence of that occurring through additional training, business procedures, accountability, and technology steadily over the last five months. Results indicate that we are fixing this problem.

When it comes to the issue of ratification, in each instance, we want to learn where we went wrong so that we can correct the process and we want to make sure that both the government and the vendor were fairly treated. And that is our goal in this process, to comply with the law and to make sure that those two things are brought into balance.

We believe that most, if not all, of the transactions are likely to be ratified. If they are not, if we find there is a reason that it should not be ratified, we will take that action and we will pull money back for that services from McKesson.

At the end of the day, McKesson had someone call them from VA who they would fairly have reason to believe had the authority to place an order. They accepted the order and delivered. And a veteran used that medicine to get well. And now we are coming back through our process to ratify that that transaction was fair for both parties. And we are intent on doing that and we are in the middle of doing it now.

The CHAIRMAN. And there is not a Member of this Committee, either side of the aisle, that does not want the veteran to get their medication and to get well.

Mr. GOULD. Yes.

The CHAIRMAN. The issue that we are all trying to get to the bottom of is all of a sudden in November of last year——

Mr. GOULD. Right.

The CHAIRMAN. —there was a sea change at VA. Something was done prior to and we are trying to get to the bottom of why was it done that way.

And with that, Mr. McNerney and then we will have an opportunity to have another round.

Mr. MCNERNEY. Thank you, Mr. Chairman.

It appears to me that there are two issues here. First there are illuminating past errors and to decide if there is blame to be as-

signed and the second is to make sure that future pharma deliveries are done properly, accurately, safely, and timely and that there are no overpayments.

So let's talk about the first issue in my mind first. What I do not understand is how, and the Chairman has hit on this before, how these unregulated purchases were allowed to take place for so long despite warnings dating back to 1998.

So was there intentional obstruction? Specifically did Mr. Haggstrom or others refuse to comply with Committee requests for information? Those are my questions.

Mr. GOULD. No, I do not believe that to be the case. I think the Chairman put it nicely a moment ago. In November, there was a sea change. Why I think that happened is that this management team that you see testifying here today recognized they had a problem, took corrective action, and now five, six months later, we are seeing the results of that corrective action clearly and objectively.

Mr. MCNERNEY. Okay. But why would it take so long for that to come about and was there obstruction or was this panel or others in the VA intentionally obstructing us in this Committee from getting information?

Mr. GOULD. No, sir. Our intent and everyone at this table is to live the first of our five values as an organization and that is integrity.

So if there is any issue about the amount of time that it took, and we all believe that it took a while to get here, it is not because of a lack of integrity of any member here, but the process of finding out, getting the facts, doing the analysis, obtaining legal opinion, working through the contentious issues, and packaging that up to come up here to The Hill.

Mr. MCNERNEY. Is there blame to be assigned for this lack of—for how long it took to correct the unauthorized purchases?

Mr. GOULD. Sir, our view is that as soon as we recognized there was a problem, the senior management team here took action.

As I have testified previously, we first knew, I first knew in September. By November, we had policies in place, training. We had gone through a legal review, endless hours of review inside the building.

And since that moment, we have seen a steady decline in the number of unauthorized commitments. I would submit that when we knew what we knew, we took decisive action and now five, six months later, you can see the results of that. Things have changed. There is a sea change at VA.

Mr. MCNERNEY. Okay. About future performance. Your graph does show dramatic improvement.

Mr. GOULD. Thank you.

Mr. MCNERNEY. But what I am concerned about is that the right questions are not being asked or answered. So I will just ask what I think is the basic question.

How often do vets not get the specific drugs as ordered and how often are there overpayments?

Mr. GOULD. So thank you for raising the question about quality of service once again.

And I want to come back to the team and make that clear how well we have been doing as an organization, that no veteran listen-

ing into this should be concerned that they are getting the right drugs at the right time and the right place.

Michael.

Mr. VALENTINO. So similar answer as before. Drug shortages do occur in this country. We have a very good way of addressing these through restricting quantities, shifting to other drugs, in some cases postponing procedures. We are affected just like everybody else in the country. We do the very same things.

This contract, I do not have concrete information to suggest that this contract and the way we have changed our procedures has exacerbated or directly caused a veteran to not get a necessary drug.

Mr. MCNERNEY. So as far as you are concerned, there is no cases of a veteran getting the wrong or a bad drug or not getting it on time?

Mr. VALENTINO. I am just saying I am not aware of any cases or significant trends in that area. I cannot say that it has never happened anywhere ever.

Mr. MATKOVSKY. What we are saying is that it is not causally because of this contract and this mechanism of managing our pharmaceutical supply.

Mr. MCNERNEY. All right, Mr. Chairman. I will yield back.

The CHAIRMAN. Mr. Denham.

Mr. DENHAM. Thank you, Mr. Chairman.

Is it your belief that even though federal acquisition regulations were not being followed that the VA was getting a good value for its purchase?

Mr. GOULD. Yes. We went back and researched all of the prior transactions looking at them from a price standpoint, quality, I think, unambiguously there.

Fifty percent of them were at the price that was then prevailing in the market. About a quarter were below it and about a quarter above.

We think that in the final analysis which will be delivered by the IG possibly as early as next month, that we will show that there was no economic consequence to these unauthorized commitments.

Mr. DENHAM. And what other matrix do you use to show that we are getting a good value? Is it just price?

Mr. GOULD. Oh, of course not. The number one thing is the health of our veterans and making sure that the specific drugs that we use are targeted to have the positive effect on disease and disease management which is one of the reasons why we so carefully watch and monitor our formulary. Mr. Valentino is an expert in that.

Mr. DENHAM. Isn't that what Mr. Valentino just testified to was that we are not sure how many times or what percentage we are getting correct? We do not know if your answer to Mr. McNerney's question was we do not know how many times we have got it wrong. Why wouldn't we know?

Mr. VALENTINO. We are not aware of any instances where that—where a drug shortage situation has been directly linked to our prime vendor program or exacerbated.

Mr. DENHAM. Well, when you say you are not aware, what does that mean? Do you have a matrix in place that you can say we are a hundred percent compliant, we have never made any mistakes?

Mr. VALENTINO. We monitor—I think we might be mixing some issues. In terms of service delivery to the veteran, we do monitor that. Four out of five prescriptions are mailed to our consolidated mail-out patient pharmacies. We have performance metrics for timeliness, right drug, various things. And we operate at above six sigma for the majority of those.

That is one of the reasons why our customers surveyed by J.D. Power have given us such high ratings. So in terms of accuracy, we are extremely accurate. Do mistakes occur? Yes, they occur. But it is—six sigma is essentially less than four issues of nonconformance per million transactions. So we are extremely, extremely accurate. And I think it is not really related to the supply issue.

Mr. DENHAM. What percentage of our pharmaceuticals are outside of McKesson?

Mr. VALENTINO. Prior to September, a very, very small amount.

Mr. DENHAM. Well, what is a small amount?

Mr. VALENTINO. It—I do not have those exact figures. I would estimate less than one percent. Since that time, we have continued to order some non-contract drugs through McKesson using other procedures and other vendors, but it is still a very, very small amount. I would guess at this point in time that it is probably less than seven or eight percent that do not go through McKesson. That is a—that is just a guess. We can provide the Committee with detailed information if that would be desired.

Mr. DENHAM. Thank you.

I yield back.

The CHAIRMAN. Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman.

And I have to confess. I am still confused about a couple of things. One, so one agreement that this does not represent, what actually happens?

The CHAIRMAN. Put the veteran and his doctor. If you just put veteran and doctor——

Mr. REYES. Okay.

The CHAIRMAN. —and they order to VA. That is the drop ship.

Mr. REYES. Okay. So the way it is portrayed here, it is not accurate because it still goes through McKesson, right, on the chart here; is that correct?

The CHAIRMAN. In the hand-drawn chart, it shows going—where I asked the question in regards to a third party, you say that is incorrect?

Mr. REYES. That is incorrect in regards to how we process transactions with McKesson?

Mr. VALENTINO. We would go directly from VA to McKesson and the arrow would come right back to us.

Mr. REYES. And so that statement down here in red says VA never sees the order, confirms the order, and, therefore, cannot say all veterans are safe and all drugs are TAA compliant. Is that inaccurate as well?

Mr. VALENTINO. You know, I do not think I have enough information to really comment decisively, but it does not seem to be——

Mr. REYES. Accurate.

Mr. VALENTINO. —an accurate statement.

Mr. REYES. Okay. But let me because I want to——

Mr. MATKOVSKY. One thing to answer, though, you know, the person placing the order would be an ordering official who has an explicit delegation for that authority. The invoice would come in and it would be reconciled by a contracting officer's representative. So on both sides of the transaction, there are now controls.

Mr. REYES. And the reason I ask that question is because I may be the only Member of the Committee that has a VA account, diabetes as a result of Agent Orange. And there is a new medication that I have been on now for two months that I intend to go to the VA and see if it can be provided through the VA because right now it is fairly expensive.

So my concern is I have from my private doctor this prescription. I can go to the VA and ask for that medication and it would go through McKesson which is the current contractor, right?

Mr. VALENTINO. It would depend on the drug. If it is a drug that is not subject to a restricted distribution, then, yes, it would go through McKesson. We would order the product. It would be shipped to us and we would provide that in a finished prescription to you.

Mr. REYES. Okay. And my other question is, in 17 years, how many—McKesson has not been the only contractor for those 17 years, correct?

Mr. VALENTINO. Correct.

Mr. REYES. So how many have been, because they bid—what is the process? They bid every couple of years or something like that?

Mr. VALENTINO. I will defer to Mr. Thomas, but the last contract was a contract for two years with three renewal options that VA could exercise. So a total of an eight-year contract. The ones prior to that were five-year contracts and there were actually two previous contracts.

This goes back to a pilot that was done in the early 1990s and then it was successful. It was converted into a multi-award contract. There were several prime vendors. We solicited a single prime vendor for five years and then eight years. And then we are going to be into our new contract.

Mr. Thomas may have some additional information.

Mr. THOMAS. Mike is correct. The last two contracts have been eight-year contracts totally, two original years and three two-year options.

Mr. REYES. So in the last 17 years, there have been three contractors?

Mr. THOMAS. To the best of my recollection, that is correct, yes.

Mr. REYES. And to the question that the Chairman asked about structured contracts, that is illegal under FAR, right, to take a contract, break it down so it is under $203,000 just to get around the issue? Isn't that illegal under FAR?

I know it is illegal when you are bidding out construction and all these other things. I would imagine that it applies to this as well.

Mr. GOULD. Congressman, I would have to agree with you. It is a hypothetical. As we responded, we do not think it has happened. We do not see any evidence of that.

But to respond to your specific question, would it be illegal, Jan, do you have a view?

Mr. FRYE. I think if someone intentionally set about to do that, it would probably be illegal. I would have to defer to counsel and we would certainly look at that if it came to our attention. As was stated earlier by, I think, Mr. Matkovsky, we have no indication that that has been done.

Mr. REYES. Yeah. But that is not on structured contracts, right, when you structure them to be under the ceiling so that you can——

Mr. FRYE. Well, again, if we did it with malice or forethought, if we did it to avoid some rule or regulation or law——

Mr. REYES. It would be illegal?

Mr. FRYE. —it would be looked at with a jaundiced eye. So—and, again, we have no indication that I know of at this point that that has happened.

Mr. REYES. Okay. Thank you, Mr. Chairman. I yield back.

And thank you, gentlemen.

The CHAIRMAN. Ms. Brown.

Ms. BROWN. Thank you, Mr. Chairman.

Once again, I think I am a little confused as to what is the real problem here. But I want you all to clear a couple of things up.

It seems as if this has been going on since 1998 which is about three or four administrations. And I am trying to figure out what is the problem, what are we trying to get to, because how many veterans do we serve per month, per year with prescriptions? And do we not require that the VA work along with the Department of Defense so we can get the best cost for the price of the drugs?

Mr. GOULD. Absolutely.

Ms. BROWN. I mean, you all do a good job with that and I want to thank you.

Not like what we did when that pharmaceutical bill we passed that we demanded that the secretary do not negotiate the price of the drugs. You all negotiate the price of the drugs, if that is my understanding, you get the best cost for the veteran. In addition to that, you need to pay them timely and then they give a credit to the veteran. Clear that up for me.

Mr. GOULD. So, Ms. Brown, our most important duty here is the uninterrupted flow of medicine to our veterans. There is no government waste here. There has been no danger to veterans. There is no incident of harm.

We have been moving toward our goal of zero unauthorized commitments. We are doing that. If I may quote the Chairman, there has been a sea change here. We have gone from 70,000 to under 450.

The concern that we continue to have is that any unauthorized commitments is inappropriate and we are bound and determined to try to eliminate them.

Ms. BROWN. Can you explain unauthorized commitment because it seems as if we think unauthorized is improper? Did the physician not write the prescription? Explain to me this unauthorized because I am real confused about who should do that.

Mr. GOULD. The best one line description of an unauthorized commitment that I have heard is any purchase by an individual without proper authority or without following proper procedures. In

no way does that get into the patient/doctor relationship which you are pointing out. That is untouched by this process.

Ms. BROWN. Unauthorized could be the drug that our colleague just mentioned and this is a drug that is not on the formulary. So, therefore, it is a procedure that they need to get reviewed before they could actually purchase that.

Mr. GOULD. I see your distinction. One is authorization to be on the formulary.

Ms. BROWN. Yes.

Mr. GOULD. The specific lack of authorization I was pointing to was not authorized to place an order with McKesson so they would have the training and the authorization to do that.

Philip.

Mr. MATKOVSKY. Ma'am, the PPV contract has access to pharmaceuticals that are on contract. These ordering officials that went from 2,000 down below 1,000 employees, and these are good staff who are working hard to try to follow the rules, when they order a medication that does not have a VA contract through the PPV, when they did that, that was the unauthorized commitment.

It could be Cisplatin, a chemotherapy drug that is on our formulary. But because there was not a contract number there for them to appropriately order that and they lack the authority, they did not have warrant authority to commit the government. That is what made it unauthorized.

Ms. BROWN. Uh-huh. Okay. You were interrupted by one of my colleagues and you were trying to make a point. Can you finish that point, sir?

Mr. GOULD. Ma'am, thank you for that opportunity.

I believe it had to do with the ratification process. And I think I subsequently got to explain that ratification is a cure, a legal process provided under the FAR and the VAR that we are scrupulously following. It involves three principal players within VA, general counsel, Office of Acquisitions, Logistics, and Construction, and our VHA team. And our goal and our efforts are to follow that process to the letter and come with a final determination.

Ms. BROWN. So in closing, because I have another meeting I have to go to, would you restate for the veteran that is listening that his prescription is safe, timely, cost effective for the veterans?

Mr. GOULD. Yes, ma'am. This is the largest direct health care system in America. We do 90 million patient visits a year. We do 200 million lab reports. We fill 137 million prescriptions. This is a system whose quality is second to none.

This very, very tiny area, less than one percent of all the activity, we are spending all of our time focusing on the exception. And the number of exceptions is below 450 in a half million events a month.

Our veterans should be confident that this is a system that is built to deliver quality to them. And this process can be better and it is getting better due to the leadership of this team.

Ms. BROWN. Well, thank you so very much for your service and may God continue to bless America.

And I yield back the balance of my time.

Mr. GOULD. Thank you, ma'am.

The CHAIRMAN. Thank you very much, Ms. Brown.

Mr. Gould, has VHA in the past—I know there has been a sea change. We agree to that.

Mr. GOULD. Thank you, Mr. Chairman.

The CHAIRMAN. Did VHA procure non-emergency covered drugs through the open market and agree to pay an unadjusted open market price instead of the federal ceiling price? Has that occurred?

Mr. VALENTINO. If I understood your comment and your question, you are asking if we purchased a non-contract drug through the prime vendor?

The CHAIRMAN. A non-emergency covered drug.

Mr. VALENTINO. Okay.

The CHAIRMAN. Non-emergency covered drug through the open market, like a noncompliant drug, and agree to pay an unadjusted open market price instead of the federal ceiling price.

Mr. VALENTINO. We are aware that that has occurred. If you take a step back and ask why would somebody do that, there—it is very common for the manufacturer to want to sell you a whole case or a dozen of a product.

And there are cases where we do not need a dozen. We need one. So there have been situations where ordering officers have ordered that single unit through the prime vendor at a price that could be higher than the contract price to avoid buying an extra 11 units that they do not need.

So, yes, that is an issue. We—it is one of the things that we need to fix. We need to try to bring those drugs through the prime vendor distribution system or alternately have those made through a warranted contracting officer and try to negotiate with the manufacturer for smaller quantities.

The CHAIRMAN. And the reason I ask the question is because I have got a memo basically that talks about that and says the Office of General Counsel has always been of the opinion that it is illegal to do that.

So my colleague, Ms. Brown, and I, I think we are on the same side but something happened. Somebody all of a sudden figured out that prior to November of last year, something was not being done correctly and it has been changed.

I am interested to know. You talked about reaching back to McKesson if they are, in fact, during your ratification process you find that, in fact, they were overpaid.

If McKesson was, in fact, meeting the contract, are there not penalties in place for the employee that, in fact, may have made the error and other than a letter in the file? What happens then?

Mr. GOULD. Other than the suspension that we have already done, the retirement in lieu of discharge that has already occurred to hold people accountable. And there is a tiered process that we have for accountability.

The CHAIRMAN. What level was the person that retired? What level person was that in the——

Mr. GOULD. He resigned.

Mr. MATKOVSKY. It was an ordering official.

Mr. GOULD. Yeah.

The CHAIRMAN. Okay.

Mr. MATKOVSKY. Sir, the—it was stated earlier that this was somehow or another a rubber stamp process. I think it is very important to underscore that the person who is going through the ratification process, she herself is a warranted contracting officer and could lose her warrant if it is found that she is doing a perfunctory or otherwise pass-through process. So I do not think she is doing that.

If the contracting officer identifies that a set of transactions, a transaction, a commitment cannot be ratified, the government can seek recompense from the employee. We have that within our authority. And we can use a mechanism of offset from their paycheck to enforce that recoupment. We have not found that yet. And, again, this is a warranted official who is going through this process.

The CHAIRMAN. Okay. Thank you.

Dr. Roe.

Mr. ROE. I just have one big question that Mr. Reyes brought up. And are there or is there a circumstance, again so I understand this, where VA would go around McKesson to provide a drug that I have written a patient at the VA a prescription for, because the way I understood you saying that, that there is not?

He asked that question and you said, no, this diabetic drug he has would go directly to McKesson. That would then go out.

Are there circumstances where that would not occur in a nonemergent basis?

I could understand an emergency where you have got to go out and get something if it is helpful or whatever it might be.

Mr. VALENTINO. If a blue box that goes from VA to the—and it says unaffiliated, no contract company, so we have no relationship with them, we do believe that that has occurred a small number of times. And we are investigating that. But I would point out——

Mr. ROE. The correct answer is, yes, it could happen?

Mr. VALENTINO. Yes, it could happen. But there are very legitimate reasons for doing drop ship with companies we do have a relationship with. And that does occur.

Mr. ROE. See, I think that was where my—I thought that could happen and I think I would be careful about making a statement that there is absolutely no incident of harm that occurred to the VA because you do not have the quality control when that occurs. You have great quality control measures in here and I like what is going on. Let me just say that.

This has been a tremendous improvement over a year ago. It is unbelievable the amount of improvement you have made. But it would be hard to make a statement that Mr. Gould that you—because when you do that, you do not know you should have those quality control measures. That is the point I was——

Mr. REYES. Dr. Roe, because I think what is pertinent here is that it is labeled down here under the blue box unaffiliated, no contract company.

You just said that at times when you do have an established contract or affiliation with that company, that is when you think that might happen; is that correct?

Mr. VALENTINO. I think everything is correct, but let me clarify. The FDA sometimes will say this drug has some issues, we want

to control the distribution. We cannot get it through McKesson. So we place the order through McKesson. McKesson transmits that order to the manufacturer or the manufacturer's distributor. It comes back to us and then the payment goes through there.

But we do believe that there—there have been some reports. We have not fully investigated them, we have not fully investigated them, where in March, ten times we may have ordered a non-contract drug through a third party and it was drop shipped to VA, but it came to us. It came to us. It did not go right to the patient.

Mr. REYES. To the veteran?

Mr. VALENTINO. Right. So we had an opportunity to review what that product was.

Now, not to muddy the waters too much, but I will also say that there are situations with medical surgical supplies where we have a formal contract with a vendor to drop ship adult diapers, catheters, those kinds of things directly to the patient. It is a formal contract we have with the manufacture—with the distributor. We have agreed upon prices, agreed upon service delivery, but these are——

Mr. ROE. That is a different issue.

Mr. VALENTINO. These are med surge issues.

Mr. ROE. That is a different issue.

Mr. VALENTINO. Right.

Mr. ROE. I yield back, Mr. Chairman.

Mr. REYES. Thank you, Dr. Roe.

The CHAIRMAN. Mr. Walz.

Mr. WALZ. Thank you, Mr. Chairman.

Just a quick follow-up. Again, I have said it a lot of times in here and I know all of you feel that this is a zero sum proposition with our veterans. Our goal is to try and get a hundred percent compliance.

But you are telling me now, Mr. Gould, you are at 99.99991 in terms of those 456 is where it is at.

My question would be is, if I took this diagram and I crossed off VA and I put in my hospital out there and crossed out the hospital here, 40 percent of our drugs are coming from overseas manufacturers, is that correct, on this in the general population roughly?

Do you know that, Mr. Valentino?

Mr. VALENTINO. I do not.

Mr. WALZ. I think that is WHO's numbers, the World Health Organization's numbers or whatever. The chance of getting a drug this—by the way, that this is a concern and you talk about the ten. You were talking about the unaffiliated. That is happening in the private sector, right, as the norm?

Mr. VALENTINO. Yeah. Sir, that is a good point. The, you know, the pharmaceutical market is a world market now. It is not a domestic market as it once was. These drugs are being manufactured all over the world, raw materials coming from everywhere, FDA approved manufacturing plants everywhere. This is a global pharmaceutical——

Mr. WALZ. Because I think this is a very important point we are bringing up and I think looking for and doing our oversight is absolutely appropriate of what we should be doing, asking you to come here and do that.

But when I started to look and doing a little research in preparation for this, global drug procurement is a huge issue in developing nations, in developed nations on how you are reaching that and how those models are followed between the public and private sector of getting there.

What I want to be very clear of is that, yes, the law is being followed, yes, we are doing those things, patient-centered, safety, making sure that accountability to the taxpayers and all that.

I also, though, want to be careful that we are not closing the door to potential avenues of making all those things more efficient if that potential lies there.

Mr. VALENTINO. I personally believe—this is—I am not speaking on behalf of VA, but I personally believe that the Trade Agreements Act holds VA and other federal agencies to a significantly higher standard. The threshold is much higher for us to make sure that we have a——

Mr. WALZ. And does the data show that holding that to a higher standard improves patient safety would be the question I would ask?

I think that the default position is, I think FDA and we should have control over those manufacturing facilities, but if they can be certified, if they can be policed accordingly or whatever, are we then cutting off our veterans from the ability to be able to get the drugs they need at a cheap rate?

That is a broader question here, but I think that brings up the—I would yield back, Mr. Chairman, then the remainder of my time.

The CHAIRMAN. Mr. Denham, do you have any questions?

Mr. DENHAM. No.

The CHAIRMAN. Mr. Reyes? Mr. Michaud?

Mr. REYES. Mr. Chairman, just one question.

You stated that about seven percent of your drug purchases are not being done through McKesson or under PPV. Where are you purchasing the drugs from?

Mr. MATKOVSKY. When we instituted the new restrictions, anything that was going to be north of micro purchase limit could not be purchased anymore by an ordering official. It was to be purchased by a warranted contracting officer.

So we have examples where our field contracting officers are competing and awarding contracts to other than McKesson, sir. So—but it is a contract. It is a contract action. It is competed. It is let by a warranted contracting officer, et cetera.

Mr. REYES. And can you furnish us with the number of those kinds of contracts? Is it——

Mr. MATKOVSKY. I think we volunteered that we would collect the data, yes, sir.

Mr. REYES. Okay. All right. That is it. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Valentino, you said, I think, if my notes are correct, that VA used the inappropriate drop ship. I say illegal, but whatever, you know. It was used approximately ten times in March? Does that sound——

Mr. VALENTINO. Yeah. We have had ten—when we look at the unauthorized commitments, we asked for a reason. And based on the data that we have from March, we have not fully investigated this, we believe the number is approximately ten give or take.

The CHAIRMAN. If you know that, can you give me an idea of from like November 2011 to date? I mean, you talk about March. How about prior to March?

Mr. VALENTINO. We—as each month progressed, we began to collect more and more specific information, so we could really drill down on the causes. I am not certain that we have been collecting those standardized reasons back to November.

Initially it was a free text field that obviously requires a lot of work on our part to categorize those. So we can attempt to do that. We will do our best to collect that information.

The CHAIRMAN. Is it correct to say then to the best of your knowledge, there was no work-around from the November time frame of 2011 to date, and that is what the diagram is kind of implying, that there was a way that you did not do it directly with McKesson, but you went to a third party back doored into McKesson, but to your knowledge, that did not occur——

Mr. VALENTINO. To my knowledge——

The CHAIRMAN. —except on limited occasions like the ten?

Mr. VALENTINO. Yeah. And, I mean, there are—you know, I am guessing, but there are plausible reasons why that happened ten times.

So, for example, prior to October, we essentially had one payment mechanism with McKesson, the payment card. On October 1st, we established credit card accounts with McKesson so that we could order open market products. So it is not inconceivable that when somebody contacted the manufacturer for a drop ship order that they gave them the wrong account number.

We have instituted read back procedures now so when we do give a number, we ask the vendor to please read that back to make sure that we have the right one.

The CHAIRMAN. And that raises another question. When I asked one question, you talked about gave them the incorrect number. Could they have purposely given the incorrect number in order for that to occur?

My question is, I do not know where there would be anything plausible since it is illegal where there would be a plausible reason that they—unless, as you said, it was an error. And I am again just trying to—but you all have been here and taken our questions and we appreciate that.

I would ask if there are any other Members that have any questions that they may want to ask, any comments or statements since I was pretty quick to shut you down after going through testimony, but if you do have some questions. And, again, I think this Committee will all agree that from the November 2011 time frame to date, you have been making great strides. We are trying to go backwards to figure out why it was done for so long, the way it was done.

And Ms. Brown and I will have an opportunity to talk. You know, if there was a need for a change, all we would ask is let us have an opportunity to—if it is a statute, give us a chance to fix it so that you can better do your job.

But I am still not convinced that prior to the time that you began to make these changes that something was not happening within the system that goes prior to the Obama administration to the

Bush administration to the Clinton administration. So this is not political in any way. Just happens to be when we happened to figure it out.

But with that, if you have any closing comments, Mr. Gould.

Mr. GOULD. Mr. Chairman, thank you for your questions here today.

I know that on both sides of the aisle the spirit is taking care of our veterans and making sure that they get the services that they need.

I particularly appreciate your recognition of the sea change. When this team brought forward the problem and took corrective action, we were hoping to see the kind of results that we have been able to produce for you here today and we are convinced that there is a new culture that is a part of VA.

And I want to thank the front-line individuals who are making that happen each and every day. Thank you.

The CHAIRMAN. And, Mr. Gingrich, one quick question. When could the Committee expect to see the results of the investigation that is ongoing now that we have been talking about for the last two hours?

Mr. GINGRICH. You are talking about the IG investigation, sir? It is supposed to——

The CHAIRMAN. Your internal investigation into what happened prior to November 2011.

Mr. GINGRICH. Sir, the plan is to have the ratifications done in series and we will have the first come to you by July or in July.

The CHAIRMAN. Okay. Thank you very much. Thank you.

And what I would like to do is take about a five-minute break if we can and we will reconvene in five minutes.

[Recess.]

The CHAIRMAN. The Committee will reconvene. Thank you very much for allowing us a short break and thank you very much for sitting through the last couple of hours of questioning.

The second panel we are going to hear from, Ms. Linda Halliday, the assistant inspector general for Audits and Evaluations at the Department of Veterans Affairs, Office of Inspector General. She is accompanied by Mr. Gary Abe, director of the Inspector General's Seattle Office of Audits and Evaluations who could very well be Secretary Shinseki's twin brother.

We will also hear from Maureen Regan, counselor to the inspector general, and she is accompanied by Michael Grivnovics, close, director of the Federal Supply System Division in the IG's Office of Contract Review.

Both of your complete statements will be entered into the record.

And, Ms. Halliday, you are recognized for five minutes.

STATEMENTS OF LINDA A. HALLIDAY, ASSISTANT INSPECTOR GENERAL FOR AUDITS AND EVALUATIONS, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY GARY ABE, DIRECTOR, SEATTLE OFFICE OF AUDITS AND EVALUATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS, MAUREEN REGAN, COUNSELOR TO THE INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY MICHAEL GRIVNOVICS, DIRECTOR, FEDERAL SUPPLY SYSTEM DIVISION, OFFICE OF CONTRACT REVIEW, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF LINDA A. HALLIDAY

Ms. HALLIDAY. Chairman Miller and Members of the Committee, thank you for the opportunity to discuss the results of the recent OIG report addressing VA's pharmaceutical prime vendor fast pay system.

Our work was done at the request of the Committee and the VA secretary. We reviewed the internal controls of the VA's fast pay system in support of provisions of the prime vendor contract. We focused on the ordering, receipt of pharmaceuticals, and payment activities.

Our review assessed controls in pharmacy operations at four VA consolidated mail outpatient pharmacies and four VA medical centers along with the Financial Services Center and the National Acquisition Center and included a review of the invoices paid.

Our review found VA was providing payments to the prime vendor within 48 hours of the prime vendor's shipment of an order. VA was paying an accurate amount for the actual goods received, processing payments to the prime vendor in accordance with laws, regulations, and the current terms of the prime vendor contract, and receiving reimbursement by other government agencies in a timely and accurate fashion.

Controls over corrections of overpayments are critical under the fast pay system since corrections are identified and adjustments are made after payments are processed.

The pharmacy benefits management's business practice is to review prices for pharmaceutical items purchased from the prime vendor each month beginning three months after the purchase. This process experienced delays as the National Acquisition Center contracting officer redirected his efforts to plan the future contract.

The NAC contracting officer continued to provide the pharmacy benefits management price reviews to the prime vendor. However, he did not follow-up on the results.

The total value of the potential pricing differences identified in the monthly reviews of the prime vendor purchases from December 2009 through April 2011 was approximately $46.4 million.

We want to emphasize and be very clear on this that these are pricing differences, not payment errors, and that pricing corrections occur for several reasons such as retroactive price adjustments, item count errors, and product returns.

We determined that VA's controls did not reliably ensure timely resolution of the pricing differences. However, we also found that

there was reasonable assurance that the pricing differences were resolved over time during McKesson's credit and re-billing process.

We also assessed pharmacy ordering and receiving operations to address whether VA had established adequate controls by examining the ordering and receiving duties of pharmacy staff to ensure they were adequately segregated.

We determined controls were not effective at three of the four VAMC pharmacies we visited. These sites did not segregate duties among staff to prevent any one individual from having the ability to both order and to receive non-controlled pharmacy supplies.

Our report offered recommendations to ensure timely completion of price analysis, proper segregation of supply ordering and receiving duties, and adequate verification of supply receipts.

The VA officials presented acceptable implementation plans to correct the weaknesses identified in our fast pay review.

Mr. Chairman, Maureen Regan will now address open market purchases. This concludes my statement and we would be happy to answer any questions.

[The statement of The Office of Inspector General appears in the Appendix]

STATEMENT OF MAUREEN REGAN

Ms. REGAN. Good afternoon. Thank you.

The primary purpose of the current review that is being conducted by the Office of Contract Review is to quantify purchases identified as open market for fiscal year 2011. We used a database maintained by McKesson and VA to identify those purchases.

To conduct a review, we identified purchases as open market when there was no underlying contract number listed in the appropriate database field. And what we found was a little bit surprising.

Of the $4.3 billion in purchases through the prime vendor, we found that about $290 million were identified as open market in the database. Of that, $283 million represented pharmaceutical purchases. The other $7 million was medical surgical items.

We reviewed all the purchases for 100 of the top selling pharmaceuticals identified as open market and these purchases represented about $108 million of the $283 million or 38 percent. Of that, 43 of the items or 58 percent of the dollars in our sample were actually contract items. They had been misrepresented as open market in the database.

And, we went back and looked at pricing and we found that they were sold at the contract price when pricing was not affected by allocations.

We learned through this process that pricing and other adjustments are made continuously by the PPV to reflect price changes due to contract awards and modifications. Therefore, purchasing information cannot be quantified by simply reviewing data captured for a period of time. You have to look at data a long period of time because of the process of adjusting the dollars.

We concluded that McKesson has done a good job of correcting pricing through credits and re-billing when the prime vendor system is updated by VA to reflect changes in contract pricing.

But we also found that there are delays in updating the system and those are due in part to poor communication between Pharmacy Benefits Management and the National Acquisition Center's FSS and National Contract Divisions.

In our sample, we identified nine items that were purchased open market. The products were actually on Federal Supply Schedule contracts, but they were purchased through the prime vendor by VA at open market prices.

This happened because the manufacturer did not agree to sell their product through the prime vendor. So McKesson was not required to give the VA the prime vendor price. By purchasing through the prime vendor, VA overpaid $4.8 million for these items.

This was of concern to us because we identified this problem through our post-award reviews back in 2007 and reported it to VA. We were told that the purchasing system was changed to block purchasers from buying these products through the prime vendor.

However, when we reported the problem again in 2011, also through our post-award reviews, we learned that at VA's request, the system allows the purchaser to override the block.

We also reviewed the accuracy of VA's reported .4 percent in open market sales through the prime vendor contract in December of 2011. We found that the procedures implemented in November 2011 did not preclude or prohibit open market purchasing. Instead open market purchases were shifted from the PPV contract, the prime vendor contract, to other financing accounts.

We identified approximately $7 million purchased through the new open market purchasing system which represented about two percent of the total purchases by VA through McKesson, so the appropriate amount of open market purchases was about 2.4 percent, not .4 percent as reported.

Based on the review that we conducted of the open market purchases and our ongoing pre- and post-award audits of the federal supply schedule contracts, we know that open market purchasing through the prime vendor is impacted by several factors including items that are not on contract but are needed to provide care to our veterans, a growing number of product allocations and shortages which necessitate purchasing items open market at non-contract prices, and purchasing items through the prime vendor for convenience instead of buying direct from the manufacturers who do not participate in the program.

We also know again through our pre and post award work that a growing number of generic drugs are not on contract. Unlike branded drugs, there is no requirement that manufacturers offer generics on FSS contracts.

In addition, an increasing number of products are no longer manufactured in the United States or a designated country and, thus, cannot be offered on contract due to Trade Agreement Act requirements.

We are currently reviewing open market purchases to determine whether the purchasers violated federal procurement laws and regulations including the Trade Agreements Act.

This concludes our statement. We will be happy to answer any questions the Committee may have.

[The statement of The Office of Inspector General appears in the Appendix]

The CHAIRMAN. Thank you very much.

If you would, and this may dovetail on what you just talked about, Ms. Regan, and, Ms. Halliday, I think you touched on this a little bit, but in VISN 8, evidence suggests, and this is a peninsular part of Florida, that they purchased Letrozol—is that the right name, I assume it is, it is the generic name for Femara—on the open market even though there was a contract for the medication.

And according to an email exchange that VA provided to us, they overpaid for the medication and violated their own directives and additionally it does not appear that Letrozol is Trade Act Agreement compliant. It apparently is manufactured in Macau, in China.

And I would just like to know. Tell me what you know about this, if you know that specific instance, and is this an issue?

Mr. GRIVNOVICS. I do not know of the specific instance you are referencing, but in talking to people at the CMOPs and at some of the facilities that we had visited, they do occasionally get noncompliant TAA products delivered either to the CMOP or to the individual facility pharmacy.

And the individuals that are there receiving and recording that information do check to see if those products are coming from a designated country. And if they find that they are not, they do send them back the PPV. Does this happen in all instances, I cannot say for sure, but they do check to make sure the products are compliant with TAA.

The CHAIRMAN. So if there was a contract, if the drug was on contract and no open market, would it not be required to come from a TAA compliant country?

Ms. REGAN. Not knowing all the facts, were they buying the generic brand or were they buying the branded drug?

The CHAIRMAN. They were buying the generic and I think that is where you just said the generic may not have to comply with that.

Ms. REGAN. With the generic itself, if the generic is on a federal supply schedule or national contract, it does have to comply with the Trade Agreements Act. But generic drugs are not required to be on contract. The branded drug can be on contract, but a lot of times your price difference is very significant between buying the branded drug which would be on contract and buying the generic product open market.

We would be happy to look at the issue if you want.

The CHAIRMAN. If you would. The drug is spelled L–E–T–R–O–Z–O–L. That is the generic name. It appears that the brand name is Femara.

Ms. REGAN. Right.

The CHAIRMAN. And maybe McKesson can answer this when they come up. But the evidence that I have is that there is a contract for the medication. And if that is the case, then it should be TAA compliant. Go ahead.

Ms. REGAN. If they were buying the drug that is on contract, in other words, the NDC number would have to be the branded drug

that is on contract, not a generic brand, either manufactured by the same company or manufactured by another vendor.

The CHAIRMAN. So you are telling us that a generic drug does not have to come from a TAA compliant country?

Ms. REGAN. If the generic drug is bought open market, there is no contract that requires TAA compliance by the manufacturer.

The CHAIRMAN. Okay. I thought there was something we were talking about that there was a $203,000 level of purchase, not whether it was on contract or not.

Ms. REGAN. I would have to see the specifics of how this was purchased in order to answer your question.

The CHAIRMAN. Thank you.

Did your audit investigate payments made before delivery of the pharmaceuticals under the fast pay system?

Ms. HALLIDAY. Yes. We tested several transactions to look at the ordering and to look at the payments. Traditionally the fast pay system makes—payment within 48 hours.

What we wanted to make sure was that there was reconciliation between what was being received and the order so that we did not have any problems or disconnects there and then that would put VA in a situation of paying for something they had not received.

The CHAIRMAN. Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman.

In your report, you state that one medical facility pharmacy purchased $29.1 million of non-controlled substances from the PPV in 2011, yet the pharmacy staff did not inventory PPV shipments of non-controlled pharmaceutical supplies with the invoices.

So a couple of questions. What is your observation about this issue and can you please provide us some examples of what are non-controlled supplies versus controlled pharmaceutical supplies?

Ms. HALLIDAY. We considered that a significant weakness at that medical center and that is the exact scenario that I just described that could put VA in the position of paying an invoice, yet possibly not receiving the goods.

There has to be that reconciliation that you know you have received what you are paying for. It is more critical in the fast pay system because the payments are made upon shipment of goods.

Now, adjustments are made. It takes a little time, but we also followed that process and found that the adjustments were happening when there was an item count difference like I referenced in my statement.

So I think that there was generally a good control at most places, but the sites that we went to, there was the one site at the VAMC in Dallas that they said they were spot checking, but we could not find evidence of that when we were on site.

Mr. REYES. And the other question I have involves the limits that the Chairman just mentioned about $203,000. In your investigation, were there any what is commonly referred to as structured contracting which means they would break it down just so it would be under the in this case $203,000 limit? Was there any instance or any evidence of that?

Ms. REGAN. We have not seen any evidence of that yet, but the review is still ongoing. So we could see some as we continue to go through the data, but we have not seen that yet.

Mr. REYES. Okay. All right. Thank you, Mr. Chairman. I yield back.

The CHAIRMAN. Mr. Michaud.

Mr. MICHAUD. Thank you, Mr. Chairman.

Dealing with the Trade Act adjustment, have you looked at, and it is my understanding that $203,000 is the limit, have you been able to look at the drugs below that purchase amount that has been purchased from overseas, whether it is China, India, and what type of drugs those are?

Ms. REGAN. That is one of the issues that we are still looking at to see if we can quantify that. What we do know from our pre- and post-award work is that drugs from non-designated countries is a huge issue. There are some drugs that you cannot buy on contract because they are not manufactured in the U.S. or a designated country. And so that is a problem.

But we have even had a couple of voluntary disclosures from companies with contracts that mixed up TAA compliants and non-compliant products. One of them had some product made in this country and some made overseas and they sent the wrong one. The Trade Agreements Act only applies to the Federal Government purchases. But there are a lot of drugs that are just not manufactured here anymore.

Mr. MICHAUD. Now, have you also looked at, I know there has been some discussion that you can buy them overseas as long as they are FDA approved, have you looked at the process whether FDA is actually doing the appropriate approval in those particular areas?

Ms. REGAN. The issue is whether or not they are manufactured in FDA approved plants. And that is an FDA issue. Our contracts have a clause that require FDA compliance not just where they are manufactured but also for improper marketing, kickbacks, things like that in the pharmaceutical industry.

I know we have worked with the Department of Justice on two cases in which products were sold to us that were made in plants that had not been certified or had been decertified. One of them was actually a plant in Puerto Rico, the Sidra case. And there is another case being settled now by the Department of Justice.

So we work with them to make sure that VA's interests get protected. But we do not have any authority to go out and look at the plants or anything else.

Mr. MICHAUD. Because that would be my second concern is whether or not a plant is supposedly an FDA approved manufacturing plant when, in essence, it is not complying with the laws.

In your opening remarks, you talked about on the open market sales through PPV that it is at 2.4 percent. The VA said it was, I believe, four percent as VA reported.

Why the discrepancy?

Mr. GRIVNOVICS. The open market purchases that went through the PPV contract are 0.4 percent, but we found that the facilities can still also buy from McKesson through a different account. I will just call it an open market charge account, let's say. So facilities can still go that route and it is not through the PPV contract anymore. So that is that two percent that we referred to.

Mr. MICHAUD. Okay. Great. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Walz.

Mr. WALZ. Well, thank you, Chairman.

And, again, thank you all for being here. In full disclosure, I am a big fan of the IG, so I never make any bones about that.

Ms. Halliday, in listening to Deputy Secretary Gould's assessment, and I know it is a subjective term, that there has been a sea change since last year, does your work reflect that would you say?

Ms. HALLIDAY. We looked at the fiscal year 2011 transactions and we could start to see what we thought were improvements, especially tightening up controls in the contracting piece. I think that significant deficiencies existed over time. The ordering officials and the reviews by supervisory contracting officers that had been very weak, we see attention to that now.

Mr. WALZ. And does your analysis then show is there any correlation in doing that with either a decreased amount of service to veterans or an increase in their service or——

Ms. HALLIDAY. I could not comment to that.

Mr. WALZ. —is that hard to—that is hard to say?

Ms. HALLIDAY. Yes.

Mr. WALZ. Because I am still getting my mind wrapped around if use of PPV, if it is helping the veterans and at the long run, obviously that caused part of it.

Did you see, and I listened, you know, your detailed description, the PPV program, is it fraught with fraud, waste, and abuse or is it simply could have been managed better?

Ms. HALLIDAY. Well, when we looked at the fast pay procedures, we found it to be a good system. You are processing millions of transactions and there were controls over these transactions and the payment. There seemed to be a conscious effort to try and reconcile the payments with the actual invoices.

Mr. WALZ. And that is to be a good partner with our private sector suppliers, correct, and make sure that they are not waiting?

This was always a big problem I had on small contracts. Nobody wanted to mow the yard at the armory because they were not sure they would get paid or that type of thing.

Ms. REGAN. One thing about the prime vendor contract, and I know I am dating myself here, but back in the early 1990s, we bought direct from the manufacturers. We did not use a prime vendor and we had a large depot system. When the Federal Acquisition Streamlining Act and the Federal Acquisition Reform Act were passed in the mid 1990s, all that had to go away.

I know from our pre and post awards at that point in time, we were actually paying a little more for the product because the manufacturers and commercial customers go through a prime vendor, a distributor. So McKesson does not just have the VA. They have a lot of other hospitals in the private sector.

Mr. WALZ. Walmart, correct?

Ms. REGAN. Yes. A lot of your hospital systems used a prime vendor before VA did. And, actually, it is a negative fee that the VA gets for using the prime vendor.

Mr. WALZ. I found this kind of interesting, Mr. Chairman. I have to say I was noticing again the title of this hearing. The through the looking glass part I am getting at is we are kind of arguing

against using private sector for reduction of costs which might be my through the looking glass.

But that aside, two last questions. Ms. Regan, you mentioned something that was—it sounded somewhat troubling to me and it was in your testimony. The VA was able to override the block they had and shift from the PPV to other areas.

What did that mean exactly or what was happening there?

Ms. REGAN. Manufacturers are not required to sell through the prime vendor. They have to actually have an agreement with McKesson. To get into detail, it is a charge back issue. If McKesson pays $100 for the drug and our price is $80, there is a charge back system that they would get back the $20.

So there has to be an agreement with the manufacturer of the product and the prime vendor. And there are some manufacturers who have not agreed to do that. So VA is supposed to order directly from the manufacturer to buy these products. These are usually branded drugs which means prices are capped at the Federal Ceiling Price. We are not supposed to pay more than the contract price.

When it is purchased not from the manufacturer in those cases but through McKesson, we do not get and we do not have any right to get the contract price. We have done a couple reviews where we paid a lot more than the contract price. In fact, in this one, I think it was about $9 million in sales of which 4.8 of that was overpriced. That is significant——

Mr. WALZ. Yeah.

Ms. REGAN. —even though it is a few products. When we recognized it in 2007, we talked to VA about it and they told us they blocked it so that when a purchaser went in the system, they could not buy it. We found in 2011 when we did other work that the purchases were not blocked.

And so I worked with the IPT for the new contract and the issue came up. And that is where I found out that, the block is there, but they can just override it.

Mr. WALZ. Now, that is an important oversight piece. And I am going to ask you this and I ask from your experience on this. Just ask you to be candid on this.

Has McKesson been good actors in this for you? I mean, you have got a private sector company trying to do what they should do, make profit.

Ms. REGAN. I think as we said, we thought McKesson has done a really good job. This is really complicated especially with contract pricing changing every couple days. I mean, the new prices for branded drugs go into effect in January. With modifications, additions, subtractions, the prices on other drugs are changing all the time. And as we looked over the issues over time, we found we were paying the contract price. So we did not find any problems with McKesson.

Mr. WALZ. So if there were overpayments, it was not the case of McKesson or a private entity overcharging on purpose? They were following the rules, following the——

Ms. REGAN. Right.

Mr. WALZ. —procedures that were in place?

Ms. REGAN. I would say what we found was VA overpaid because they did not order correctly. But as far as McKesson, the prices

that they charged the VA were comparable to the contract prices. The other problem you get into is with allocation and shortages where we do not get the contract price sometimes.

Mr. WALZ. Right.

Before I yield back, Mr. Chairman, I know this is not your area, but maybe you can influence the look at this. I keep coming back to this Trade Agreements Act with the very changing dynamics of global pharmaceuticals. And I think in the future, that is going to be even a bigger issue. And if this Committee can drive some of that talk, it would be great.

But I yield back.

The CHAIRMAN. Thank you very much.

Members, any other questions?

I apologize for shortening our question period, but we are about to back up against a vote and I would like to get the next panel before us for their testimony and their questions.

So thank you very much for your work and your testimony this morning. You are excused.

Ms. HALLIDAY. Thank you.

The CHAIRMAN. And as the second panel leaves the table, I invite the third to come on forward. And on this panel, we will hear from Mr. Paul Flach. He is the vice president of Health Systems National Accounts for McKesson Corporation.

Mr. Flach, you have heard me say this already. Your complete written statement will be made part of the official hearing record. Thank you for being here with us today and you are recognized for five minutes.

STATEMENT OF PAUL FLACH

Mr. FLACH. Thank you, Mr. Chairman.

Good afternoon, Mr. Chairman and Members of the Committee. My name is Paul Flach, as the Chairman had stated, and I am vice president of McKesson Health Systems National Accounts for McKesson Corporation.

On behalf of McKesson, the company committed to our veteran employees and to the contract we have with the VA, I would like to acknowledge and thank the Committee and the Department of Veterans Affairs for all that you do for America's veterans every day.

Mr. Chairman, as you know, McKesson provided testimony on the pharmaceutical prime vendor contract before this Committee earlier this year. We understand your oversight responsibility for the Department of Veterans Affairs and particularly as it relates to the PPV contract.

We recognize the importance of this contract to the VA's health care system and ultimately to America's veterans.

I am here today to provide the Committee with some additional information about the PPV contract as well to answer to your questions.

As our PPV contract requires, McKesson provides thousands of products to the VA at prices set under federal supply contracts which the VA has secured through direct negotiation with pharmaceutical manufacturers.

In April of 2012, the VA purchased through the prime vendor contract 99.83 percent of its products under the VA negotiated contract with manufacturers.

There are circumstances, however, when contracted pharmaceuticals are in short supply or other critical medicines are needed to treat patients.

Purchase of pharmaceuticals that are not on contract are frequently referred to as open market purchases. Stated simply, open market purchases are for products which are not subject to a contract price negotiated by the VA with the manufacturer.

We would like to emphasize that all pharmaceutical products purchased by the VA from McKesson whether under VA contract or an open market item have the required FDA approvals.

Purchases of open market products are a standard practice in the private sector. In the private sector, for instance, 30 to 40 percent of the purchases made by hospitals and institutional customers are for open market products.

Since November when the VA asked for our assistance, we have been working closely with them to restrict open market purchases under the PPV contract.

As a result of these efforts and other steps taken by the VA, open market purchases under the PPV contract have dramatically declined from less than five percent previously to less than 2.1 percent in November 2011 and to .17 percent in April of 2012.

In collaboration with the VA last fall, we modified our on-line electronic ordering systems. Open market items can no longer be viewed on the ordering screen by those who are placing an order under the PPV contract. McKesson was given 48 hours to make this change and we met the VA's deadline.

McKesson is preparing for the new PPV contract that will go into effect in August. We will be enhancing our technology beyond what is required to meet the VA's intention to restrict open market purchases.

Our systems are complex and must be able to process over a million line items on a daily basis. Therefore, we are making these enhancements judiciously because the VA relies on the timely delivery of the medications and orders to provide medical care for our Nation's veterans.

As part of developing technology enhancement, we are building a restrict and notify component with plans for this functionality to be available later this fall. If the VA attempts to order a pharmaceutical product from our distribution centers, it will result in an open market purchase under the PPV contract. Our system will automatically remove the item from the order and send a corresponding notification back to the VA.

This notice will alert the VA that we are not delivering the specified pharmaceutical product and enable it to identify alternatives to meet the patient's need on a timely basis.

Mr. Chairman, in April, McKesson was selected by the VA to continue as the pharmaceutical prime vendor. The VA conducted a rigorous competition for this contract award and we are honored to be selected again as the PPV and are committed to continuing to deliver outstanding value and service to the VA and our veterans.

On behalf of McKesson, I want to thank the VA for the trust they continue to place in our performance, our people, and our company. McKesson is very proud of our unique ability to improve the delivery, cost efficiencies, and quality of care for our Nation's veterans. America's veterans deserve the best health care and McKesson is committed to a partnership that continually enhances the VA's ability to provide critical services to the veterans they serve.

Mr. Chairman, thank you for the opportunity to appear here today. I am happy to answer your questions.

[The statement of Paul Flach appears in the Appendix]

The CHAIRMAN. Thank you very much, Mr. Flach.

If you would, we have heard from a couple of panels that there are ways that VA employees can purchase a pharmaceutical off contract, and what I would like to get from you is, if you would, are you aware of the methods that they may be using and can you explain your understanding of the methods that they may use?

Mr. FLACH. Mr. Chairman, by purchasing off contract, you mean off the PPV contract, purchasing open market product?

The CHAIRMAN. Yes.

Mr. FLACH. Open market product, as I mentioned, in November, we put in a block that restricted the ability for the VA facilities to be able to view any open market product on the ordering system of McKesson. That would not allow them to place any orders directly into the system.

However, there are instances, such as the scanning of the shelf, where like Walmart, Costco, they use these hand-held order entry devices to scan to order product. They scan the bar code label on the shelf and if one of those items happens to be an open market product and they import that into our ordering system, that item will go into that purchase order to be ordered.

Now, we have informed the VA that we had this issue and that, there were ways that the facility could identify those items and delete them from the order.

When we put this enhancement in place in the late fall with the new contract, that component will not be there anymore. That will go away because if they do scan that item and it does go into the system, it will be eliminated from the order and we will notify the facility that that has taken place.

The CHAIRMAN. The question would be, do you think it was done unintentionally, was it done intentionally by the employee in order to get the item ordered?

I mean, we have all seen where people take a bar code and tape it to something and then they just zip, zip, zip. You see it as you go through a home building store.

And my question is, why would an employee want to do that?

Mr. FLACH. Mr. Chairman, I really cannot speak to whether or not they are doing it intentionally or not. I mean, the fact of the matter is the shelf label may have the bar code there that indicates it is a non-contract product. And when they scan it, it ultimately is imported into the ordering system.

The CHAIRMAN. So you do not believe that a VA employee is attempting to do a work-around after the November 2011 time frame in order to keep being able to buy that open market product?

Mr. FLACH. I would not believe that they would do it intentionally. I think it would probably be inadvertent, that it was done when they scanned the shelf.

I will say, though, also that when they do that scan, they have the ability at that point to eliminate that item off the hand-held unit as well as eliminate the item from the order when it gets transmitted into the system.

So the capability does exist to remove the item from the order before they transmit to McKesson.

The CHAIRMAN. Can you talk about the differences that you have seen recently within VA in their ordering process?

Mr. FLACH. As I mentioned, dramatically the number of orders and the dollars have gone down from November 2011 to almost nothing in the month of March or April. It was like $600,000. Understanding that as the Committee strives to get this number to zero, the drop has been dramatic. I mean, the open market purchases have decreased on a substantial basis.

The CHAIRMAN. Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman.

And as a veteran with a VA account, I want to thank you for the diligence that McKesson has in providing drugs to the VA for our veterans.

But I want to ask is there a circumstance where VA would purchase from you but not under the PPV contract?

Mr. FLACH. Yes. There are other ways to order from McKesson besides the PPV account.

Mr. REYES. Can you explain some of those?

Mr. FLACH. When we were approached in October or back in 2011, we were informed that in October the open market purchases were no longer going to be allowed on the PPV contract.

At that point in time, there was no other vehicle for which the VA could order through McKesson because it was only that prime vendor account that was in place.

So we, working with the VA, put together a credit card account that would allow them to purchase within the micro threshold of $3,000. So they could, in fact, order open market product under that credit card that would not then go under the PPV account.

Mr. REYES. And it is also my understanding that the discount under the new contract is 8.65 percent which is up from the previous 5.15.

Can you tell us or explain to the Committee how you arrive at this percentage and can you explain to us how the discount works?

Mr. FLACH. How the discount basically works is you get 8.65 percent off of any product that is purchased or any item purchased through the prime vendor program.

As far as the details on how that price is derived, I would have to default to our accounting folks on that piece because it is a very convoluted and complex process how they come up with that pricing. So I am not sure if the Committee wants to get into all that today.

Mr. REYES. Okay. I will yield back, Mr. Chairman.

Thank you very much.

Mr. FLACH. Thank you.

The CHAIRMAN. Mr. Michaud.

Mr. MICHAUD. Thank you, Mr. Chairman.

Thank you very much for coming today.

You mentioned the open market has dropped dramatically since November from the VA.

Are you concerned of where the VA might be getting open market products from or——

Mr. FLACH. Obviously when they purchase the open market product, according to the regulations as I understand it, they have to have fair and open competition. They have to go to other companies to get pricing in my understanding.

We may win, we may lose on the price. I mean, obviously we would like to keep that business. But if through their process it goes to another company, then that is the nature of the game unfortunately.

Mr. MICHAUD. Uh-huh. You heard a lot of discussion this morning about the Trade Act Agreement and what the VA might be purchasing from overseas and not McKesson as a whole.

I know that the VA has to comply with the Trade Act. But for your total products that you provide for whether it is hospitals or what have you, how much of it is—do you do analysis if it is Trade Act compliant even though you do not have to or is a lot of it coming from overseas?

Mr. FLACH. Sir, we only buy from FDA approved suppliers. Now, you have the restriction within the VA of the TAA compliance component. And we have always been under the impression that the TAA compliance for this contract was at the discretion of the VA.

Now, as you have heard testimony on the next contract, McKesson is going to be responsible for the TAA compliance in that new category that they have designed called WAC price generics.

At that point, we will be compliant. We will have to be compliant to TAA. The only way we can be compliant with TAA on those products is we have to go to the supplier for them to tell us if they are compliant to the TAA. There is no other way for us to know that information.

Mr. MICHAUD. Uh-huh. But for your other customers other than the VA, do you know if they are, even though they do not have to be, do you know if they are TAA compliant?

Mr. FLACH. It is my understanding that the majority, if not all the commercial customers that we do business with, do not take into account the TAA compliance.

Mr. MICHAUD. Okay.

Mr. FLACH. They could buy from whatever country that it is manufactured in.

Mr. MICHAUD. Okay. Now, you mentioned you would have to go to the supplier manufacturer to find out whether or not they are FDA approved.

How would you know if they really are? I mean, if they tell you they are, but they are really not, I mean, how would you really check that out?

Mr. FLACH. Our agreement with any supplier that we do business with requires that they are the FDA approved supplier. It has to be verified by that supplier that the FDA has, in fact, approved them.

My assumption, and I cannot speak for the purchasing folks, but my assumption would be that if we find out that they are not, we would no longer do business with that company.

Mr. MICHAUD. Okay. And in your contract with those particular companies, if on day one they might be FDA approved, but 30 days into the process they are not for whatever reason, what would happen with your contracts with that particular company?

Mr. FLACH. It would be my understanding that we would, and, again, I would have to defer to the processes in place for our purchasing department, but it would be my understanding that we would stop business with that customer, that supplier.

Mr. MICHAUD. But how would you know unless they told you and if they were going to deceive you in the first place, what makes you think that they will let you know that they are no longer FDA compliant?

Mr. FLACH. I am sure somehow along the way it will come to light and we would address it. I mean, we would have to go by what they tell us or if someone else, a customer, whoever it may be, would find out that they are no longer FDA compliant or the FDA notifies us that they are not compliant, we would then cease and desist business with that customer, that supplier.

Mr. MICHAUD. Thank you very much.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Mr. Flach, a great deal of attention was paid to a drawing whose artist will remain unnamed this morning, but basically it was showing possibly where a doctor would prescribe a drug, VA would go to a third party, and I can get the artist to sign that for you if you would like.

Mr. FLACH. I will have it framed later.

The CHAIRMAN. It would go to a third party and that third party then would order from McKesson. McKesson would drop ship it then to the veteran.

Are you aware of this ever occurring?

Mr. FLACH. Yes. In the commercial world, this is common practice.

The CHAIRMAN. I am just talking about within VA.

Mr. FLACH. In the VA, yes. I mean, as Mike Valentino addressed, there are situations where there are products that we cannot handle. The supplier has specifically stated that it is a specialty product that has to go through the supplier. It cannot go through McKesson as the prime vendor.

It may require special handling such as vaccines that the supplier does not want to go through the wholesaler or it may be manufacturer control problems where the supplier says, look, I do not want to put it in the wholesale channel because what is going to end up happening is you are going to have a hoarding of that product, so I want to control the supply chain. So it has to be purchased direct.

Those situations occur all the time and I am sure that they have occurred with the VA.

The CHAIRMAN. But why wouldn't VA deal directly with McKesson, McKesson go to the third party and backwards? Why would the VA go around to the other supplier? If you are the PPV,

why would they go to somebody else and then the billing come through drop shipping and billing through you?

Mr. FLACH. My understanding, and correct me if I am wrong, Mr. Chairman, but the third party in my mind is the supplier. When a drop ship is ordered, the customer can either call the supplier directly and place the order and have the order shipped to them and then the supplier can either bill the facility directly or they can do what we call a drop ship bill through where they would drop ship the product to the customer and then they would bill through McKesson.

The other situation occurs where the VA facility can call McKesson. We have a dedicated VA service department, all they handle is the VA. The VA could call the VA service department. They would say I want to order these products. Here is my account number. We would then call the supplier on behalf of the VA and place the order with the supplier. Then the same situation occurs. The supplier then ships the product directly to the VA without having to go through another party which is McKesson and then bill through us.

The CHAIRMAN. It seems to me as the PPV, that is the way you would want it to occur so you have pretty much control over what goes on instead of you being left out of the original ordering of the product.

Mr. FLACH. I am sorry. I missed——

The CHAIRMAN. Well, you said there are two options.

Mr. FLACH. Yes.

The CHAIRMAN. One, they can go to McKesson.

Mr. FLACH. Yes.

The CHAIRMAN. McKesson can make the request of the manufacturer or VA can go straight to the manufacturer.

Mr. FLACH. Correct.

The CHAIRMAN. Why wouldn't they just go to the PPV? Why wouldn't they go to McKesson? Why would they go around you?

Mr. FLACH. There are instances when they may not want to bill through McKesson. Now——

The CHAIRMAN. But can you think of a reason why they wouldn't want to go through the people who hold the largest contract in the VA?

Mr. FLACH. One of the things they do have at their discretion is there are some items that are on our ordering screen that are drop ship only like the Baxter IVs, that they can order those directly on the system and it goes directly to Baxter electronically.

So that can be done in that manner. Now, under the new agreement, all the drop ship orders, it is my understanding, are to go through McKesson. They want them to be called into McKesson.

Now, when that happens, what that does is that gives us the ability to ask the customer or verify that the item you are buying is, in fact, on contract. And if it is on contract, we are going to use your prime vendor contract account. If it is not on contract, it is open market, then we are going to use your open market account. So we can help eliminate more of this open market issue.

The CHAIRMAN. Mr. Reyes, any questions?

Thank you very much. We have six minutes to get to the floor for our vote. Thank you, McKesson.

Mr. FLACH. Thank you, Mr. Chairman.

The CHAIRMAN. And I apologize for not swearing you in by the way. I do not want VA to think we singled them out. I actually should have done the second and third panel.

But I appreciate everybody coming today for this second leg in this PPV issue.

All Members will have five legislative days for which to revise and extend and add any extraneous material. And without objection, so ordered.

And this hearing is adjourned.

[Whereupon, at 1:25 p.m., the Committee was adjourned.]

A P P E N D I X

Prepared Statement of Hon. Jeff Miller, Chairman

Good morning. This hearing will come to order.

Before we begin, I would like to note today's important place in world history as the anniversary of the Allied invasion of Normandy, better known as D–Day.

Nearly 160,000 troops bravely fought for- and obtained- a foothold in Europe that would prove pivotal to our victory.

Many of those troops gave the ultimate sacrifice, and to the veterans who took part, including those no longer with us, we say thank you.

This Committee will always remember your efforts and work to ensure we fulfill our obligation to you and all veterans.

I want to welcome everyone to today's hearing titled "Through the Looking Glass: Return to PPV."

We are returning to our examination of VA's Pharmaceutical Prime Vendor (PPV) contract after a hearing this Committee held in February.

The PPV contract is the largest contract at VA, valued around $4 billion.

When executed correctly, the "just-in-time" delivery system of the PPV contract ensures pharmaceuticals are delivered to VA's medical facilities in a timely fashion and at a competitive price.

As the February hearing revealed, an important aspect of the PPV contract was not executed correctly for a long period of time.

A subsequent information request to VA, spurred by a subpoena authorized by this Committee, confirmed this.

When a needed pharmaceutical is either not available due to a supply shortage, or not available through the PPV, federal acquisition regulations outline a clear path toward acquiring the pharmaceutical through an open market purchase.

The open market process provides protection through due diligence, competition, and a contract.

The actions of purchasing officials at VA wilfully ignored these protections and were, in fact, illegal.

In February, the illegal purchases were described as the routine way of doing business, and according to the testimony we heard, no one within VA was held accountable.

Now that VA has had even more time to consider the actions of its employees, it is my hope that the illegal purchases are no longer occurring and that the many employees involved in this throughout VA have been held accountable.

The problem is neither of those outcomes has been achieved.

While VA may boast about a reduction in unauthorized purchases of pharmaceuticals, this hearing will reveal that they still occur despite new training and policies throughout the entire department.

VA also identified employees who made unauthorized commitments and the disciplinary course of action was letters of counseling "where appropriate."

Not much of a disciplinary action, given the egregious violations identified.

As VA will point out, there are ways outlined in federal acquisition regulation to review and "ratify" unauthorized commitments.

The guidelines for ratification are clear, and I caution against oversimplifying and misusing the ratification process as a way of dismissing the hundreds of thousands of unauthorized commitments made by VA employees.

I am further disappointed to know that there was strong pushback from many within the department in implementing new procedures intended to minimize the illegal purchasing of pharmaceuticals.

The illegal purchasing does not help veterans; it is another example of VA wishing to take the easy route instead of doing what is right and required as outlined in law, regulation, and VA policy.

Despite VA's new policies and procedures and occasional counseling letters, I remain concerned that there will be employees who continue trying to find some

workaround, and that supervisors will not hold these employees or themselves accountable for their actions.

The precedent of not holding anyone accountable is a bad one to follow.

The fact is, VA knew they were heading down a slippery slope with regards to pharmaceutical purchases back in the 1990s, yet minimal effort was made to address this until this Committee put its oversight spotlight on it, over a decade later.

Many of those that did try to call attention to the problems were dismissed by their peers and even their supervisors for trying to do the right thing.

We already know the problems exist- what we need to know now is not only the detailed actions VA is taking to fix them, but also how it will prevent these same problems in the future.

It is my hope going forward that when VA identifies problems such as this, it is forthcoming with Congress about them, and we work together to fix them.

Receiving VA's testimony less than 24 hours before this hearing, however, does not help in that effort.

With that, I now yield to the gentlelady from Florida, Ms. Brown.

Prepared Statement of Hon. Corrine Brown,
Acting Ranking Democratic Member

Thank you, Mr. Chairman, for holding this hearing.

Today we are going to examine what steps the Department of Veterans' Affairs has taken to correct problems identified in the Pharmaceutical Prime Vendor (PPV) contract since the Committee's February 1, 2012 hearing. The hearing will also address concerns regarding the PPV contract that have come to light since the hearing, including accountability.

I believe it is important to hold follow-up hearings to examine if VA is making progress, but also to ensure that the recommendations that are implemented are effective, efficient and being monitored for those purposes.

The recent IG audit showed that the VA's Fast Pay System consistently provided payments within 48 hours to the PPV from the prime vendor's shipment of an order; VA was paying the accurate amount for actual goods received; VA was processing payments to the PPV in accordance with laws, regulation, and current terms of the PPV contract; VA was reimbursed by other government agencies in a timely and accurate fashion. All positive steps.

However, the audit report determined the VA did not have reliable controls to ensure timely correction of improper payments and the controls were not sufficient to reduce the risk of program fraud or abuse.

This is not a new issue for VA. Lack of management controls and not following established procedures is a common theme in many former reports as well.

The VA has proven that when determined to make corrective actions they can successfully implement measures to do so. I don't understand why the VA has to wait for a hearing or an IG audit report for them to take those measures.

Additionally, I would like to hear from VA what action it took with about how the National Acquisition Center's PPV contracting officer who did not execute his responsibilities properly for several months effectively stopping the process put in place. Was this individual reprimanded, provided additional training, removed from his or her post?

Finally, I look forward to hearing from VA on progress made since the last hearing to prevent unauthorized purchases through the PPV contract and how is the new agreement different from the previous contract.

Thank you and I yield back.

Prepared Statement of Mr. Gould

Chairman Miller, Ranking Member Filner, and members of the Committee, thank you for the opportunity to appear before you today to discuss the Department of Veterans Affairs' (VA) Pharmaceutical Prime Vendor (PPV) program and the activities we have undertaken to improve internal controls since we testified before this Committee on February 1, 2012. I am accompanied today by Mr. John Gingrich, VA's Chief of Staff; Mr. Glenn Haggstrom, Principal Executive Director for the Office of Acquisition, Logistics and Construction; Mr. Jan Frye, Deputy Assistant Secretary for Acquisition, Logistics and Construction; Mr. Steven Thomas, Director of National Contract Service at the National Acquisition Center; Mr. Philip Matkovsky, Assistant Deputy Under Secretary for Health for Operations and Management for Admin-

istrative Operations, Veterans Health Administration (VHA); and Mr. Michael Valentino, Chief Consultant for Pharmacy Benefits Management Services, VHA.

When we testified before this Committee in February, we described how VA's PPV system provides timely access to pharmaceuticals for Veterans with very favorable pricing for the Department and the American taxpayer. In fiscal year (FY) 2011 alone, the PPV contract returned $225 million to VA through purchase discounts and provided significant additional service delivery benefits to VA. We also described some of the problems we experienced with our execution of the PPV contract, specifically related to conformance with all applicable Federal procurement laws and regulations. Today, I will describe the actions we have undertaken with the PPV program to improve conformance with procurement laws and regulations and the effect of these actions during the five month period between November 2011 and March 2012. I will also describe the initiatives we will implement that will further improve our procurement compliance.

Background

Initial concern about the PPV program grew from an internal review early in 2011 that revealed that four percent of our total PPV expenditures were unauthorized commitments. An "unauthorized commitment" is any purchase of a pharmaceutical item from the PPV made by an individual without the appropriate authority or made without following the proper procedures. This occurs when a Pharmacy Ordering Officer (OO) orders an item that is not currently covered by a valid government contract. VA has made procedural and systems changes that have significantly reduced the incidence of unauthorized commitments. Today, the number of unauthorized commitments is less than 0.1 percent.

VA has continued its efforts since November 2011 to improve the PPV program in several key areas by: improving training and implementing systems and process changes; bringing unauthorized commitments into conformance with laws and regulations via a review and formal ratification process; increasing management oversight; and implementing personnel actions when necessary to hold individuals responsible for violating procedures.

Improving Training and Processes

VA has implemented procedural changes, reduced the number of authorized pharmacy ordering officers, provided repeated training, and increased management oversight to reduce unauthorized commitments. As a result of these efforts, between September 2011 and March 2012, VA has reduced PPV unauthorized commitments from 70,309 in September 2011 to 434 in March 2012, and reduced the number of employees making unauthorized commitments from 327 in November 2011 to 81 in March 2012. The following graph shows the reduction in unauthorized commitments from September 2011 through March 2012. In March 2012 there were approximately 490,000 line items ordered. Of the total, roughly 434 individual line items may have constituted unauthorized commitments. This reflects less than one-tenth of one percent of all items ordered in the month of March. Those orders were placed by 132 ordering officers. Of the 132 individuals, 81 individuals placed orders that were not due to either system or vendor errors.

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Ratifying Unauthorized Commitments

As I noted earlier, an unauthorized commitment is any purchase of a pharmaceutical item either made by an individual without warrant authority or made without following proper procedures. When a vendor has acted in good faith to provide VA with a good or service and VA has received that good or service, Federal Acquisition Regulation (FAR) provides a mechanism for that unauthorized commitment to be reviewed and retrospectively brought into conformance with the FAR. FAR Subpart 1.602–3 provides a policy for ratifying unauthorized commitments and restrictions for performing those ratifications. VA has applied ratification processes to unauthorized commitments. Unauthorized commitments that occurred before November 10, 2011 were determined by the Office of General Counsel as institutionally ratified. Unauthorized commitments occurring after November 10, 2011 underwent a formal ratification process in accordance with the Federal Acquisition Regulation. The approximately 434 unauthorized commitments that occurred in March are currently undergoing formal ratification. These formal ratification actions bring the unauthorized commitments into conformance with the FAR. It must be noted that, in addition to following the policy and restrictions of FAR Subpart 1.602–3, agencies are required to make positive efforts to minimize unauthorized commitments. VA has undertaken significant efforts to minimize these unauthorized commitments.

For example, VA implemented a number of procedural changes that placed new management responsibilities on our field staff and required our staff to change how they use the PPV system. To ensure staff members are adequately trained, VA has taken several important steps. VA identified and designated a Contracting Officer Representative (COR) for each PPV ordering location. The FAR and VA Acquisition Regulations (VAAR) require that CORs have separation of duties to prevent the same individual who places an order against the PPV contract from also receiving that order. CORs were officially appointed in writing by the Administrative Contracting Officers (ACO) and have completed Federal Acquisition Certification (FAC–COR) Level I training. This 8-hour training course requires a final exam that the student must pass with a score of 100 percent. COR training completion is documented in VA's Talent Management System. The Office of Acquisition and Logistics (OAL) also has developed supplemental specialized COR training specific to the PPV contract. The PPV specific training helps ensure that PPV CORs conduct their duties under the direction of the Procurement Contracting Officer (PCO) at the National Acquisition Center (NAC). Currently, all 317 CORs have completed their training.

In addition, the Pharmacy Benefits Management (PBM) office developed several tools for use by its 984 Ordering Officers (OO) including a SharePoint page with

daily reports from McKesson of unauthorized commitments. The purpose of these tools is to provide an additional means for OOs to monitor PPV purchases at a facility level.

Fast Pay Payment Reconciliation Training was provided to all Chiefs of Pharmacy on March 21, 2012, and all VISN Pharmacy Executives on March 27, 2012. The training provided instruction on: checking in; signing and dating pharmaceutical receipts; and, accurately reconciling invoices to ensure payments to the PPV are made only for drugs that have been received.

Approximately 81 OOs were identified who potentially made unauthorized commitments in March 2012. VA provided targeted training to each of these individuals to manually check and ensure that unauthorized commitments are prevented. The training occurred on May 18th, 2012, for all OOs on duty and will be completed for the remaining OOs on the day they return to duty.

Increasing Management Oversight

VA also has strengthened oversight of PPV contract administration. The NAC's Procurement Contracting Officer (PCO) is now supported by ACOs and CORs. The CORs monitor proper execution of the OOs' responsibilities in accordance with the contract assigned to each PPV ordering location. The CORs report contract administration issues to the ACOs. A working group of ACOs, CORs, and other representatives are in the process of fine tuning the duties, responsibilities and communication processes for the ACOs and CORs to further improve the oversight function. The Office of Acquisition, Logistics and Construction (OALC), the Office of the Under Secretary for Health, and the Pharmacy Benefits Management Service jointly monitor purchase data.

Implementing Personnel Actions

PPV Ordering Officers were required quickly to learn new ordering procedures for open-market pharmaceuticals. VHA has employed a tiered approach beginning with training. If inappropriate ordering continues to occur after appropriate training is administered, counseling is given followed by administrative action, possible removal of delegated ordering authority or loss of employment.

The individuals that made unauthorized commitments for pharmaceuticals were identified by location and name. To date, no malicious intent was found, but network and facility management were apprised of all the named employees who had executed unauthorized commitments. This number was 342 individuals. All orders were reviewed by VA headquarters and network management staff, and, where appropriate, formal letters of counseling were issued to the individuals. In fact, as a result of this process of progressive discipline, one VA employee elected to resign rather than face disciplinary action.

Although it will be difficult to achieve a zero defect standard based on the volume of orders and human involvement, our goal remains compliance with the FAR. Efforts to date have yielded significant results. A preliminary review of the March data indicates that there are substantially fewer unauthorized commitments than during any previous month. PPV ordering data will continue to be monitored. We will take appropriate personnel actions where required. The Under Secretary for Health and Principal Executive Director for OALC recently issued a joint memo to Veterans Integrated Service Network (VISN) directors, medical center directors, and designated PPV ordering officers. The memo clearly reiterated the expectation that any improper ordering of non-contract items must cease. It provided three additional opportunities for ordering officers to prevent unauthorized commitments, and confirmed that individual ordering officer delegations may be removed or suspended if unauthorized commitments continue.

Expanding the Number of Drugs Under Contract

VA believes awarding additional contracts for VA's known pharmaceutical requirements also will help resolve the majority of open market purchases and will help bring previously unauthorized commitments further into conformance with applicable laws and regulations. VA has pursued two simultaneous approaches to increasing the number of drugs available under contract: awarding a new PPV contract, and awarding additional contracts for pharmaceuticals.

The New PPV Contract

There will always be pharmaceutical needs of Veterans that are not fully met by existing government contracts. VA will need to retain FAR compliant purchasing flexibility to meet Veterans' needs. The new PPV contract does not include open market purchasing, but does include a mechanism to reduce the need for open market items. The mechanism is termed Wholesale Acquisition Cost (WAC) Based Priced Generics (WBPG), which results in PPV contract pricing for generic drugs

that have a published WAC, a National Drug Code (NDC), and are Trade Agreement Act (TAA) compliant. The WBPG items are last in the priority of purchasing after all other government contract vehicles are exhausted. VA's policy for obtaining drugs not available through any contract will be to either: procure them through the Government Purchase Card program if the dollar value of the purchase is no more than $3,000; or have a warranted contracting officer execute the procurement using the streamlined acquisition procedures allowed by the Federal Acquisition Regulation.

Looking forward, a new PPV contract was competitively awarded to the McKesson Corporation on April 10, 2012, following all applicable procurement laws and regulations. The contract allows for a 120-day implementation period which ends on August 10, 2012. The initial period of performance for this contract will be from August 10, 2012 through August 9, 2014. The contract has three 2-year renewal options. A bridge contract covering the period May 10, 2012, (when the current PPV contract expired) through August 9, 2012, was recently awarded to provide continuity of access to pharmaceuticals.

Like the previous contract, this new contract provides drugs and supplies to VA and other government agency customers to over 750 separate accounts, including State Veterans Homes, the Virgin Islands, Saipan, Puerto Rico, and Manila, Philippines. This is accomplished through a seamless supply system that typically delivers drugs within 24 hours (often less) of order placement and provides VA a discount on all purchases. Pricing for the majority of the pharmaceutical products distributed through the PPV is established through other contracts (e.g., the Federal Supply Schedule (FSS), or national contracts) awarded by OALC. Unlike the previous contract, the new one places many formerly open market drugs under contract at the WBPG price, which was determined by a warranted contracting officer to be fair and reasonable. This single change in the new contract will resolve the vast majority of the concerns with the previous contract.

VA will further improve the structure of the follow-on PPV contract to ensure from the onset that only medications available under Federal contract are viewable on the electronic catalogue from which ordering officers place their requirements, and that any inadvertent orders placed are not delivered by the PPV. There will be no option for OOs to obtain non-contract supplies under the contract. In addition, improved training will continue to be provided for ordering officers as the need arises.

Using a Federal Acquisition Regulation compliant mechanism that was not included in the previous contract, the new contract will preserve the ability to get needed drugs from the PPV. The health and safety of Veterans will not be put at risk with the new sourcing methodology.

On May 17, 2012, VA's Office of the Inspector General (OIG) issued its report entitled, "Review of the Controls for the Pharmaceutical Prime Vendor Fast Pay System." The report concluded that the Fast Pay system provided timely payments to vendors and that VA paid accurate prices, but that inadequate controls were in place to ensure timely correction of improper payments and to reduce the risk of program fraud or abuse. VA has concurred with the report and the Action Plan to address the OIG recommendations is underway.

We look forward to the results of the second OIG review of PPV, which will provide additional information on the underlying causes of the unauthorized commitments and the magnitude of those purchases. We will quickly address any actionable findings to improve our pharmaceutical procurement processes.

Awarding Additional Contracts for Pharmaceuticals

The long-term plan to reduce the need for open market items is to increase the number of items on government contracts. There are currently 87 national contracts in place, and VA has 48 additional procurement requests in process for solicitation and award. VA, in collaboration with its partners in the Department of Defense, Indian Health Service, and other Federal agencies, will continue to identify drugs or drug classes suitable for national contracting.

Conclusion

VA staff members have worked diligently and conscientiously to provide needed pharmaceuticals to our Veterans where and when they are needed. We have also worked to ensure that applicable laws and regulations are being followed. Our frontline staff have proven their commitment to serve Veterans, by learning new procedures, changing their use of the PPV system, and collectively reaching current performance in excess of 99.9 percent. Our procurement staffs have instituted ratification processes that ensure any unauthorized commitments subsequently conform to the FAR. VA managers continue to monitor performance and provide oversight for

the current PPV contract. VA has lowered the number of OOs in the system and increased the numbers of drugs on contract without increasing outages. Where educational efforts to prevent unauthorized commitments were unsuccessful, VA has taken and will continue to take appropriate personnel action. Again, the PPV ordering problems largely were procedural breakdowns that affected a small volume of pharmaceutical purchases and in no way compromised Veterans' safety.

Mr. Chairman, thank you for the opportunity to discuss on the record what actions we have accomplished, as well as the remaining work that needs to be accomplished as we transition to the new PPV contract in August 2012. We have been entrusted with the responsibility to effectively administer and oversee health care for Veterans and their families, and to do so responsibly using the resources appropriated by Congress. My colleagues and I are prepared to answer your questions.

Prepared Statement of The Office of Inspector General

Chairman Miller and members of the Committee, thank you for the opportunity to discuss the results of a recent Office of Inspector General (OIG) report dealing with Pharmaceutical Prime Vendor (PPV) Fast Pay System and provide an update on our continuing work to review purchases that were allegedly made in violation of the PPV contract. The OIG is represented by Ms. Linda A. Halliday, Assistant Inspector General for Audits and Evaluations; Ms. Maureen Regan, Counselor to the Inspector General; Mr. Gary Abe, Director, OIG's Seattle Office of Audits and Evaluations; and Mr. Michael Grivnovics, Director of the OIG's Office of Contract Review, Federal Supply Service Division.

BACKGROUND

In 1994, VA implemented the PPV program to reduce the costs for storing and distributing pharmaceutical supplies. The McKesson Corporation was awarded the most recent PPV contract that expired on May 9, 2012. VA competitively awarded McKesson a long-term contract effective August 10, 2012; a bridge contract was established to ensure continuation of services in the interim. Use of the PPV is mandatory for VA pharmacies and optional for certain Other Government Agencies (OGAs) and authorized users, such as the Indian Health Service (IHS) and State Veterans Homes. In fiscal year (FY) 2011, VA purchased approximately $4.3 billion pharmaceuticals from the PPV. The PPV contract is for distribution services only. Pharmaceutical pricing is established through Federal Supply Schedule (FSS) and other national contracts awarded by VA's National Acquisition Center (NAC). Except for local Veterans Integrated Service Network (VISN) contracts, contract pricing data in the PPV purchasing system is entered by VA, not McKesson. The issue that arose in 2011 was that VA and other agencies were using the PPV contract improperly to purchase pharmaceuticals and other items open market. A related issue was whether the fast payment procedures in the PPV contract resulted in a lapse in controls regarding the purchasing and receipt of products.

The Federal Acquisition Regulation (FAR) allows the use of fast payment procedures to help agencies meet payment timeliness requirements of the Prompt Payment Act. The PPV contract defines the Fast Pay system as an expedited payment procedure whereby payments are made to the PPV within 48 hours of shipment of an order. The current PPV contract requires all VA PPV orders to be processed using the Fast Pay system. The Fast Pay system procedures generally occur in the following sequence: authorization and ordering; receipt of the invoice; payment approval and authorization; disbursement of funds; and receipt and acceptance of items ordered.

Fast Pay allows agencies to authorize and pay vendors after the vendor's invoice is received but prior to receipt and acceptance of the order. Payments are made when the invoice is received, based on the vendor's certification that it has delivered the supplies on the invoice and will remedy deficiencies in the supplies it delivers. The reliability of the Fast Pay system depends on promptly verifying that purchased items have been received, ensuring that receiving reports and payment documents match, and correcting discrepancies after payments have been made.

VA's Fast Pay system uses a U.S. Bank credit card-like account to pay the PPV for each VA pharmacy ordering facility's prime vendor purchases. When the PPV fills a facility's order, U.S. Bank processes the purchase through the facility's Fast Pay account using an electronic interface between the prime vendor and U.S. Bank. U.S. Bank pays the PPV each day for the orders it receives and transmits a daily transaction file of purchases to VA's Financial Services Center (FSC).

The FSC staff reviews the files before transmitting payment information to VA's Financial Management System (FMS). The FSC staff issues a single payment to U.S. Bank for the prior day's purchases from the PPV then charges each facility's prime vendor obligation account for the payment amount of the billed PPV pharmaceutical supplies. Facilities then reconcile payments made to the PPV with their prime vendor orders.

REVIEW OF THE CONTROLS FOR THE PHARMACEUTICAL PRIME VENDOR FAST PAY SYSTEM

In this report, which was done at the request of the Committee and the VA Secretary, we reviewed the internal controls of VA's Fast Pay System, specifically assessing the adequacy of VA's internal controls in support of the provisions of the PPV contract. We focused on the ordering, receipt of pharmaceuticals, and payment activities. Specifically, we examined the controls at four Consolidated Mail Outpatient Pharmacies (CMOPs), four VA Medical Centers (VAMCs) pharmacies, the payment controls at the FSC and the NAC, along with reviewing a sample of invoices. We also reviewed a sample of orders placed by Other Government Agencies [1].

Our review found:

- VA was consistently providing payments to the PPV within 48 hours from the prime vendor's shipment of an order.
- VA was paying the accurate amount for actual goods received.
- VA was processing payments to the PPV in accordance with laws, regulations, and current terms of the PPV contract.
- VA was reimbursed by other Government agencies in a timely and accurate fashion.
- VA did not have reliable controls to ensure timely correction of improper payments and the controls were not sufficient to reduce the risk of program fraud or abuse.

Accurate Prices for Actual Goods Received

Each week, at the eight VA facilities we reviewed, the staff reconciled their prime vendor purchases with summary payment reports provided by the FSC, ensuring that payment amounts were correct. VA financial management staff also researched FMS transactions that had been rejected during payment processing by the FSC and monitored the facility's PPV obligations. We did not identify reconciliations that were not resolved or unresolved exceptions such as open items on reconciliations, or rejected transactions that were not paid timely.

Seven of the eight ordering facilities had sufficient controls in place to ensure that pharmaceutical purchases were checked against invoices at delivery and discrepancies corrected.

Consistent Compliance with Federal Laws

We found VA uses Fast Pay provisions of the Prompt Payment Act to meet contractual requirements to pay the PPV within 48 hours of shipment of an order.

Other Government Agencies Reliance on PPV

The PPV contract allows other entities to use the PPV program and the Fast Pay system. According to FSC officials, only the Indian Health Service (IHS) used the Fast Pay system. In FY 2011, IHS purchased about $46 million in pharmaceutical supplies, representing about 1 percent of the total $4.3 billion of PPV purchases. We did not review PPV items purchased by OGAs that did not use VA's Fast Pay System because no VA funds were at risk of loss to VA.

IHS reimbursements were paid in the correct amounts, and IHS reimbursed VA within an average of 23 days from the date an order was placed. We considered IHS reimbursements to VA timely based on the Prompt Payment Act requirement that payment be made within 30 days.

Resolving Inaccurate Payments

Controls over corrections of overpayments are critical under the Fast Pay system since corrections are identified and adjustments made after payments are processed. In addition to our eight facilities, we reviewed procedures for identifying and resolving overpayments at the NAC and the Pharmacy Benefit Management (PBM) Services. We found no evidence that all of these responsibilities were properly executed.

PBM's business practice is to review prices for all pharmaceutical items purchased from the PPV each month, beginning 3 months after the purchase. For example,

[1] In February 2012, VA reported that State Veterans Homes, Howard University Hospital, the Indian Health Service, Bureau of Prisons, Peace Corps, U.S. Public Health Service, and Department of Homeland Security used the PPV contract.

purchases made in July 2011 would be reviewed in October 2011. This delay allows sufficient time for price adjustments initiated by purchasing activities or the PPV to be adjusted to reflect correct amounts. PBM provides the NAC contracting officer a monthly price analysis, which shows differences between amounts paid and the contract prices for specific pharmaceutical items. The contracting officer is responsible for resolving PPV pricing anomalies.

PBM staff completed their March 2011 pricing analysis in August 2011 (2 months late). Their price analysis for April 2011 purchases was completed in December 2011 (5 months late). According to PBM officials, they reprioritized their work because the NAC's PPV contracting officer was not timely resolving potential pricing differences identified by the PBM and completing additional analyses would only have increased the contracting officer's backlog.

The process of resolving potential pricing differences, which the NAC put in place, had stopped. As a result, VA was at risk of not processing appropriate pricing adjustments. The total value of potential pricing differences identified by PBM for the monthly reviews of PPV purchases from December 2009 through April 2011 was approximately $46.4 million. The contracting officer stated the primary reason for the delay in resolving pricing differences with the PPV was that he needed to use that time to prepare the future PPV contract. While we found that PBM and NAC controls did not reliably ensure timely correction of potential pricing differences, our subsequent work in the ongoing review of PPV open market purchases for FY 2011 has shown that these potential pricing differences had been satisfactorily resolved through the credit and rebilling process.

Facility pharmacy staff made timely payment corrections for overpayments. According to PPV records, the PPV reimbursed VA pharmacy facilities a total of approximately $23.5 million (.5 percent of $4.3 billion) in overpayment corrections and about $15.4 million (.4 percent) in return credits in FY 2011. Pricing corrections occur for several reasons, such as retroactive price adjustments, item count errors, and product returns. For example, a retroactive price adjustment is required when the PPV changes a price of an item on January 5, 2012, but applies it to all purchases of that item from January 1, 2012. We determined that controls at VA facility pharmacies were considered adequate and that facility pharmacy staff made timely payment corrections for overpayments.

Protection Against Possible Fraud and Other Abuses

As the highest area of risk, we assessed pharmacy ordering and receiving operations to address whether VA has established controls to reduce the risk of fraudulent payments and other program abuses for PPV. At each pharmacy, we assessed whether the ordering and receiving duties of pharmacy staff were adequately segregated.

In general, we determined controls were not effective in mitigating the risk of program fraud. Segregation of duties is a strong fundamental control in ordering and receiving functions. Duties such as ordering supplies, receiving supplies, making payments, and certifying funding should be assigned to separate individuals to the greatest extent possible. By separating certain duties within an organization, no single employee should be in the position to perpetrate and conceal fraud. For example:

- Three of four VAMC pharmacies needed to strengthen controls to ensure an adequate segregation of duties existed. They did not segregate duties among different staff to prevent any one individual from having the ability to both order and receive non-controlled pharmacy supplies. With regard to controlled substances, at the four VAMC pharmacy the duties were properly segregated.
- The four CMOPs had adequate controls to segregate duties among designated ordering officers and staff who verified that ordered items were received. Controls in place were working effectively to ensure ordering officers and receiving staff held separate system access keys to log into the prime vendor account. At no point were individuals allowed to perform ordering and receiving functions. VA policy requires CMOPs establish unique individual user identification and passwords for all functions related to inventory maintenance and control, to include ordering and receiving on the PPV and CMOP automated inventory systems.

QUANTIFYING OPEN MARKET AND PRICING ISSUES

Currently we are completing our review of PPV purchases for FY 2011. The purpose of the review is to quantify the open market sales, identify reasons why items were not purchased through existing contracts, and evaluate whether VA was overcharged for items on contract. We also reviewed purchasing data for December 2011, to verify the accuracy of the reported 0.4 percent in open market purchases for that month and validate whether controls implemented in November 2011 were effective

in controlling open market purchases. In addition, we are reviewing open market purchases to determine whether they violated procurement laws and regulations and whether the purchases were in compliance with the Trade Agreements Act. We expect to issue a final report in July 2012. We also have reviewed the new PPV contract to determine if additional terms and conditions will reduce open market purchases.

FY 2011 Open Market Purchases

Our review found that it is not possible to easily quantify open market purchases by simply reviewing purchasing data captured for a specific period of time. Due to delays in processing new pricing through contract modifications and entering the information into the PPV system, purchasing information is updated continually by McKesson through a system of credits and rebills. This process corrects data relating to whether the item was on contract versus open market and adjusts the price paid to reflect the correct contract pricing.

We identified $4.3 billion in overall reported sales in FY 2011 of which approximately $290 million was identified as open market because there was no underlying contract number listed in the appropriate data field. Approximately $283 million of the $290 million represented pharmaceutical purchases and remaining $7 million represented medical/surgical items.

We selected 100 of the top pharmaceutical items identified as open market for review, which represented $108 million (43 percent) of the open market pharmaceutical purchases.

- We found that 43 of the 100 items ($63 million) were on contract at the time of purchase. This represents 58 percent of the dollar value of 100 items in our sample. Of the 43 items, 29 ($36 million) were sold at the contract price. The 14 remaining items ($27 million) were sold at a price that exceeded the contract price with potential overcharges of $9.4 million. However, upon further review, we found that $5.5 million of the potential overcharges was due to product allocation [2], not overcharging, and the remaining $3.9 million related to delays in contract pricing adjustments, which appear to have been corrected through the credit and rebilling process.
- We determined that 48 of the 100 items were not on contract for all or part of FY 2011. These items represented $36 million (33 percent) of the open market purchases in our sample. We identified comparable items on FSS contracts for 15 of the 48 items ($9.1 million). For 12 of the 15 items, ($7.6 million), the FSS prices were lower. However, we found that many of the comparable items on FSS were not available at the time of purchase due to manufacturer shortages and backorder issues. We concluded that for those items that a comparable FSS product was available, VA paid $904,000 more than it would have paid if the contract item had been purchased. Although the prices paid for the remaining 3 items ($1.5 million in purchases) were less than the FSS price, the items should have been purchased from the FSS as required by VA policy. We could not identify with any degree of certainty a comparable item on FSS for the remaining 33 items ($26.6 million). These items were purchased at McKesson's list price.
- We also identified 9 items ($8.6 million) that were on FSS but purchased at open market prices through the PPV. Most of these were covered or branded drugs on FSS at the Federal Ceiling Price, which is the highest price VA can pay when purchasing from the manufacturer or the manufacturer's authorized distributor. Because the FSS contractor elected not to participate in the PPV program, the PPV is not required to offer the FSS price. These purchases resulted in up to $4.8 million in overpayments. We have not identified a legitimate reason to justify purchasing these products open market through the PPV instead of the manufacturer. We initially identified this problem through our post-award reviews and raised this issue to VA in 2007 and again in 2011. In 2007, we were told that the PPV purchasing system was changed to block purchasers from buying these products through the PPV. However, in 2011, when we found the problem continuing, we learned that at VA's request the system allows the purchaser to override the block.

We concluded that McKesson has done a good job of correcting pricing through credits and rebilling when the PPV database is updated by VA to include changes in contract pricing. However, we believe delays in identifying and correcting contract pricing are caused by poor communication between PBM and the NAC's FSS and National Contracts divisions.

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[2] For some pharmaceuticals VA is guaranteed a fixed quantity. VA can purchase additional quantities but those would be at open market prices.

Review of December 2011 Purchases

We reviewed the accuracy of VA's reported 0.4 percent in open market sales through the PPV contract for December 2011. However, we found the procedures implemented in November 2011 did not preclude or prohibit open market purchasing. Instead, open market purchases were shifted from the PPV contract to other financing accounts. We reviewed purchases through the new open market purchasing system and identified approximately $7 million in purchases, which represented 2.0 percent of the total purchases by VA through McKesson. The percentage of open market purchases by VA through McKesson was approximately 2.4 percent, not 0.4 percent as reported. Our review of open market purchasing trends under the new system was inconclusive because a large number of the products were actually on contract.

In addition to reviewing the purchases identified in the FY 2011 data as open market, we sampled items identified as contract sales. We did not find significant problems with overcharging. As with the open market items, corrections are made over time as adjustments to the contract price are awarded and entered into the PPV system.

Open Market Issues

Based on our review and our ongoing pre-award and post-award audits of FSS contracts, we believe that open market purchasing through the PPV is impacted by several factors including items not on contract but needed to provide care, a growing number of product allocations and shortages necessitating purchasing items at non-contract prices, and purchasing items through the PPV for convenience instead of buying direct from manufacturers who do not participate in the PPV program. A growing number of items are not on contract because there is no requirement that manufacturers offer generic drugs on FSS contracts. In addition, a growing number of products are no longer manufactured in the United States or a designated country and thus cannot be offered on contract due to Trade Agreement Act requirements. We are currently reviewing open market purchases to determine whether the purchasers violated Federal procurement laws and regulations, including the Trade Agreements Act.

Review of Terms and Conditions in Recently Awarded PPV Contract

We also reviewed the changes made to the new PPV contract to determine if such changes will preclude open market purchasing and if prices paid for products previously classified as open market will be fair and reasonable. The new PPV contract states non-contract (open market) items are excluded from the PPV contract and Ordering Officers are prohibited from buying open market items through the PPV contract. Generic items that are not on a Federal government contract and have a published Wholesale Acquisition Cost (WAC), are approved by the Food and Drug Administration, and are compliant with the Trade Agreements Act, can now be purchased through the PPV contract at a price negotiated prior to award. These products are known as WAC Based Priced Generics (WBPG). For the most part, open market purchases should decrease significantly with the availability of WBPGs. However, open market purchases can still occur by buying such open market products via a different payment account. Such purchases are not considered a PPV purchase because they are not processed through the PPV account.

We are also concerned that FSS vendors who sell generic products may remove their products from their FSS contracts and have them sold by the PPV as WPBGs. The FSS will no longer receive a discount off the FSS vendor's list price but will pay the listed WAC price less a discount equal to the awarded distribution fee. Based on our experience conducting pre-award reviews of proposals for FSS contracts, we have concerns whether the negotiated PPV price for these generic products is fair and reasonable.

CONCLUSION

VA has implemented controls to provide timely and accurate payments for pharmaceutical items processed through VA's Fast Pay system as well as following laws, regulations, and policies. However, system controls to identify and correct pricing differences by the PPV and to reduce the risk of fraud and other program abuses were either not in place or were not effective. Without strong system controls, VA risks paying the incorrect price for pharmaceuticals as well as increasing their vulnerability to program fraud.

Our review of open market purchases found that the open market purchases were significantly less than originally stated. We found that McKesson was doing a good job of adjusting prices through credits and rebillings to ensure that contract items are purchased at contract prices when VA provides data. It is not uncommon for

pricing changes to be implemented months after the fact due to delays in contract modifications that result in retroactive pricing. In addition, due to product shortages and allocations, VA does not always get contract pricing.

Mr. Chairman, this concludes our statement and we would be pleased to answer any questions you or other members of the Committee may have.

Prepared Statement of Mr. Flach

Good morning, Chairman Miller, Ranking Member Filner and Members of the Committee. My name is Paul Flach, and I am Vice President of McKesson Health Systems, National Accounts, for McKesson Corporation.

Mr. Chairman, before I begin today, I would like to say that my company appreciates the veterans who work for McKesson and feels both enormous pride and responsibility for our selection as the Pharmaceutical Prime Vendor to the Department of Veterans Affairs. I know that all of you on this Committee and at the Department of Veterans Affairs are working hard for America's veterans every day. Thank you for your efforts.

For 179 years, McKesson has led the industry in the distribution of medicines and health care products. Today, a Fortune 14 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in health care settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 200,000 physician practices, and over 10,000 extended care facilities and 700 home care agencies. In addition to the Department of Veterans Affairs, McKesson delivers medicines to the Department of Defense and other government facilities. We are also one of the nation's largest distributors of biotechnology and specialty pharmaceutical products and services for providers and patients.

Mr. Chairman, as you know, McKesson provided testimony on the Pharmaceutical Prime Vendor (PPV) contract before this Committee earlier this year. We understand your oversight responsibility for the Department of Veterans Affairs and particularly as it relates to the PPV contract. We recognize the importance of this contract to the VA's health care system and, ultimately, to America's veterans. I am here today to provide the Committee with some additional information about the PPV contract as well as to answer your questions.

As the Department's Pharmaceutical Prime Vendor since 2004, McKesson is proud to partner with the VA to provide pharmaceuticals to more than five million veterans and to continue delivering excellent quality and service to the VA. Through the deep negative distribution fee in our contract with the VA, we have provided the Department with $526 million in savings over the VA's prior PPV contract. We have been able to do this while consistently exceeding the requirements of the contract and providing state of the art technology and unparalleled quality and value to the Department.

Pharmaceutical Purchasing Through McKesson

As the Pharmaceutical Prime Vendor, McKesson delivers pharmaceutical and certain medical/surgical products to more than 700 VA locations, including over 270 medical centers and seven consolidated mail order facilities (CMOPs).

As our PPV contract requires, McKesson provides thousands of products to the VA at prices set under federal supply contracts which the VA has secured through direct negotiations with pharmaceutical manufacturers. McKesson's state of the art technology allows authorized VA buyers to purchase products through an electronic order entry system which drives them to the lowest priced item under a VA-negotiated contract. If a contract product is out of stock, the system directs the buyer to the lowest priced generic equivalent product that is on a VA-negotiated contract.

When an authorized VA buyer orders product by 6pm, it is delivered the next morning, thereby assisting the VA with inventory management and saving the Department millions of dollars in working capital. McKesson has a dedicated "VA-only" customer service department. Our accuracy in fulfilling orders is 99.9 percent. Through the transparency afforded by our electronic ordering and inventory management systems, the VA can manage and track their inventory and has real-time access to invoice and ordering data. Furthermore, McKesson holds the largest inventory of any pharmaceutical distributor to ensure our world-class service levels. I am proud to say that we have consistently exceeded the PPV requirements for service and quality.

PPV Purchases Are Almost Exclusively VA–Negotiated Contract Products

The VA has successfully negotiated a significant number of contracts with manufacturers for the purchase of pharmaceuticals, which exceeds, by far, the number of pharmaceutical manufacturer contracts typically held by health care institutions within the private sector. In April 2012, the VA purchased, through the PPV contract, 99.83 percent of its products under VA-negotiated contracts with manufacturers.

There are circumstances, however, when contracted pharmaceuticals are in short supply or other critical medicines are needed to treat patients. Purchases of pharmaceuticals that are not on contract are frequently referred to as "open market" purchases. Stated simply, open market purchases are for products which are not subject to a contract price negotiated by the VA with the manufacturer. We would like to emphasize that all pharmaceutical products purchased by the VA from McKesson, whether under VA "contract" or an "open market" item, have the required FDA approvals.

Purchases of open market products are a standard practice in the private sector. In the private sector, for instance, 30–40 percent of the purchases made by hospital and institutional customers are for open market products.

Dramatic Decline in Open Market Purchases

Since November, when the VA asked for our assistance, we have been working closely with them to restrict open market purchases under the PPV contract. As a result of these efforts and other steps taken by the VA, open market purchases under the PPV contract have dramatically declined from less than 5 percent previously to less than 2.1 percent in November 2011 and then to 0.17 percent in April 2012.

In collaboration with the VA last fall, we modified our online electronic ordering systems. Open market items can no longer be viewed on the ordering screen by those who are placing an order under the PPV contract. McKesson was given 48 hours to make this change, and we met the VA's deadline.

Additional Steps With the New Pharmaceutical Prime Vendor Contract

McKesson is preparing for the new PPV contract that will go into effect in August. We will be enhancing our technology, beyond what is required, to meet the VA's intention to restrict open market purchases. Our systems are complex and must be able to process over a million line items on a daily basis. We are making these enhancements judiciously because the VA relies on the timely delivery of the medications it orders to provide medical care for our nation's veterans.

As part of developing this technology enhancement, we are building a "restrict and notify" component with plans for this functionality to be available later this fall. If the VA attempts to order a pharmaceutical product from our distribution centers that would result in an open market purchase under the PPV contract, our system will automatically remove the item from the order and send a corresponding notification back to the VA. This notice will alert the VA that we are not delivering the specified pharmaceutical product and enable it to identify alternatives to meet patient need on a timely basis.

Conclusion

Mr. Chairman, in April, McKesson was selected by the VA to continue as the Pharmaceutical Prime Vendor. The VA conducted a rigorous competition for this contract award. We are honored to be selected again as the PPV and are committed to continue to deliver outstanding value and service to the VA and our veterans.

On behalf of McKesson, I want to thank the VA for the trust they continue to place in our performance, our people and our company. McKesson is very proud of our unique ability to improve the delivery, cost efficiencies and quality of care for our nation's veterans. America's veterans deserve the best health care, and McKesson is committed to a partnership that continually enhances the VA's ability to provide critical services to the veterans they serve.

Mr. Chairman, thank you for the opportunity to appear here today. I am happy to answer your questions.

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