

**EXAMINING VA'S PHARMACEUTICAL PRIME
VENDOR CONTRACT**

HEARING
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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CONTENTS

February 1, 2012

	Page
Examining VA's Pharmaceutical Prime Vendor Contract	1
OPENING STATEMENTS	
Chairman Jeff Miller	1
Prepared statement of Chairman Miller	45
Hon. Michael H. Michaud, Acting Ranking Democratic Member	2
Prepared statement of Congressman Michaud	46
WITNESSES	
The Honorable W. Scott Gould, Deputy Secretary of Veterans Affairs, U.S. Department of Veterans Affairs	5
Prepared statement of Hon. W. Scott Gould	47
Accompanied by:	
John R. Gingrich, Chief of Staff, U.S. Department of Veterans Affairs	5
Glenn D. Haggstrom, Executive Director, Office of Acquisitions, Logistics, and Construction, U.S. Department of Veterans Affairs	5
Jan R. Frye, Deputy Assistant Secretary, Office of Acquisition and Logistics, U.S. Department of Veterans Affairs	5
Philip Matkovsky, Assistant Deputy Under Secretary for Health for Adminis- trative Operations, Veterans Health Administration, U.S. Department of Veterans Affairs	5
Steven A. Thomas, Director, National Contracting Service, National Acquisi- tion Center, U.S. Department of Veterans Affairs	5
Michael Valentino, Chief Consultant, Pharmacy Benefits Management Serv- ices, U.S. Department of Veterans Affairs	5
Linda Halliday, Deputy Assistant Inspector General for Audits and Evaluat- ions, Office of Inspector General, U.S. Department of Veterans Affairs	30
Prepared statement of Linda Halliday	51
Accompanied by:	
Mark Myers, Director, Healthcare Resources Division, Office of Contract Re- view, Office of Inspector General, U.S. Department of Veterans Affairs	30
Michael Grivnovics, Director, Federal Supply System Division, Office of Con- tract Review, Office of Inspector General, U.S. Department of Veterans Affairs	30
Sharon Longwell, Vice President, Health Systems, National Accounts McKesson Corporation	38
Prepared statement of Sharon Longwell	53
MATERIAL SUBMITTED FOR THE RECORD	
Post-Hearing Questions and Responses for the Record:	
Hon. Bob Filner, Ranking Democratic Member, Committee on Veterans' Af- fairs to Hon. Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs	57
Responses from Hon. Eric K. Shinseki, Secretary, U.S. Department of Vet- erans Affairs to Hon. Bob Filner, Ranking Democratic Member, Committee on Veterans' Affairs	59

EXAMINING VA'S PHARMACEUTICAL PRIME VENDOR CONTRACT

WEDNESDAY, FEBRUARY 1, 2012

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

The Committee met, pursuant to notice, at 10:02 a.m., in Room 334, Cannon House Office Building, Hon. Jeff Miller [Chairman of the Committee] presiding.

Present: Representatives Miller, Stearns, Bilirakis, Roe, Stutzman, Flores, Johnson, Denham, Runyan, Benishek, Buerkle, Huelskamp, Amodei, Reyes, Michaud, McNerney, Donnelly, Walz, and Barrow.

OPENING STATEMENT OF CHAIRMAN MILLER

The CHAIRMAN. Good morning. This hearing will come to order. And I want to thank everybody for coming today to a hearing entitled Examining VA's Pharmaceutical Prime Vendor Contract.

We started investigating PPVs and the contract well before the stories on this topic hit the press and we found enough that questions were raised to warrant the hearing that we are going to hold today and possibly subsequent hearings in the future.

Now, the PPV contract when written and executed correctly is intended to ensure VA medical facilities receive the needed pharmaceuticals at a competitive price and in a timely fashion.

Medical facilities throughout the Nation rely on this system to ensure that the patients get the best care, that the Veterans get the care they need, they deserve, and they have earned.

The Committee's investigation began when discrepancies appeared in how VA ordering officials had been handling open market purchases of items not available on the PPV contract.

These purchases go back much further than just the last year or two. In fact, they span multiple administrations showing many within VA chose to ignore rather than to fix a problem they knew about.

While Federal acquisition regulations outline clear procedures on how agencies can acquire items when they are not on a contract, VA officials for years have ignored those procedures when purchasing supplies that were either not available at the time or not on the PPV contract.

Instead of actually performing due diligence in its open market purchasing, VA officials took the easy route and requested the PPV to deliver the needed pharmaceuticals or in some cases non-pharmaceutical items.

An open market purchase requires a degree of competition. VA's practices willfully ignored requiring competition thereby compromising best value to the taxpayer and potentially compromising patient safety.

In short, what VA has been doing is not mere bureaucratic oversight, it is illegal with serious potential ramifications for Veterans.

I am disheartened by VA's treatment of this matter. We know that senior officials at the department have known these practices for a long time, yet did little to address the issue and certainly were not forthcoming about it to Congress.

In fact, VA has acknowledged open market purchases through the PPV could be problematic as far back as December of 2010, but only in November of 2011 did they take formal action. And this action was little more than a restatement of current laws that employees should already have been following and the leadership should have been enforcing.

One thing, we will get to the bottom of this, who knew of VA's illegal buying and did nothing about it. As has been the case of several other problems identified by this committee, weaknesses in contracting at VA are a major cause of the illegal purchases we are discussing here today.

Instead of applying temporary bandages to cover up problems, VA needs to address the recurring causes within its own department and fix them. Whether a complete contracting overhaul is needed or simply new leadership that can enforce existing law, it is my sincere desire that this committee and the department can resolve these issues and move forward.

My concern about the depth and duration of this illegal purchasing is serious enough that I have partnered with Chairman Issa of the Oversight and Government Reform Committee in requesting needed documents and information from VA to fix this problem.

I want to thank Chairman Issa for his help in investigating this matter and I look forward to VA's full and timely cooperation with us and his committee.

Lastly, I want to note VA's continuing habit of not providing requested information to this committee. One request is now a month overdue and another is 5 months overdue.

I want to work with your department to get our Veterans the services and care they deserve and that is going to require your congressional affairs team working with us to deliver the appropriate solutions.

I now recognize the Ranking Member, Mr. Michaud, for an opening statement.

[The prepared statement of Chairman Miller appears on p. 45.]

**OPENING STATEMENT OF HON. MICHAEL H. MICHAUD,
ACTING RANKING MEMBER**

Mr. MICHAUD. Thank you very much, Mr. Chairman, for having this hearing and for your leadership dealing with the Veterans' issues.

I also want to thank Representative Donnelly for his leadership in this particular issue as well.

We are here because once again VA has demonstrated an inability to properly perform its responsibilities to follow its procedures and policies and applicable laws and regulations.

The VA admits that it did not follow all applicable laws and regulations for approximately \$1.2 billion in what was called open market drug purchases since 2004.

VA assures us that changes have been implemented to fix deficiencies at hand. Frankly, Mr. Chairman, we have heard this before.

Today I have three questions. First, what did VA officials know and when did they know it? In December 2010, the VA decided to not include an open market clause in the upcoming PPV contract. What was the impetus behind this decision? Was there an awareness in 2010 that there were serious problems with open market purchases, yet nearly a year lapse before VA took decisive action?

During this period, did anyone in VA leadership simply insist that open market purchases conform with VA policy, regulation, and law? Have these \$1.2 billion in purchases that were not in accordance with applicable laws and regulation, have they been ratified by the VA?

In 2009, the inspector general found a litany of problems with improper open market purchases for medical equipment and supplies. VA management and leadership should have been put on notice that problems might exist in other prime vendor programs, but no proactive steps seemed to have been taken at that time.

I find it hard to believe that as the VA states, and I quote, "The process that was in place since 2004 had become routine," end of quote. I have to ask what is routine about failure to follow established policies and procedures?

Title 38 requires VA to submit an annual report on the health care procurement experience. I look forward to receiving those reports from VA dating back to 2004.

My second question is, who should be held accountable for this failure? Time and time again, VA comes up here and testifies that it has wonderful policies and procedures in place. Unfortunately, no one ever seems to follow these policies and procedures and there seem to be no consequences for the failure to follow these procedures.

And time and time again, the IG, the GAO testify concerning serious problems with VA management and controls. And time and time again, VA ignores these findings and fails to take action.

VA testimony includes an illustrative example of a GS5 pharmacy specialist confronted with the choice of ordering an open market item or doing without. Let me offer an example of how management responsibility for overseeing GSA making sure that pharmacy specialists knew what VA policy and procedures were required and ensuring that they follow them. It is management's responsibility.

Third, how is this going to be fixed and how will this fix process improve the care we provide to our Veterans? How will the absence of an open market clause in the new contract, how will that affect our Veterans? Is VA still making open market purchases either through PPV or through other suppliers and how can we be sure that proper procedures are in place and, more importantly, being actively supervised by management?

I want to be sure that VA open market purchases are from reliable suppliers and that all purchased drugs and pharmaceuticals meet all safety requirements.

There is a saying of ignorance of the law is no excuse. I hope that VA can help us understand today what accountability we should expect from the failures that seem to arise from ignorance, you know, or willful neglect of VA policy and procedures in existing laws and regulations.

I mean, there is no excuse for VA management in this regard and there is no need to blame a GS5 position. This is a management failure, a failure which hopefully we will be able to get to the bottom of this.

And it is my hope that because of this failure, that those in management did not receive a bonus. One point two billion dollars is a lot of money.

So with that, Mr. Chairman, I yield back and look forward to working with you in this regard.

[The prepared statement of Hon. Michaud appears on p. 46.]

The CHAIRMAN. I thank the Ranking Member.

And following our standard practice here on the Committee, I would ask any Member that has an opening statement if you would hold it at this time and you may either give the statement when your turn for questioning arises or it may be submitted into the record here if that is your choice.

Our first panel today, a large panel, as everybody can see. I will introduce Mr. Gould. Secretary Gould is here with us today. He is Honorable W. Scott Gould, deputy secretary of the Veterans Affairs.

And, Secretary, what I would like to do instead of me introducing everybody at the table, I understand you have modified your comments today to introduce everybody at the table with you.

And I would ask the clerk not to begin the clock until everybody has been introduced.

You are recognized.

STATEMENT OF 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; 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; PHILIP MATKOVSKY, ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH FOR ADMINISTRATIVE OPERATIONS, VETERANS HEALTH ADMINISTRATION, 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

Mr. GOULD. Mr. Chairman, thank you for the privilege of reporting to the Committee today.

As you asked a moment ago, I am accompanied by Mr. John Gingrich to my right, VA's chief of staff; Mr. Glenn Haggstrom, Principal Executive Director for the Office of Acquisitions and Logistics and Construction; to his left Mr. Jan Frye, Deputy Assistant Secretary for Acquisition and Logistics; to his left Mr. Steven Thomas, Director of National Contracting Service at the National Acquisition Center; further to my right Mr. Philip Matkovsky, Assistant Deputy Under Secretary for Health for Administrative Operations within Veterans Health Administration; and, finally, Mr. Mike Valentino, Chief Consultant for Pharmacy Benefits Management Service.

Also seated behind me are Mr. Craig Robinson, Associate Deputy Assistant Secretary for National Healthcare Acquisitions and Ms. Phillipa Anderson from the Office of General Counsel.

With your permission, sir, I would like to submit my written testimony for the record.

The CHAIRMAN. Without objection.

Mr. GOULD. At your request, our testimony and our questions today will center on a VA contract for distribution of drugs within VA called the pharmaceutical prime vendor contract or PPV.

The PPV fits into a larger system of rules, regulations, contracts, and management procedures designed to provide a continuous supply of quality drugs for our Veterans.

Let me say at the outset that VA has identified several areas where it did not follow applicable law and regulation for some drug transactions. This flawed approach was confined to transactions known as open market purchases under the PPV distribution contract.

Since the current contract came into existence in 2004, open market purchases amounted to 4 percent of the total value of purchases through the PPV.

Now, open market purchases are purchases made through the PPV of pharmaceuticals that are not on a VA supply contract or

from vendors with contracts who do not agree to sell through the PPV.

These deficiencies were the responsibility of VA to identify and correct. The deficiencies were not criminal. And the remaining 96 percent of the transactions followed all applicable laws and regulations.

At no time were our Veterans put at risk. The drugs supplied were FDA approved and complied with applicable Trade Agreement Act requirements with the exception of a portion of a single transaction of \$2,000.

We paid fair and reasonable prices for 96 percent of the purchases. We cannot, however, verify that we did the same for the open market purchases since we did not compete these transactions as we should have on an individual basis.

In fact, in some cases, the ordering officers were requesting generic equivalents to brand medication which we all know typically costs much less.

We point out that the distributor we used provides pharmaceutical products for such cost conscious companies as Walmart, Target, Rite Aid, and Costco among others.

When we recognized we had a problem, we acted to correct it. Beginning on November 8, 2011, VA mandated cessation of this flawed process and replaced it with a new process that conforms to all applicable regulations.

We did four things. First, we removed the ability of ordering officers to see any drug not available through Federal contract on the McKesson portal. The McKesson portal is the device through which the ordering occurs.

Next, we mandated training for employees authorized to place those orders.

Third, we placed qualified contract officer representatives at the facility level to ensure compliance.

And, finally, on a parallel track, we continued to move forward with a process begun in June of 2011 to issue a new RFP for a replacement PPV contract that will not allow the mistakes of the past to be repeated.

Mr. Chairman, we thought deeply about the issue of accountability and after extensive internal deliberations and analysis concluded that there is no one individual to hold accountable for the pervasive misuse of the open market clause. It was a team failure simply put.

The process began many years ago. It broke down to such an extent that the wrong way became the way we have always done it. The middle and senior level managers who made these initial decisions have left VA.

Despite these shortcomings, timely delivery of FDA approved medications was not interrupted further masking the discovery of the problem.

The managers involved have learned to test their assumptions more carefully, even those governing well-established processes, and to increase the amount of training, administrative review, and oversight of these contracts at every level.

The corrective actions we have taken will preserve VA's access to necessary drugs and complies with all applicable law and regulation.

We will continue to provide our Veterans with high-quality care with their unique medical needs as our first priority and we will continue to improve our pharmaceutical acquisition management.

Thank you for the opportunity to testify before the Committee and I look forward to your questions.

[The prepared statement of W. Scott Gould appears on p. 47.]

The CHAIRMAN. Thank you, Mr. Secretary.

In your testimony, you make it clear that the purchase of pharmaceuticals off contract without competition did, in fact, occur; is that correct?

Mr. GOULD. That is correct.

The CHAIRMAN. Is this a violation of the law?

Mr. GOULD. Yes.

The CHAIRMAN. When did, if you would again, and I know you mentioned some dates in your testimony, but when did senior leadership first learn of the unlawful purchasing?

And I would like to ask each individual at the table independently to let me know when you first heard about it and what you specifically did when you heard about it.

Mr. GOULD. Sir, to be responsive on that question then, each of us will answer that. What you will see is a range of dates as the problem escalated through the system.

To answer personally for the senior management team, I first knew about this issue in September of last year, September of 2011.

The CHAIRMAN. And we will start down here, Mr. Valentino.

Mr. VALENTINO. I became aware of the issue with open market purchases in December of 2010 when the clause was removed from the draft solicitation.

Mr. MATKOVSKY. I became aware in September of 2011.

Mr. GINGRICH. I became aware in September of 2011.

Mr. HAGGSTROM. With respect to the improper use of the open market clause, I became aware of it in March of 2011.

The CHAIRMAN. When did you hear about the illegal use?

Mr. HAGGSTROM. March of 2011.

The CHAIRMAN. Okay.

Mr. FRYE. I became aware in March of 2011, March 29th to be exact.

Mr. THOMAS. And I became aware in January of 2009 when a logistics manager from the CMOP identified this as an issue. At that point, I worked with general counsel, acquisition review, IG, others at the NAC, VHA, including PBM, and the CMOP to try to correct the issue for the CMOP which we became responsible for at the National Acquisition Center in December of 2008.

I tried to add items to the Federal supply schedule as much as possible to cover that gap. I tried to have additional things put on requirements, types of contracts that we had limited success on. But the main thing I did was I corrected the issue for the CMOP so the CMOP follows appropriate procedures at that point. And that was the area of responsibility that I had.

Mr. GOULD. So, Mr. Chairman, today you have just gone down the list to see when people knew what they knew. The people at the table today collectively identified the problem, took action, and we are collectively responsible for that fact.

The CHAIRMAN. Mr. Thomas, you took great pains just a second ago to talk about all the things you tried to do. Can you explain why you were unable to do some of the things you wanted to do?

Mr. THOMAS. Yes, sir.

The CHAIRMAN. Could you turn your mic on, too, please?

Mr. THOMAS. I apologize. Yes, sir.

I think what we have in this case is a changing industry to a certain degree. As you probably are aware, there are a lot of drug shortages that are currently going on right now. There is a Trade Agreements Act that we have to be responsible for to make sure that products are coming from appropriate countries. And a lot of the manufacturing for drugs right now are going overseas to India and China and those two countries are not Trade Agreement countries. So there are a number of issues going there.

When we put our requirements contracts out for some of the generic products, we were able to award about a third of them as they came through. It did not stop our efforts in that, but it made us try to figure out how we could get more products on contracts.

In the meantime, realizing that the CMOP was the largest purchaser of the pharmaceuticals on the prime vendor contract, we fixed that problem. We decided to do open market solicitations at the National Acquisition Center for products that were open market and we have been doing that ever since.

The CHAIRMAN. A wide range of times that people knew, but I guess the memorandum went out in November.

Mr. GOULD. Yes, sir, November 8th.

The CHAIRMAN. November 8. How much was spent illegally after the 8th of November because purchasing kept going for a month or two afterwards. Can you tell me how much was spent?

Mr. GOULD. Mr. Chairman, that, of course, is critical that not for one day did we want the flow of drugs to be interrupted to our Veterans. And one of the great challenges here in evaluating options and figuring out how to go forward is to preserve that need to deliver the drugs at the same time that we comply with the law.

The number of transactions now that are not compliant has dwindled to 0.4 percent. And I would like to ask Mr. Matkovsky to amplify on that analysis and our ongoing effort having identified the problem to correct it.

Mr. MATKOVSKY. Thank you, sir.

We are conducting a monthly review at this point with OALC on all of the transactions to determine which of them are open market. And for those that are, and the number was 0.4 percent of all transactions for the month of December, each one of those transactions is going through a warranted contracting officer's determination for ratification to bring it into conformance with the FAR.

The CHAIRMAN. I apologize, Mr. Secretary, if I did not hear you, but did you give me a number of what was spent after the 8th?

Mr. GOULD. Two numbers. The first number was for the month of December which we are analyzing is roughly \$1.4 million. The

total number of transactions which we are reviewing for ratification is 5,733 transactions.

The CHAIRMAN. You talked about drugs and certainly can understand your desire to keep pharmaceuticals going to the Veterans who need them, but this was not all about pharmaceuticals either, was it?

Mr. GOULD. That is correct. There are other non-drug items on the pharmaceutical prime vendor contract. And as you are aware, we have other agencies participating in the PPV, so other non-drug items are purchased on that contract.

I might ask Mr. Haggstrom to comment in more detail on that issue.

Mr. HAGGSTROM. Mr. Chairman—

The CHAIRMAN. Your mic.

Mr. HAGGSTROM [continuing]. As part of the contract, we do, in fact, have certain items that would be considered medical and surgical items on the contract that the prime vendor is allowed to purchase and distribute to our customers. These particular items are normally found in pharmacies and distributed with the purpose of distribution for our pharmacy customers. When you look at it, it is a very limited item because we have other contracts in place to do that.

The CHAIRMAN. Like the MedSurg?

Mr. HAGGSTROM. That is correct, sir.

The CHAIRMAN. I just do not want the conversation today to be solely focused on pharmaceuticals, although I do have a great concern even with the trade agreements that are out there in regards to how we know for sure that there were not adulterated drugs that were being used, but that is for another time.

And the other thing that I want to get to because I know everybody has questions that they want to ask, but the fast pay system, there are some issues with the auditing of the fast pay and some of the things that were just discussed.

But I will go ahead and yield to Mr. Michaud for questions that he may have.

Mr. MICHAUD. Thank you very much, Mr. Chairman.

Mr. Gould, do you have copies of the existing waiver request under the VA handbook 7408.1 for the \$1.2 billion in open market purchases dating back to 2004?

Mr. GOULD. Mr. Michaud, let me just consult with the team here.

Mr. Frye.

Mr. FRYE. Sir, I am not familiar with your question. A waiver for what again?

Mr. MICHAUD. A waiver request for open market purchases that is required under the handbook. That is 7408.1.

Mr. HAGGSTROM. I am not aware of any waivers. You are correct. The proper process is if the pharmacies desire to purchase other than through our VA national contracts or through our Federal supply schedule holders, there was a waiver process to be required. I am not aware of any formal waivers that came in.

Mr. MICHAUD. So since 2004, no waivers?

Mr. HAGGSTROM. I am not aware of any, sir.

Mr. MICHAUD. Okay. Mr. Gould, you indicated that VA had decided in December of 2010 to take the open market purchase clause out of the next contract, PPV contract.

What led to that decision back in 2010?

Mr. GOULD. No, sir, I did not say that the decision was reached in December of 2010, did you say?

Mr. MICHAUD. 2010, between 2010, there was a determination to not include open markets into the contract.

Mr. GOULD. In June of 2011, we took action to reach out to the private sector to issue an RFP for a new PPV contract which will be competed and decided in March and go into place in May of this year.

Mr. MICHAUD. But in 2010, it was decided at that time that open market would not be part of that new contract.

Mr. GOULD. In the new contract going forward, that is correct. We will not have open market purchasing in that contract.

Mr. MICHAUD. And in 2010, what led to that decision not to have open market in that new contract?

Mr. GOULD. Let me ask Mr. Haggstrom to comment on that.

Mr. HAGGSTROM. Sir, we realized, although under the current contract, we had an open market clause which has been well vetted with our general counsel in terms of legality and usage, what we discovered, and this issue goes back to being raised by the contracting officer, was do we really need this particular clause in the contract in terms of the usage. There was much discussion amongst our customer who is VHA and ourselves. We vetted it with the team through an IPT process and we came to the realization that we felt it would be better that we did remove this particular clause from the future contract.

As a result of the solicitation that was put out to industry in June of last year, that particular clause was removed knowing full well that we would have to address the issue of how to obtain those drugs that were not available to us through either a national contract or through the supply schedule.

Mr. MICHAUD. The chairman had talked about the drugs since November 8th that were purchased on the open market.

What percentage of those drugs was actually purchased through McKesson since November 8th?

Mr. GOULD. Philip.

Mr. MATKOVSKY. Since November 8th, we have been acquiring drugs in two mechanisms. One would be through a warranted contracting officer. And I am sorry. I will take for the record the specific amounts that have been awarded to what kinds of firms. I do not have that today.

But in those cases, we would be competing a contract action. We have several examples that we were reviewing that have gone to other firms. We will prepare the specific breakout.

Mr. MICHAUD. Okay. And maybe McKesson might know off the top of their head since November 8.

Do you have any waiver requests for those drugs? Did you have any?

Mr. MATKOVSKY. For the ones that are on the contract, we do not have them. If we have a situation where there is no availability on contract, we default to an open market. And that is usually what

we are doing, sir. So when there is none available and you still require the medication, you have to acquire them through other means.

Mr. MICHAUD. My last question actually is for Mr. Thomas. You had mentioned following, you know, on trade deals. I guess my concern with the drugs that are coming in from India, particularly China, what do you do to make sure that those drugs are safe, if anything?

Mr. THOMAS. Well, first of all, we are not allowed to purchase drugs from China or India based on the Trade Agreements Act. So we prevent that as much as possible.

The second issue regarding that is those facilities, although there is manufacturing being done in China or India, there still is an FDA approval process there. So I do not think there is really a safety issue with that. It is more of a government issue and the fact that we do not allow products from non-TAA countries.

Now, if you shop and go to your local pharmacy to get your prescriptions filled, you will get product from India and China. It is the government that cannot purchase those products from those countries.

Mr. MICHAUD. And as far as trans shipment, drugs going to China to another country that might have a trade deal, do you focus on that as well or is that out of your purview?

Mr. THOMAS. Well, there is something called substantial transformation that comes into play to a certain degree, but that is not something that we are responsible for. That is actually a Customs' responsibility.

Mr. MICHAUD. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. Roe.

Mr. ROE. I thank the chairman.

Let me just start by going back. And I called my local VA yesterday and spent some time on the phone with them to find out exactly how this process worked. And the way I understand this is you have a formulary that is approved and most of the time, you can fill the needs with that formulary and it works very well.

With McKesson, you have lessened the supply chain, less stock on the shelf, less cost to the VA. I understand that and that has been in place for several years. The issue is with the drugs out there that you cannot get.

Let's say there is a medicine on short supply. What does the VA do? And to make sure that I understand exactly, let me give you an example.

Yesterday I talked to my local VA. Versed is an injectable drug that doctors cannot get. It is used to calm patients in the ICU, for procedures like a colonoscopy. They cannot get that because it is in short supply. I think chemotherapeutics right now are also in very short supply.

So what do you do right now? In some of the testimony I read I found that if you bought something in the open market, it did not necessarily cost more than what was on the formulary.

It is like someone who comes in to me and has a co-pay for \$20.00. And I said, well, why would you pay a \$20.00 co-pay when

you can get a generic for \$4.00 at CVS or Walmart or wherever you shop.

So how do you do that and how do you make sure that that is done legally? And the second question I have, are there any penalties—it is a civil law, this law is not criminal—but are there any penalties for the people who knowingly broke this law?

Mr. GOULD. Do you want to cover the first one?

Mr. VALENTINO. I can answer part of that question, sir. You are exactly right. The issue of drug shortages is occurring with increasing frequency at the national level and we do struggle. Many times we have to look for alternative products.

So in the case of Midazolam and Alprazolam which are in short supply, we have to use other benzodiazepines. For other examples—

Mr. ROE. Why don't you give them the brand name because nobody understood a word of what you just said.

Mr. VALENTINO. Versed, Ativan, Lorazepam—

Mr. ROE. Valium.

Mr. VALENTINO [continuing]. Valium, these are the benzodiazepines that are similar but have different uses. And some are substitutable in certain clinical situations and not in other clinical situations. So we have been wrestling with this issue for a long time.

If you go to look at the American Society of Hospital or Health System Pharmacists Web site, at any one point in time, you might see 200, 250 drugs that are in short supply. We struggle with this. We have to contact physicians sometimes to change therapy.

But to get to your other point, that often is a situation that we confront. We will go to the prime vendor Web site and we will see out of stock, out of stock, out of stock, out of stock for the contract items.

What we then do is we look and see if there are non-contract items that have availability and, if so, we choose the lowest cost one that we will order. Did we do that appropriately in the past? No. Are we doing that appropriately now? Yes. Does the new contract fix that situation? We believe, yes.

Mr. ROE. Because what happens, I can tell you if I am the doc in the VA and I do not have medicine for my patient in the ICU who is having problems, I am going to be beating on the administrator that day to get me what I need to take care of that patient. I can promise you I am going to be doing that.

Mr. VALENTINO. Yes, sir, that happens.

Mr. ROE. And every day it is happening.

Mr. VALENTINO. Yes, sir.

Mr. ROE. And I talk to folks. I had a discussion with one of our folks at the VA and this very thing of drug shortage happened to an OIF/OEF Veteran who had severe PTSD and they were going to have to change his anti-anxiety medications. The guy threatened to kill somebody because he was doing so well on what he had. It is a real problem.

The other thing that is a real problem, Mr. Michaud, that you hit on that is extremely important is the importation or large amounts of generic drugs to this country. This goes beyond the VA the safety of these drugs. With China and India, it is a very serious

problem. And it is not just the VA. It is our whole supply chain of drugs, I think, and that is a whole different hearing.

The violation you did not mention. Is there any penalty if you violated this?

Mr. GOULD. Sir, if I may, thank you for drawing that distinction within the FAR, a collection of a lot of regulations, some of them very serious with criminal consequences, others not.

I would like to ask Ms. Phillipa Anderson from general counsel to go at that more nuance since these are not criminal acts, but are there any consequences on the less serious side.

Ms. ANDERSON. Thank you.

With regard to the unauthorized commitments, those transactions entered into by personnel not authorized to do so as well as the competition requirements of the FAR as well as the VAAR, there are no penalties attached or sanctions attached within the VAAR or the FAR itself.

Mr. ROE. Okay. Thank you. I yield back.

The CHAIRMAN. Mr. Donnelly, you are recognized.

Mr. DONNELLY. Thank you, Mr. Chairman.

When allegations of potential improper pharmaceutical purchases by the VA were brought to my attention last fall, my first concern was the safety of our Veterans.

Could we verify that the drugs met FDA and other Federal standards? Were any Veterans put at risk?

My next thought was about the cost to the taxpayer. Were these open market purchases totaling in the hundreds of millions of dollars or more wise uses of taxpayer dollars? Did the VA pay more than they should have for these drugs?

And third, what steps are being taken to ensure that Federal and VA rules are followed in the future, that the continued safety of our Veterans is not compromised and that taxpayer dollars are spent responsibly?

And so I want to follow-up on something I just heard where you mentioned you would go and it would say out of stock, out of stock, out of stock, out of stock and you would be forced to go open market then.

Isn't it a requirement of the contract that the supplier have these products in stock?

Mr. VALENTINO. I will actually defer to Steve for some additional comments. But there are fill rates that are associated with the contract. It is an overall global measure, but certainly the expectation is that the vendor will have these in stock. But they cannot stock what nobody has. And so there are—

Mr. DONNELLY. What does that mean?

Mr. VALENTINO. Well, if it is a national shortage and there is just none being produced, none is going into the supply chain, our wholesaler as well as other wholesalers simply have no stock of that item.

Mr. DONNELLY. So then if nobody has any stock, what do you then do?

Mr. VALENTINO. Then we will look and see if there are non-contract items available.

Mr. DONNELLY. That is a similar product to the product that you cannot obtain?

Mr. VALENTINO. It is a generic equivalent.

Mr. DONNELLY. Well, why can't we put that on a contract too?

Mr. VALENTINO. We would love to have as many of those as we possibly can on contract. And Mr. Thomas alluded to some of the things that he was doing. About a third of the time it is possible and the rest of the time it is not possible for a variety of reasons.

But you are absolutely right. In a perfect world, everything we need we would have on contract and we would simply order it through the prime vendor for delivery.

Mr. DONNELLY. Well, I am not even talking about a perfect world, but like a just in time supply chain. That is the whole idea about the VA not having to stock everywhere is that somebody else will have that for you. You can call and then it is done.

And I would think that part of the process would be, well, if we cannot get A, then B is available. And, you know, you mentioned that a third of the time, B can go on contract, but for a variety of reasons, it cannot.

Why would we not be able to contract these other products?

Mr. THOMAS. I think part of that is the reasons that I talked about earlier.

The CHAIRMAN. If you could, talk into the mic.

Mr. THOMAS. This is certainly a changing industry. There are generic manufacturers that are falling out of this business that are moving their market share to other manufacturers who then cannot ramp up fast enough to pick up whatever is being—

Mr. DONNELLY. But you at some point identify here is the other product we have to get, right? And so you know that that product is out there.

Is there any ongoing program with the vendor to say, hey, we need to put a contract on this product now and on this product? I mean, it does not come up to you in one day that this product is now out on the market. You know, what is the process for that?

Mr. THOMAS. Yes, sir. And what I would like to do is give you a balanced perspective on two sides. One is Mr. Valentino sort of keeping an eye on this whole process, evolving demands, new drugs, how do we get position, and then swing over on how we do that on a going forward basis to make sure that we compete and get as many of these new drugs into the system.

So, Mike, if you would start there, please.

Mr. VALENTINO. Yeah. It is a moving target for us. And in the situation that you described with shortages, we may have one manufacturer that is in a situation where they cannot ship product for one reason or another. There is an FDA action or there is a raw material shortage, but that is not affecting another company.

So our primary goal, as you have heard, is, and as Mr. Roe has mentioned, is to get the product that we need for patient care using all appropriate and available—

Mr. DONNELLY. Right. First and foremost is always make sure the vet gets what they need.

Mr. VALENTINO. Yes, sir.

Mr. DONNELLY. And we have to do whatever we have to do to do that. My biggest problem is I do not understand how we do not have some type of ongoing system that these other products are on contract as well.

Mr. GOULD. We do, sir.

And, Jan, if you would address that.

Mr. FRYE. Yeah. I do not think, Mr. Donnelly, that there is anyone here at the table that does not agree with you, that if something is not on contract, because our associates here, the supplier, use our contract—

Mr. DONNELLY. Right.

Mr. FRYE [continuing]. We develop the contracts. We negotiate the prices. But if we have a drug that is not on contract, I do not think anyone at the table would sign up to go rogue and not use contracts. It happened, but that is not the way it was supposed to have happened. The way it is supposed to happen is if something is not on contract, then you go to a contracting officer and put an appropriate contract in place.

Now, granted, we know there were shortages. There are shortages across the Nation in both our hospitals and other civilian hospitals. But in our case, we were able to get those drugs.

So I think you have got a very pertinent point. Why didn't we put contracts in place. And as the deputy secretary has already stated, we did not do it right.

Mr. DONNELLY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Just to follow-up, Mr. Donnelly, on your line of questioning, if you could not get a certain type of drug, to what extent or limits did you go to to find out where the drug could be found or did you go as it appears you did straight to the PPV?

Mr. GOULD. Sir, if I could, to start, we go through a hierarchy and the folks were trained to do that and did it well.

First, they started with national contracts. The number one goal is to get the drugs that are on contract and, therefore, have gone through the fair and reasonableness price competition and everything is buttoned down and we are complying with the law.

So we start with the national contracts first. Then we go to the Federal supply schedule which, again, on contract, already been committed and so forth. And there are other categories of contracts that exist on the McKesson portal before we get to the point where we would consider going to the open market.

And I would like to ask Craig to comment on that process where we move through all of the available contracts to a point in time when we realize that we do not have stock available and we need to meet Mr. Donnelly's point of continuous flow of drugs.

Mr. ROBINSON. Thank you, sir. Yes.

The CHAIRMAN. If you could, state your name for the record, too, please, sir, your name.

Mr. ROBINSON. Craig Robinson.

The CHAIRMAN. Okay, sir.

Mr. ROBINSON. There is a provision in the VA's supplement to the FAR which was a result of the procurement reform task force of 2002 that establishes a hierarchy of contracts within the VA. It was put together in order for us to leverage our spend, to be able to capitalize on the volume that the VA has.

And it starts off basically with any available stock that we already have that is legitimate stock that is available on hand.

The next tier is national contracts. We then go down to Federal supply schedule contracts starting off with BPAs. They are written at the national level. We then move down to VISN instruments, local instruments, and the lowest tier in the hierarchy is open market.

And I will say we have used open market here in the context of the McKesson contract as a bad thing. And in this case, it was in that these items were not on contract. But an open market purchase in many cases is a legitimate purchase when the proper processes and procedures are followed.

The CHAIRMAN. Thank you.

I am a bit confused and, Mr. Johnson, I am coming to you next because I cannot find it, but I have seen a document from the OGC that basically says you did not follow those steps as they were outlined.

Are you aware of that?

Mr. GOULD. Mr. Chairman, that reference from the IG comes from reports that were written not on the PPV but on other prime vendor contracts related to Med-Surge and subsistence. So the observations made in those IG reports, if I am understanding you correctly, sir, do not pertain to the PPV.

The CHAIRMAN. Yeah, this is not the IG report. This is from the Office of General Counsel. And I will try and find the document to allow you to have an opportunity to see it.

Mr. GOULD. Thank you.

The CHAIRMAN. Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman.

Just a brief comment before I ask my question. Secretary Gould, I certainly respect your testimony and your opinion that at no time were any Veterans put at risk. I take a little bit of a different slant on that, though.

With the priorities that we have to get a single electronic health record in place, to eliminate the backlog, to address the homeless Veterans' issue, I submit that when we are potentially wasting or misspending, illegally spending billions that could be targeted elsewhere that indeed we are putting Veterans and their benefits at risk. So I just wanted to make that clarification.

Mr. Valentino, I think you said that you became aware of—

Mr. GOULD. Mr. Johnson, would it be inappropriate for me to respond to that—

Mr. JOHNSON. Not just yet.

Mr. GOULD [continuing]. A moment ago?

Mr. JOHNSON. Not just yet. We may get to it.

Mr. GOULD. I will have an opportunity to do so—

Mr. JOHNSON. We may get to it.

Mr. GOULD [continuing]. In a moment. I do not think it is the case.

Mr. JOHNSON. Okay. We may get to it.

Mr. Valentino, if I understood your testimony correctly, you said that you found out about the improper purchasing of open market pharmaceuticals through the PPV in December of 2010, correct?

Mr. VALENTINO. I found out that the clause was removed in December of 2010. The issue of whether it was removed because of improper purchases had not yet surfaced.

Mr. JOHNSON. Had not yet surfaced. I am a little bit curious because I am having trouble connecting the dots.

Mr. Haggstrom, you testified that the clause in the contract to allow the purchase of off contract items through the open market had worked. You thought it was an acceptable process, that indeed now you have the problem of figuring out how to solve that problem, and there was this great discussion in 2010 about that clause and removing it from the next contract.

Why? I mean, if it was such a good idea and it is a big problem to solve, what were the pros and cons discussed in 2010 that led you to the conclusion that it should not be included in the next round?

Mr. HAGGSTROM. Mr. Johnson, if I could, I was not part of those discussions. Could I ask Mr. Craig Robinson to address that—

Mr. JOHNSON. Sure.

Mr. HAGGSTROM [continuing]. As the head of the NAC?

Mr. ROBINSON. I think as the issue originally arose, it really was not directed towards the process. The fact that the items were not being competed, the things that we looked at, the—

Mr. JOHNSON. So let me make sure I understand that. So you found out at that point or you knew in December of 2010 that the process was not working right?

Mr. ROBINSON. We knew that the process was a vehicle that allowed VA to get drugs to the Veterans. We knew that at that point in time from an acquisition perspective the procedure was not correct.

Mr. JOHNSON. Okay. It was not correct. So, in essence, there was an acknowledgment then that there were improper purchases of pharmaceuticals through this process, correct, because it was not working right?

Mr. ROBINSON. It was working in that there were medications, to continue to allow the delivery of medications to Veterans. But, yes, in the contracting community, a lower level employee did question the fact that the items were all being bought through McKesson and were not being competed.

The issues that we looked at—

Mr. JOHNSON. Okay. You have answered my question.

The CHAIRMAN. Would the gentleman yield real quick?

Mr. JOHNSON. Absolutely.

The CHAIRMAN. Sir, before you sit down, you keep talking about the process and that the Veterans received what they need. If you did not follow the process or procedure, how could it have worked? I mean, is success just the Veteran ultimately gets what they need?

Mr. ROBINSON. No. I mean, this goes back to the issue of the practice, though it was broken, it became the normal accepted practice for getting the medications to the Veteran. As Secretary Gould mentioned before in his testimony, that was something that we acknowledged. We acknowledged in looking back that that procedurally was not correct.

However, as it relates to the operational aspects here, I think that the folks from the pharmacy community will say that that vehicle is what allowed a continuous supply of the needed medications to the Veteran population.

The CHAIRMAN. If you would, put a minute back on the clock for Mr. Johnson.

Mr. JOHNSON. I am still a bit confused. So if it was acknowledged in 2010 that the process was not being followed or not sufficient, that, in essence, is an acknowledgment that these pharmaceuticals were being purchased not in compliance with that process, therefore, not in compliance with the law.

Who did you tell? Who else knew about your findings that the process was broken at that time?

Mr. ROBINSON. I mean, I think you heard the individual answers across the table here. As we started in—

Mr. JOHNSON. That was in December of 2010. So the earliest date in 2011 that I heard was sometime in March.

So was there no discussion about this broken process and the potential illegality of it between December of 2010 and March of 2011?

Mr. ROBINSON. At different levels, there were, but the—

Mr. JOHNSON. And who knew?

Mr. ROBINSON. At the working level, the issue came up because—

Mr. JOHNSON. No. But you are not at the working level.

Mr. ROBINSON. No. No.

Mr. JOHNSON. Okay. So who above you did you tell “we have a process problem here?”

Mr. ROBINSON. Through the period of time from December until March, there were discussions at the working group level related to how we get—

Mr. JOHNSON. Who did you tell? Did you tell anyone above your level that there was a potential illegal violation of the law as it pertained to the execution of this process?

Mr. ROBINSON. I mean, I would have to go back and look at my notes.

Mr. JOHNSON. We would like you to go back and look at those notes and let us know who you informed.

I have additional questions, Mr. Chairman, but I will yield back at this point.

The CHAIRMAN. Mr. Donnelly, do you want to?

And I would remind folks at the table that we have subpoenaed documents. You are aware of that, correct? Yes, no?

Mr. GOULD. I had heard the potential for a request but have not received any subpoenas.

Has anybody at the table received a subpoena or, general counsel, any knowledge that we received a request for information?

Ms. ANDERSON. A request for information.

Mr. GOULD. Request for information only, sir, no—

The CHAIRMAN. Chairman Issa’s committee on January 19 has made that request through a subpoena.

Mr. GOULD. We are only in receipt just a few days ago of a letter requesting information. No knowledge that a subpoena has been employed to get that. And counsel appears to be nodding that a subpoena has been issued. That is news to us.

The CHAIRMAN. Okay. Because if it is not there, it is coming.

Mr. Donnelly.

Mr. GOULD. Mr. Chairman, in that same spirit, if I might add, when a senior executive like the one that just spoke would encounter a problem like that, I believe its first instinct would be to acknowledge the problem and then start developing options.

And so I think the paper trail that you have requested will show hard work to develop principal options and bring those up the chain of command.

The CHAIRMAN. All right. Before I yield to Mr. Donnelly, the earliest date we have heard today is January of 2009. We are February now of 2012.

What happened, Mr. Thomas, from the time you discovered it and why has it taken so long to work its way through the bureaucracy?

Mr. THOMAS. Well, I think our responsibility for it is the consolidated mail-out patient pharmacies. What we do is we do specific orders for them. So when this was identified to me back in January of 2009, we went through the process and we said, as I think Mike has said—

The CHAIRMAN. And could you lay the process?

Mr. THOMAS. Sure. I met with people who I felt were—

The CHAIRMAN. Who were those people?

Mr. THOMAS. People from general counsel, people from acquisition review, people from the IG, others at the NAC including the Federal supply schedule, and representatives from VHA, from the PBM and the CMOP side.

The CHAIRMAN. And what was their response?

Mr. THOMAS. We need to fix this.

The CHAIRMAN. And we had not fixed it until just recently?

Mr. THOMAS. As far as cutting off the open market purchases, you are correct, except for the CMOP. On the CMOP side, we did a separate process to make sure that we were not ordering open markets anymore from CMOP because we were responsible for that process.

The CHAIRMAN. Mr. Donnelly.

Mr. DONNELLY. Thank you, Mr. Chairman.

Since 2001, the inspector general has been reporting and has issued at least 49 reports since that time with concerns about open market purchases.

How did this continue to grow and no controls were put in place?

Mr. GOULD. Mr. Donnelly, I would like to ask Mr. Frye to respond.

Mr. FRYE. We are talking about two different issues here, Mr. Donnelly. The open market purchases, as already explained by Mr. Robinson, are in and of themselves perfectly legal.

Mr. DONNELLY. Right. Okay.

Mr. FRYE. And so the open market purchases that were looked at by the inspector general then were in the context of are we using the proper order which was specified in this book and codified in our VAAR in 2002.

The Secretary said that we would use a very specific order. I will not go through them all, but he did mention national committed use contracts first, VA Federal supply schedule, group 65 and 66 and so on.

So the IG and my office, frankly, have always been concerned when people use open market buys which in this context means contracting with others than those that we specified that we wanted them to use.

So if somebody was supposed to have used the prime vendor contract which would utilize Federal supply schedules for those drugs, then perhaps they were not getting that economy of scale or that leverage that Mr. Robinson talked about earlier.

I just wanted to put that in context. It is apples and oranges.

Mr. DONNELLY. Mr. Frye, you keep talking about open market. Explain to me the difference between open market and extra contractual.

Mr. FRYE. Certainly. The open market, as again distinguished by Mr. Robinson here, on the pharmacy prime vendor contract equals no contract. So the default was and there was a clause in the contract that said that if the drugs were not contained on the lists that were given to the pharmacies by McKesson, then they could use this open market provision.

What that means is they have to follow all the rules and regulations. It is clearly stated in the clause. It does not mean that you just default to a drug that is not on contract. But over time, as has already been explained, starting many, many years ago, that methodology was used.

And, unfortunately, we never caught it. We thought, I thought that we were doing the right thing on the pharmacy prime vendor contract and on our other Federal supply schedules.

In fact, we hire out of the OIG about 30 auditors who help us audit those individual contracts. And, frankly, they return millions of dollars to us a year when they find mistakes from pharmaceutical companies or Med-Surge companies. Because of the price of reduction clause, we are able to recoup millions of dollars a year.

But what we did not have, what we have never had that I know of is a full-blown audit of the pharmacy prime vendor financial process. So we did not have insight and I did not test my assumptions. My assumptions since I have been there is this thing is purring along. There are no problems. There were no indications of any problems and it was not until I found out about it in March, of course, that those became a real problem to me.

Mr. GOULD. There were a set of tools that have been created in the last 3 years that dramatically changed VA's ability to deal with the issue. And they included a new management team, streamline authority, the introduction of a capability to deliver micro purchases. We have reduced the number of HCAs in VA from 30 down to six.

So a lot of the tools that we have called upon to so quickly and clearly solve the problem when we new about it and effective on November 8th have come in place in the last 3 years by virtue of the effort of the team that you see here. So this is the team that is responsible for that failure.

We identified the problem at a senior level and it took us 6 weeks to solve the problem. We issued clear direction to the field to drive a stake through the misunderstanding that we could somehow continue this practice which was not compliant with the FAR. And that is what we have gone at to fix and it is fixed now.

The CHAIRMAN. Is it your testimony that the time frame between January of 2009 and today is 6 weeks?

Mr. GOULD. No, Mr. Chairman. As I said a moment ago and you went down the list of folks here when did senior management know and I have testified that I knew in September. And by November 8th, the problem was solved.

The CHAIRMAN. Does it bother you that you have somebody sitting at the table that knew of the issue in January of 2009 and you or somebody at that table did not know?

Mr. GOULD. Sir, of course it does. And as I have testified, that is a problem for which we are collectively responsible and accountable. I am very unhappy with the escalation of this risk up the chain of command.

All I am saying is that it did not happen and when it did, it was absolutely solved by this team. We got together and resolved the issues and came up with a clear course of action to fix the problem.

Mr. DONNELLY. When you find that a drug is out of stock, is there a system that tells you here is when that was out of stock this week, out of stock last week, out of stock a month ago? Is there any type of system that you had that told you here are the ones we are really struggling with and was there any form of preplanning where you said, okay, if this is not available, here is the backup, we do not have a contract on that, we better put something in place?

Mr. VALENTINO. Yes, sir. We monitor several different sources that collect information on drug shortages. One of them I mentioned earlier is the American Health System Pharmacists Web site.

Mr. DONNELLY. But does your own system tell you these are the ones we are out of stock on?

Mr. VALENTINO. Yes, sir. We also have close communication with our vendor and they advise us when there are shortages or projected shortages. So we combine a number of different sources of information and compare that to our needs and then we figure out what we are going to do.

Are we going to reduce the quantities that we dispense from 90-day supplies to 30-day supplies to get over the hump? Is it going to be so severe and so prolonged that we have to substitute drugs and contact providers and educate patients that their drugs are going to be switched?

So, yes, sir, we do. We collect information from every source we can. We work on that with our clinicians across the system and develop a plan.

Mr. DONNELLY. And in the goal of trying to have contracts on these things, do you do any planning meetings where you go, okay, if it is not this, we have B and we have C, we do not have contracts on these, we need to get this done? I mean, is there any type of framework instead of looking up and going, oh, my gosh, we are out of stock, what do we do now?

Mr. VALENTINO. Yes, sir. That is a great question. And they are really not linked. A drug shortage does not trigger us to say, oh, we have to get a contract on that. We know our utilization. We are always trying to get the contracts on as many drugs as we can.

So the shortage situation amplifies that we do not have a contract in place for a particular drug.

Mr. DONNELLY. What would be the problem in getting that contract on these other things? Is it just that you did not think about that particular one or is it that in working with the vendor, you were not able to come to terms or—

Mr. VALENTINO. Sir, we develop our requirements. We know what we need. We hand that information off to our colleagues at the National Acquisition Center and they turn that into a tender or a solicitation.

At that point, it is really up to the manufacturers to decide whether they want to bid or not. Those bids are reviewed if we get them and then the contracting officer determines whether they can make an award.

Steve may have some things to add to that, but that is the macro view of how we deal with that.

Mr. DONNELLY. And how long does that process take?

Mr. THOMAS. A couple of things I would like to comment on. First of all is we do look at the National Acquisition Center on a weekly basis at shortages and we publish a newsletter on a weekly basis to the field facilities, all the medical centers, and also our other government agencies that participate in our contract. And we inform them about issues that we know about, here is a shortage, here is a contract change, here is a new contract in place, et cetera, to minimize this as much as possible.

The other thing I want to stress that I do not think we have talked about yet regarding the McKesson contract is that the McKesson contract has a fill rate of 97 percent. I see a report on a monthly basis. We are always there.

So granted there are some exclusions from that calculation in that if they cannot get the product from a manufacturer, we cannot count that against them. But McKesson has consistently delivered.

Mr. DONNELLY. I am not worried about the contract and, you know, whoever it is is honestly of no interest to me at all.

All I am trying to figure out is on the parts that are not filled, how do we get a program in place that works quickly, that works accurately, that provides safe products to our Veterans, and that we know what we are getting at a predetermined price?

Mr. THOMAS. So let me follow-up on Mike's feedback. One of the issues that we do, he is right, we get a requisition here at the National Acquisition Center for a national contract, a requirements type of contract. Generally that process, our goal is 120 days.

Mr. GOULD. Mr. Donnelly, if I might, I think you have asked a salient question which is how do we prevent, how does—

Mr. DONNELLY. My concern is, okay, we are out, now it is 120 days until we can get a contract on the backup product.

Mr. FRYE. Let me add that while a normal contracting action might take 120 days, it does not take 120 days to put a contract in place. If there is an emergency, a contract can be put in place within hours. You have to have the money, you have to know what you want, and you have to have a supplier. And a contracting officer can put a legitimate contract in place, a letter contract. That can be a phone call followed by a fax outlining the terms and conditions in very short order.

So while normal procedures might take that long, I think those procedures probably atrophied over the years as well since we did not go through that model. And so maybe it takes a little longer than it should. But there are procedures to put contracts in place very, very quickly.

Mr. DONNELLY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Roe.

Mr. ROE. Just a very quick comment. There are two issues that have been brought up. One is that the VA knowingly did not follow their procedures and two is why were the procedures not being followed? And I guess three is that there is a broader problem in the country of drug shortages. It is a huge problem. There is an entire industry out there.

Let me give you all an example of what Mr. Donnelly brought up, Tamiflu. Let's say there is a flu epidemic and all of a sudden, all the Tamiflu on the shelves is gone. Well, there is another source out there that people go to and that is called compounding.

You can go to a pharmacist, and some can do sterile compounding, some cannot do sterile compounding, to get these products that are not available on the short-term basis. Happens all the time. There is a whole industry across this country to help to supply the shortages.

As you pointed out, you can go to a Web site every Monday, look at it and see what the FDA says about a certain drug. There are shortages around the country right now that are going to create problems. Currently their drugs are being filled sort of in an open market in the private sector. It is a little harder in a government situation to fill them this way.

I am glad to hear that you can do it within hours because sometimes these needs are that quickly. And if there are two issues you have very clearly brought, it is how do we get safe drugs into this country because many of the generics are made outside and, secondly, how do we get them to our patients, either a Veteran or just to a patient I might see in the office.

It is a real problem. There are two issues here, but there is a way to get around it and these community pharmacies and others are compounding drugs that you cannot get.

I yield back.

The CHAIRMAN. Mr. McNerney.

Mr. MCNERNEY. Thank you, Mr. Chairman.

Mr. Gould, I was here for your testimony and it struck me that the gentleman on your right side did not know about the problem until September of 2011 whereas the gentlemen on your left all seemed to have knowledge before that.

But what really strikes me is that you seem to think that there are systems in place now that are reliable. And how could you get something in place that is reliable in that short of time between September, say, and November of 2011? Have you ratified any purchase since then and what gives you confidence that we are on the right track at this point?

Mr. GOULD. Thank you, sir, for the opportunity to reiterate again in my oral the corrective steps that we took and that will answer

your question about why I am confident that we have addressed this problem and that the system will work going forward.

The first thing is very, very practical. We just removed the ability of ordering officers to see any drug not available through a Federal contract from the McKesson portal. They just do not see it anymore. It is not there for a VA ordering officer. So that is a simple, practical thing we worked with McKesson to do. They were very responsive and it happened.

The second thing is we mandated training for our employees. What we are discussing today is clearly a failure of management and supervisory level individuals to tell our folks what to do and to do it in the right way. That is why I was so concerned that this conversation could turn to the point where we are trying to hold GS5 ordering officers responsible for a system that we as managers created. That is why I put that in my testimony.

Mr. MCNERNEY. So the VA can put people through training, schedule it, put them through training, and put them back in the job in a 2-month period?

Mr. GOULD. We have mandated training for our employees authorized to place orders. That will be completed by, I believe, the 28th of February, correct, right, right, to retrain, excuse me, but train them on this—

Mr. MCNERNEY. So if training is not finished, then you cannot be completely confident then?

Mr. GOULD. We have also placed qualified contracting officers in position to now manage this process. And, finally, we have continued to move forward on the new RFP which will correct the problem from May afterwards.

So in a large organization of this size, it takes some time to do those things, train, put new people in place.

We have also dramatically improved oversight. As we testified earlier, we are down to 0.4 percent of the purchases in December that use this clause and we are examining every single one of those 5,000 transactions to be sure that we followed procedures and got value.

Mr. MCNERNEY. And this has all happened, everything since November 8th following this guideline and you are highly confident at that point?

Mr. GOULD. Since November 8th, yes, sir, November, December, January, here we are first day of February. We are a large organization. We sometimes do not move as quickly as we should. But let me tell you the senior management team is focused on making sure that implementation occurs.

Mr. MCNERNEY. Another thing you said is that the people who were perpetuating the problem have left the organization. Did they leave voluntarily or involuntarily?

Mr. GOULD. Retirements, you know. If you are asking was someone fired or removed for this behavior, the answer is we did not know about it. Those individuals are simply not in the mix right now.

What you see is new managers and leaders encountering a problem that we were not aware about. We finally were made aware about it. You have heard that time table and we took action. We learned in September at a senior management level that there

were problems. We brought the team together. By November 8th, we had a solution in place and we are committed to implementing it.

Mr. MCNERNEY. And my last question, Mr. Gould, is, and you are perfectly confident that McKesson has been a good player in all this?

Mr. GOULD. I am. I think they have fulfilled their contractual obligations. When we went through the process, we could only conclude that we ourselves were the source of the problem. The contract requires us to follow the FAR and we did not.

Mr. MCNERNEY. Thank you. I yield back.

The CHAIRMAN. Mr. Johnson.

Mr. JOHNSON. Mr. Haggstrom, remind me again. When did you say you found out about—

Mr. HAGGSTROM. The latter part of March of 2011.

Mr. JOHNSON. Okay. Is it safe to say that this PPV contract is maybe because of the cost, the volume, or whatever, that that is one that you would be paying particularly close attention to?

Mr. HAGGSTROM. It is now, sir.

Mr. JOHNSON. Okay. Were you involved in the discussions in 2010 when the decision was made to omit the clause for open market purchases from the follow-on compete contract? Were you involved—

Mr. HAGGSTROM. I do not believe I was, sir.

Mr. JOHNSON. Were you informed of the decision at that point?

Mr. HAGGSTROM. I do not believe.

Mr. JOHNSON. Well, you said earlier that you knew about it. So what did you know about those discussions?

Mr. HAGGSTROM. There was a discussion over whether—

Mr. JOHNSON. What was the rationale for dropping that clause that was presented to you?

Mr. HAGGSTROM. There was discussion concerning the next prime vendor contract, whether we should retain that clause in it or not. The discussion at that time, to my recollection, did not go into the issue of whether the clause was being used properly under the existing contract.

Mr. JOHNSON. Well, the documentation that the secretary sent recently and the enclosures that accompanied his letter in response to Representative Donnelly's letter said that in 2010, it was determined to omit that clause. So a decision point was reached.

Who would make that decision?

Mr. HAGGSTROM. That was made at the working level through the stakeholders of the contract at that time in which the NAC and Pharmacies Benefit Management were working jointly together.

Mr. JOHNSON. And who is the contracting officer?

Mr. HAGGSTROM. The contracting officer is part of the NAC and Mr. Herman Archibald.

Mr. JOHNSON. Okay. All right. Mr. Frye, you said you found out in March, March 29th, I think you said—

Mr. FRYE. March 29th.

Mr. JOHNSON [continuing]. To be exact?

Mr. FRYE. Yes, sir.

Mr. JOHNSON. What did you do once you found out? Who did you tell and what did you tell them?

Mr. FRYE. We were in a meeting, myself, Glenn Haggstrom, the Chief Acquisition Officer, and a number of us to include Mike Valentino, the chief procurement officer from VHA, Mr. Fred Downs at that time. Mr. Craig Robinson was also in the meeting.

And the way I discovered this was Mike Valentino came to the meeting. The purpose of the meeting was to discuss why we were eliminating the clause from this follow-on contract. And I did not know what the open market meant in the context of this contract. So I asked Mike Valentino to explain it. And he said we are buying drugs without a contract.

And I was aghast and immediately said this has got to stop today and the Chief Procurement Officer for VHA agreed with me. Now, did he ever take any steps down that road, I do not know.

Mr. JOHNSON. I saw a letter and I have so much documentation here, I should have had it out. There was a letter that directed that the purchase of open market drugs through the PPV cease immediately. There was a big time span between March to the issuance of that letter.

Who did you tell up your chain when you became concerned that the law was being broken on these purchases?

Mr. FRYE. Well, I talked to a number of people over the course of time.

Mr. JOHNSON. By name, who did you talk to?

Mr. FRYE. Within several days, I talked to Maureen Regan from the Office of the Inspector General and relayed my concerns to her.

Later on in the process, in the August, September time frame, I sent some very pointed letters to Mr. Haggstrom, to Bill Schoenhard in VHA. I included Mr. Todd Grams, the chief financial officer. I included the deputy chief financial officer, Ed Murray, who also included Mr. Paul Kearns, the chief financial officer from VHA.

And my concern was that since this was extra contractual that this was also a finance issue. And Glenn and I eventually met with Mr. Murray because, you know, I thought it might rise to the level of a—what is that term—material weakness. Glenn and I were both concerned about that. So we brought him into the office.

Mr. JOHNSON. I appreciate that. Going to the issue of financial management, Secretary Gould, what do you think the impact of this failure, do you think the impact is on VA's lack of an integrated financial and logistics system that ties all of this together?

Mr. GOULD. Sir, I think the failure here has to do with training, with process and procedure, and with having properly warranted contracting officers in place. Our largest concern here is the people factor in the system and that is what we have moved to address.

A moment ago, you raised an issue that I wanted Mr. Matkovsky to address and I think you will find it helpful and providing a fuller answer to your question.

Mr. MATKOVSKY. Sir, relative the September meeting with Mr. Frye, it is correct that he brought this issue to Mr. Schoenhard and myself. We are on the health care operations and management segment of VHA.

What we had done with that information, we were concerned, our first reaction was we heard the word illegal. We sought advice of counsel. Upon receipt from counsel's opinion, we recognized that

this was not a criminal issue, but we did see that it was a problematic issue, sir.

We requested that we form an IPT, integrated product team. And I will tell you candidly that my preference was to fix the current contract, try to—

Mr. JOHNSON. I understand. You said, though, that it was not a criminal issue but a what?

Mr. MATKOVSKY. Problematic issue.

Mr. JOHNSON. Violation of the law is far beyond problematic, wouldn't you say?

Mr. MATKOVSKY. Right. So it was a violation of the FAR and we thought it was problematic.

Mr. JOHNSON. Okay.

Mr. MATKOVSKY. We knew we had to fix it. We fielded a team of folks including the contracting officers, folks from contracting, folks from PBM, and we went through a set of alternatives that we tried to tick off first, modify the current contract, award a national contract in scope for something of this complexity that allows us to acquire this 4 percent of dollar volume in a FAR compliant mechanism, and then lastly focus on the future contract.

When we could not negotiate the current contract, when we could not put in place a national scope contract to address this 4 percent, that left us with a curtailment of the process.

Mr. JOHNSON. Okay.

Mr. MATKOVSKY. We learned in late October that we could not change it and then we issued the instruction. I also wanted to emphasize it is not just an issue of a cease and desist. It was also the issue of making sure we had sufficient instruction for how to acquire what you needed medically necessary and enough contracting officers available over weekends or whatever to acquire the medications we had. And as soon as we had that in place, we felt confident to issue the instruction.

Mr. JOHNSON. Okay. Well, thank you for that clarification.

Mr. Chairman, the clock is not running. I do not know how much time I have left.

I would like to know, are there penalties associated with violation of the FAR?

I know in my experience, I retired in 1999, worked a lot of contracting work, the contracting officers I worked with were very, very fearful of illegal operations and violations of the FAR because it could cost them their jobs and their careers. That is in the DoD.

Are there penalties associated with knowingly violating Federal acquisition regulations?

Mr. GOULD. There are and Ms. Anderson—

Mr. JOHNSON. And have any of those penalties been pursued?

Ms. ANDERSON. I am happy to answer that question. Thank you.

There are no penalties, sanctions attached to those specific violations of the FAR that we are speaking of today. And that is again the unauthorized commitments and the failure to comply with the FAR sections related to competition.

There are other penalties, failure to comply with the Trade Secrets Act which is also part of the codification of the FAR, Procurement Integrity Act. But with regard to the violations that we are

speaking of today, the answer is no, not with the FAR or the VAAR.

Mr. JOHNSON. Okay. Mr. Chairman, I yield back.

The CHAIRMAN. Thank you very much.

One further question, and I appreciate your patience in answering the questions. And I know that all Members, I would request, that we through the Committee do one document to VA asking further questions for the record.

Mr. Matkovsky, is the PPV the largest contract within VA?

Mr. FRYE. I think it may be the largest. It is over \$30 billion. It is an 8-year contract. It is certainly one of the largest if not the largest.

The CHAIRMAN. We talked about contracting officers, but is there a contracting officer technical representative that provides oversight for this huge contract?

Mr. FRYE. There are no contracting officer representatives. We no longer use the term COTR, so that is just a technical issue. And it was never designed to have contracting officer representatives.

When this contract was designed many, many years ago, as far back as 17 years ago, apparently it was designed so that we could have very rapid delivery of these drugs. And the system was designed with a fast pay system and paperless. And I am not sure it was designed immediately that way, but later on down the line, those were the designs.

So the CORs were never part of the contract. Instead in pharmacy, there were representatives who receipted for the drugs, ordered, receipted, and stored the drugs and dispensed them in the pharmacies, in the particular hospitals, or in the respective hospitals.

The CHAIRMAN. So who is responsible for making sure that the contract is adhered to and is managed properly?

Mr. FRYE. Well, that is the structural problem that was alluded to by the deputy secretary. In my opinion, of course, looking in the rearview mirror, we should have really taken a look at this fast pay system years ago because while it is designed for velocity, perhaps it was not designed with all of the internal controls in place.

In other words, if you bring things in quickly, if you pay the supplier within 24 hours, are you taking all the necessary steps that are required to make a positive ID of the products that you ordered and put on the shelf in the hospital?

I cannot answer that at this point. We are going to have to do some more research. There has been some preliminary research done by the auditors and the Chief Financial Office in VA. And it appears that we have some problems, but I cannot go into those now because it is preliminary.

Mr. MATKOVSKY. Mr. Chairman, sir, I would simply add to Mr. Frye's comments that effective the end of January, I believe it was January 27th, we have appointed in addition to the contracting officers, Mr. Frye alludes, we have appointed three administrative contracting officers who serve as an extension of the contracting officer as well as nominated well over 200 contracting officer representatives throughout VHA.

Those folks, the ACOs and the CORs, will be formally trained by the end of February. And they will be compliant with the expected part of the FAR.

The CHAIRMAN. Who at the table is the closest to the contract in regards to oversight?

Mr. GOULD. Mr. Chairman, if I could just tee that up. That—

The CHAIRMAN. No. I teed it up.

Mr. GOULD [continuing]. Chain of command on policy side and on the customer side, very important distinction. I think you are asking the policy and oversight side and so we will go down this side of the table. And you asked closest to the front line; is that correct?

The CHAIRMAN. Well, actually, I want to know who is the most senior person who knew this was going on and chose not to do anything about it.

Mr. GINGRICH. Mr. Chairman, I will take a risk on answering that question. I am not sure people did not choose to not do something about it. I think that March to September is a long time, but I believe that people were searching through to find the answer.

Like Philip said, they were saying can we go modify the current contract with McKesson to give us the pricing vehicle that we would need to become compliant. Researched that. That did not work. It worked through the staff section. It worked between the acquisition folks and VHA.

And in September, I am the person that they came to and said we have an impasse. We need to figure out how to get at this. So I asked three questions.

The first question I asked is, are we putting any Veterans at risk? I was assured by everybody that we have not put any Veterans at risk for drugs and we are delivering the drugs that we need on time.

The second question I asked, do we have any criminal activity here? Do we have any fraud or do we have any activity like that? And the answer I got back was, no, it is not criminal, but it is a violation of the FAR and regulations and we need to fix it.

The third I asked is, how do we fix it not just for the short term but for the long term? And if we do fix it, how do we do it without breaking number one and that is the care to Veterans?

So that process which the Member asked us, how can you go from September to November so quickly is we already had people working each one of these pieces and trying to figure out how to make it work.

They came in. We had the meetings. We talked about it. I briefed the deputy and the secretary at a high level saying we are working through this problem and we have what we think is a solution. The solution was to implement a stop.

I cautioned them repeatedly as before you issue the stop of using any method other than the credit card or the purchase card which we had to get McKesson to agree to accept and before you implemented the contracting process, how do we do it as we have been cautioned repeatedly by the Members without putting a single Veteran in harm's way?

They came back, said we have that process in place. We said, okay, we are going to implement it. We started in October crafting the instructions, getting the word out to the field, briefing the right

people, and the order was cut on 8 November directing that it cease.

In fact, we had a conference of 600 plus contracting officials including from VHA which are about one-tenth of the contracting people that were trained in 2011. And it was announced on that date prior to 8 November that we were going to put this in place and it got a round of applause that we were actually putting out this.

I said it. We are going to stop the process. We have already got the directive coming. And the contracting people in that room were a round of applause that they knew that we had made the right step. And I asked them when I said that, are you ready to implement and the answer was yes.

So when it did come up, the questions were people were working around it, but the fear, concern, maybe over concern on my part as I briefed the secretary and the deputy was we could not allow a single Veteran to be put in harm's way or have a surgery late or have his chemotherapy late or any of those things that Mr. Roe has pointed out. And we had those procedures in place. It took us longer than we expected, but we did implement, Mr. Chairman.

The CHAIRMAN. I thank you for your comments.

I have to wonder if the applause was for the new policies and procedures that were put in place or the fact that they were no longer breaking the law.

Mr. GINGRICH. I think the answer was, to answer your question, that we were able to stand up and make the procedures and outline exactly what we were going to do.

The CHAIRMAN. Thank you very much. You are excused.

Thank you for your patience. On the next panel, we will hear from Linda Halliday, deputy assistant inspector general for Audits and Evaluations at the VA Office of Inspector General.

She is accompanied today by Mark Myers, director of the Healthcare Resource Division in the Inspector General's Office of Contract Review, and Michael Grivnovics, director of the Federal Supply Service System Division also in the Office of Contract Review.

Ms. Halliday, your complete written statement will be made a part of the record and you are recognized for five minutes.

STATEMENT OF LINDA HALLIDAY, DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDITS AND EVALUATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS ACCOMPANIED BY MARK MYERS, DIRECTOR, HEALTHCARE RESOURCES DIVISION, OFFICE OF CONTRACT REVIEW, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS; MICHAEL GRIVNOVICS, DIRECTOR, FEDERAL SUPPLY SERVICE SYSTEM DIVISION, OFFICE OF CONTRACT REVIEW, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF VETERANS AFFAIRS

Ms. HALLIDAY. Chairman Miller and Members of the Committee, thank you for the opportunity to testify on the OIG's ongoing reviews of VA's administration of the pharmaceutical prime vendor contract and to provide a perspective on contracting issues and

open market purchases. OIG reviews provide unique insight into how VA purchases pharmaceuticals and health care services.

Maureen Regan, the Inspector General's Legal Counsel, who provides oversight to our Office of Contract Review is unable to participate in today's hearing. She had a conflict with scheduled court proceedings.

Thus, I am accompanied by Michael Grivnovics and Mark Myers, the Directors of the OIG Office of Contract Review, both in the Federal Supply Service Division and Health Resources Division respectively.

These directors report to Maureen Regan and are directly responsible for the majority of the OIG work on the pharmaceutical prime vendor contract.

Open market purchasing is not a new issue and OIG has issued numerous public reports that have identified concerns with open market purchases. The term open market describes the purchase of goods that are not on contract.

We have consistently identified concerns that a vendor's ability to sell open market in significant volumes effectively reduces VA's ability to leverage prices using aggregate buying power.

OIG has shared their insights with VA officials to help the department develop short-term and long-term solutions to improve the current pharmaceutical prime vendor solicitation.

Short-term solutions implemented by VA have resulted in amendments to the current pharmaceutical prime vendor solicitation and included efforts to establish negotiated prices for items not on national contracts and ensure the requirements that products purchased comply with the Trade Agreement Act.

However, identifying long-term solutions will not be an easy task because the causes, which are numerous and complex, have never been quantified.

At this time, we are conducting a review of the pharmaceutical prime vendor purchases for fiscal year 2011 to quantify the extent and causes of the problems. This work includes quantifying the actual dollars spent on open market sales and identifying the patterns and trends of open market purchases of pharmaceuticals.

Further, we are assessing whether purchases have violated existing procurement laws and regulations and to what extent open market purchases have violated the Trade Agreement Act.

We are also reviewing the internal controls of the VA's fast pay system to identify the risks and vulnerabilities associated with the reliance on related payment and processing activities.

Specifically, we are assessing whether items ordered via the pharmaceutical prime vendor contract are received and correctly priced, that payment errors are corrected in a timely manner, that the contract terms are met, and we are looking to see whether an adequate separation of duties exists in the processing activities, over ordering, receipt, and payment of items.

Our auditors are reviewing orders placed at VA health care systems, orders processed through the VA consolidated mail-out pharmacies, along with the payment processing activities at the VA's Finance Service Center.

We will provide the Committee the results of our ongoing work when the reviews are complete.

Chairman Miller, this concludes my statement and my colleagues and I would be pleased to answer any questions you may have.

[The prepared statement of Linda Halliday appears on p. 51.]

The CHAIRMAN. Thank you for your testimony.

To finish up on your last comment, when do you suspect that you will finish the review?

Ms. HALLIDAY. There are two reviews going on right now. One is in the Office of Contract Review and the other is with the Office of Audit and Evaluations. We are thinking mid summer, hopefully a little bit earlier.

The CHAIRMAN. Have you received everything you have asked for from VA at this point?

Mr. GRIVNOVICS. Yes, we have.

The CHAIRMAN. Is there anything that they have not provided that you need?

Mr. GRIVNOVICS. We have not identified any additional information needed at this point.

The CHAIRMAN. When did they ask you to become involved in this matter?

Mr. GRIVNOVICS. December, late December, we were asked to begin the review of the pharmaceutical prime vendor program.

The CHAIRMAN. Do you know at this point how long VA knew about it before you were notified or is that going to be part of the outcome of your investigation?

Mr. GRIVNOVICS. That is going to be part of the review, but we do not know at this point.

The CHAIRMAN. Mr. Donnelly.

Mr. DONNELLY. Thank you, Ms. Halliday.

One question that I am wondering about is there is another contract coming up and it is coming up in a few months. Have you seen any indication that these problems are solved in the contract that is to be let?

Mr. GRIVNOVICS. There was an amendment, I believe it was amendment number six to the current solicitation, and one of the areas that was put in is that there will be, if I remember this correctly, for generics, a wholesale acquisition cost price base generic program.

My understanding is this would help potentially cure the problem where items are not currently on an FSS contract but are out there and available for sale in the pharmaceutical business. They would be priced at some percentage over or under WAC and they now would be considered a contract purchase.

Mr. DONNELLY. The reason I ask, Ms. Halliday, is in your statement, you talk about for 12 years you have been doing this. And I would love to not have you do this for a 13th. And so it seems to me that with a new contract, we ought to have in place a way to end us having to struggle with this.

Ms. HALLIDAY. Congressman Donnelly, I believe we will still have to follow-up on the effectiveness of VA's actions.

Mr. DONNELLY. We want you to continue to follow-up. We just do not want you to find any problems.

Ms. HALLIDAY. We would hope that we see positive improvements.

Mr. DONNELLY. Okay. Do you have any other suggestions as to things that the new contract should include so that we can look and see, oh, okay, the next alternative there is a contracted price because from reviewing your statements, too, I mean, we are talking about millions of dollars lost to taxpayers who every day work their tails off, you know, to raise their family and a few extra bucks left over but also pay taxes every year? Any suggestions as to what else needs to be in that contract?

Mr. MYERS. I think as Mike has already alluded to that, part of the solution is the WAC-based pricing. For any generic drug that is not on a Federal Supply Schedule contract to have it part of the PPV contract and put it in there at an agreed upon percentage, either markup or discount, whatever the proposals are going to be in the ultimate awarded contract.

We do have concerns with that. Potentially it could undermine the Federal supply schedule program. As vendors and manufacturers of generic products, it may no longer be an incentive for them to come and negotiate the contract and expend the effort needed to comply with the Federal Supply Schedule contract when now they can sell their products simply through the PPV contract and VA can purchase their drugs at a WAC price rather than a deeply discounted price that typically you find on Federal Supply Schedule contracts.

It is a solution, I think, at least in the short term, that is going to fix the procedural and process question, are you compliant with the FAR because now you are going to have a legitimate contract purchase rather than an open market purchase.

But I think one of the things that definitely needs to be done is that for certain open market purchases, for certain drugs, we have talked a lot about the generic market, but there are covered drugs.

There is sort of two divisions of drugs, generics and name brand covered drugs. The name brand drugs, those drugs are required to be in Federal supply schedule contracts and they are required to be on the FSS contract at a statutory ceiling price.

And one of the biggest concerns that we have seen as early as 2007 is that when a manufacturer who has a covered drug on a Federal supply schedule contract at the statutory ceiling price and the manufacturer does not participate with McKesson and, yet, we have seen specific instances, numerous manufacturers where those covered drugs were purchased at open market prices from McKesson when they were actually on a Federal Supply Schedule contract.

And so that gave us a lot of concern. And those types of products should be simply blocked out and blocked from purchase through the PPV system.

Mr. DONNELLY. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Stearns.

Mr. Roe.

Mr. ROE. One of the things I would like you to look at when you are reviewing this is are you finding any of the medications on the PPV, companies leaving them off because the margins are so thin, knowing that they will go around the contract into the open market system and do that?

Have you had a chance to look at that?

For instance, one of the big issues now are chemotherapeutic agents, as you know, which is really tragic because you have got a patient out there with cancer that knows the best treatment is X and they cannot get it if they are a Veteran unless they go around that.

Have you noticed that at all or found that?

Mr. GRIVNOVICS. It is early in our review but one of the things we are going to cover is looking at what was purchased open market and if there was a comparable product that was on contract, and why we did not buy that product that was on contract?

Mr. ROE. I do not know for sure, but what could be happening forcing you to the open market would be if the vendors and or manufacturers just said we cannot make any money selling this product, so we just will not provide it. We will not bid on that and, yet, it is a needed product.

Mr. MYERS. Yes, that is a potential risk. And I think that typically VA is trying to establish long-term contracts. And when the profit margins are thin, as you have alluded to, and the generic market can fluctuate wildly, I think there might be some hesitation out there because of that, but we have not validated that in a review.

Mr. ROE. That will be something you will look at, though?

Mr. MYERS. Yes.

Mr. GRIVNOVICS. I would like to add one more thing to Mark's comments. Some of the generic drugs on the market have competition from McKesson themselves. Many times when we are going to do a Federal supply schedule contract or the National Acquisition Center is, sometimes it is hard to get a fair and reasonable price because the manufacturer does not want the distributor price because the manufacturer does not want the distributor to see what prices customers are getting. They would prefer that we go direct to them and purchase. But our system, the prime vendor system is set up to go through McKesson to buy those drugs.

Mr. ROE. Okay. I have no further questions. I yield back.

The CHAIRMAN. Mr. Reyes.

Mr. REYES. Thank you, Mr. Chairman.

My first question is, in your preliminary work, have you come across any offices that have been in compliance or is it across the board noncompliant?

Mr. GRIVNOVICS. We do not have that information at this point.

Mr. REYES. Is that something you are going to look for?

Mr. GRIVNOVICS. Yes, we are. We are going to do a sample to see if any violations occurred of the FAR and based on that sample, depending on the error rate that we find, we will expand the review to see how pervasive the problem was.

Mr. REYES. Will your report give the Committee an idea, in terms of total cost how many potential millions of dollars of taxpayer money was used unnecessarily in this manner? Will we get that?

Mr. GRIVNOVICS. Yes. We will define the amount of open market purchases. We are going for those open market purchases, see if we can find a comparable item on contract, we will quantify the differences in price.

Mr. REYES. The other concern that I have is will you be able to tell if there were instances where Veterans did not get either the

correct medication or the medication in proportion to their issue because of the noncompliance with the Federal regulation?

Mr. GRIVNOVICS. I do not believe we will be able to tell that.

Mr. REYES. You will not be able to—

Mr. GRIVNOVICS. From the one discussion I had so far is that when products are ordered, if they are not available, they are just basically replaced on the PPV ordering screen. You do not know what was not ordered except if there was a national shortage. VA does reports on that and you can look at that. But from an item that was substituted, you are not going to see the original product that was ordered.

Mr. REYES. But you are satisfied that you will have in the system, in every system the ability to determine and audit the impact of this noncompliance?

Mr. GRIVNOVICS. Yes, we should be able to do that.

Mr. REYES. Okay. That is all for me, Mr. Chairman. Thank you.

The CHAIRMAN. Mr. Stutzman.

Mr. STUTZMAN. Thank you, Mr. Chairman.

And thank you to the panel for being here.

Apparently this has been a problem before in other purchasing. In 2009, there was an audit done on open market medical equipment and supply purchases. And I was reading through that review and that report.

And my question is, are you seeing any parallels to your review now to what you found and concluded in this report and also did the VA follow-up on your recommendations and make any changes to the report in 2009?

Mr. GRIVNOVICS. Do you have the title or specifics about that 2009 report?

Mr. STUTZMAN. Yes. It is the audit of VHA open market medical equipment and supply purchases.

Ms. HALLIDAY. Yes, we made several recommendations in that report and VHA moved forward to implement those recommendations. I believe all of the recommendations are closed and we would have expected that that would result in some corrective actions.

Mr. STUTZMAN. So you do not know or there has been no follow-up necessarily to—

Ms. HALLIDAY. We have not done follow-up on that report at this point. We do program follow-up reviews in, but we give the department a period of time to put the corrective actions in place so then when we go in, we can assess the true effectiveness of those actions.

Mr. STUTZMAN. Okay. I am new to this process. And I guess to me, the follow-up would take place. At some point, will you follow-up on this report that happened in 2009 as well?

Ms. HALLIDAY. We will certainly put that in our plan and look at the performance risks. And I would expect that would go into a future review.

Mr. STUTZMAN. Okay. And then typically how far back would you look at this issue in your review?

Ms. HALLIDAY. We like to keep our look as a current snapshot in time because I think that is where you really want to focus on what corrective actions are needed now. So we would probably take

the most recent fiscal year or some portion of that time period to look at the conditions.

Mr. STUTZMAN. Okay. Well, I would be interested in not only this review but also any follow-up that would have taken place on a 2009 report or any others as well because there is no point in you doing reviews and recommendations and the VA is not doing anything about it.

Thank you. I yield back.

Mr. ROE. If the gentleman would yield for just a minute. Let me put a human face on this for you. Let's say you have a shortage of methadone and you have a substance abuse patient. You have a 10 milligram and a 20 milligram and a 40 milligram and an 80 milligram. If you do not get those right, that person can die. They can overdose and die.

So this really happens out in the real world. Our VA folks are very concerned about this being done. And so this is critical. It is not just violating a statute or a law. It is about patients' lives and we have to get this right.

I yield back.

The CHAIRMAN. Mr. Stearns.

Mr. STEARNS. Thank you, Mr. Chairman.

I regret I was not here earlier to hear all the first panel, but I guess you had indicated, Ms. Halliday, that your study is going to take six and half or mid summer which would appear about six and a half months.

Is it possible to get an early summary or some information back to the chairman and to the Committee some of your tentative findings in 90 days? Is that a possibility?

Ms. HALLIDAY. I think that we probably could provide an interim briefing. It is going to take us a while because we do have teams at medical centers. We have them at the consolidated mail-out pharmacies. And the work that the Office of Contract Review is doing is very data intensive.

Mr. STEARNS. Okay. You might think about it.

Ms. HALLIDAY. We will try and do that if we can.

Mr. STEARNS. Now, you heard the first panel. Is there anything about the first panel and what they said that concerns you, that would affect your study?

I think one of the things that I have been told by talking to the staff here is that the people who are responsible are no longer there. Is that the way you understand it, too?

Ms. HALLIDAY. That is still under review.

Mr. STEARNS. Okay.

Ms. HALLIDAY. We cannot answer that completely.

Mr. STEARNS. And the number of people that were involved, do you have any idea how many people were involved that they supposedly said has left?

Ms. HALLIDAY. No.

Mr. STEARNS. Do you have a ballpark? Are we talking about 100, 200, 1,000?

Ms. HALLIDAY. No. We do not have information on that at this time.

Mr. STEARNS. Uh-huh. And your normal procedures when you do these studies, will you be able to identify people that did this that perhaps are still there?

Ms. HALLIDAY. I think we will be able to identify through the interviews what people understood the problems to be and the corrective actions they took and how they reported it up the chain.

Mr. STEARNS. That does not quite answer my question. So the question would be, if you find that they did something illegal, will you determine whether those people are still there that did the illegal operations? Will that be a fair question that you will be able to determine for the Committee?

Mr. GRIVNOVICS. If we do get down to the actual purchase order level and we look at the individual transactions if we have a need to do that, then we could go back to that individual facility and find out who placed that order.

Mr. STEARNS. I am just trying to understand. The final report, will it say these illegal operations occurred and it amounted at least to \$206 million and those individuals are still there? Would that be something that we would be told or they are not there?

Ms. HALLIDAY. If the individuals are still in their positions, we would have a recommendation for VA to hold them accountable and take appropriate action.

Mr. STEARNS. When you say hold them accountable, as I understand, the first panel saying that what they did was illegal, but there is no enforcement, there is no civil, there is no penalty. Is that your understanding?

Ms. HALLIDAY. Generally, yes. For the violations of the FAR such as not meeting the competition requirements, there are some administrative actions you can also invoke.

Mr. STEARNS. Do you mind just sharing with us what those administrative actions would be under normal situations?

Ms. HALLIDAY. Most of the buying agents will have either an ordering delegation or a contracting warrant to make the purchases on behalf of the government. You can pull those warrants and that essentially is going to make it very difficult for that person to do their job.

Mr. STEARNS. So you stop them from doing the job, but you cannot fire them?

Ms. HALLIDAY. Depending upon the seriousness of the individual's actions, it would be up to the department to determine the disciplinary action that is appropriate.

Mr. STEARNS. Okay. Thank you, Mr. Chairman.

The CHAIRMAN. Any other questions?

[No response.]

The CHAIRMAN. Thank you very much for your testimony and your patience.

Ms. HALLIDAY. Thank you.

Mr. GRIVNOVICS. Thank you.

The CHAIRMAN. Invite the third panel to the table. On this panel, we are going to hear from Sharon Longwell, the vice president for Health Systems, National Accounts for McKesson Corporation.

Ms. Longwell, your complete statement will be entered into the record.

Ms. LONGWELL. Okay.

The CHAIRMAN. And you are recognized for five minutes.

**STATEMENT OF SHARON LONGWELL, VICE PRESIDENT,
HEALTH SYSTEMS, NATIONAL ACCOUNTS, MCKESSON COR-
PORATION**

Ms. LONGWELL. Thank you, Mr. Chairman and committee.

Before I get started, I would like to say on behalf of myself and McKesson and all our employees, thank you for everything you do Veterans.

On behalf of my brother, Jim, who served two terms in Vietnam and whom we lost this last summer, thank you he would want me to say.

The CHAIRMAN. Thank you for his service.

Ms. LONGWELL. My name is Sharon Longwell and I am vice president for Health Systems, National Accounts with McKesson Corporation.

I appreciate the opportunity to speak with you today to discuss the Department of Veterans Affairs' pharmaceutical prime vendor contract.

McKesson has delivered excellent quality and service to the VA as the pharmaceutical prime vendor. Through the deep negative distribution fee in our contract with the VA, we have provided the department with \$526 million in savings over the term of the prior PPV contract.

When McKesson was awarded the PPV contract in 2004 after a highly competitive bidding process, the negative distribution fee that we offered the VA in our contract was publicly criticized within the industry. Allegations were made that we could not service the contract with such unprecedented and deep discounts in our distribution fee.

I am here today to report that in the 8 years that we have proudly served the VA, we have delivered both significant savings and exceptional service.

For 179 years, McKesson has had an unwavering commitment to the safe, rapid, and cost-effective delivery of FDA approved pharmaceuticals to all of our customers from the largest hospital system and chain drugstores to the small mom and pop pharmacies and all of our government contracts.

McKesson purchases pharmaceuticals directly from the manufacturer. All pharmaceutical purchases from McKesson by the VA, whether under a VA negotiated contract or an open market item, have the required FDA approvals.

McKesson complies with all state and Federal laws and regulations governing sourcing, pedigree, chain of custody, and drug integrity.

In our role as the PPV, McKesson delivers pharmaceutical products to more than 700 VA affiliated locations which include the VA facilities, CMOP, Indian Health Services, Bureaus of Prisons, and other government agencies.

As the prime vendor, McKesson is responsible for providing thousands of products at a price set under the Federal supply contract which the VA has secured through negotiations with manufacturers.

We have invested an additional \$9 million in dedicated software, hardware, facilities, and staff for the PPV contract to improve the service and drive down VA cost.

McKesson's state-of-the-art technology allows authorized VA buyers to purchase products through our electronic order entry system which drives them to the lowest price contract item.

If the authorized buyer attempts to purchase a product that is not on a VA negotiated contract with the manufacturer, our system directs them to the lowest price contract item.

If the product is out of stock, the system suggests the lowest price generic equivalent product that is on contract.

Through the transparency afforded by our electronic ordering and inventory management systems, the VA can manage and track their inventory and have real-time access to invoice and ordering data.

There are circumstances, however, when contracted pharmaceuticals are in short supply or where the VA may not have contracted with the manufacturer for critical medications even though they are needed to treat patients in a timely manner.

The department's statement of work for the PPV states the PPV may be requested by the customer to supply and distribute open market pharmaceutical products on their behalf. Under this provision, purchases of open market products from McKesson are permitted by the PPV contract.

It is important to note that when the VA decided to purchase open market products from McKesson, it paid the same or less than our private sector hospital and institutional customers paid for the same products.

Purchases of open market product are a standard practice in the private sector. Based on our experience, the VA purchases of open market products, which are less than 5 percent of their total, is quite low.

In the private sector, for instance, 30 to 40 percent of purchases from hospital and institutional customers can be on open market.

In summary, at McKesson, we take enormous pride in driving efficiencies that improve the quality and delivery of health care to our Nation's Veterans. We have been and will always be committed to providing the highest level of service as we safely and rapidly deliver cost-effective medications to the VA and the Veterans they serve.

I am now prepared to answer any questions you may have.

[The prepared statement of Sharon Longwell appears on p. 53.]

The CHAIRMAN. Thank you for your testimony again. Thank you for your comments about your brother. That is what this committee is all about is taking care of those who have served this Nation. And I know from your comments he is still very close to you.

Ms. LONGWELL. Yes, sir.

The CHAIRMAN. Did VA approach McKesson about modifying the contract?

Ms. LONGWELL. McKesson never received a formal request to modify the contract. There were discussions to modify the contract, I believe in the October time frame.

The CHAIRMAN. Do you know what the modifications were and why it was modified?

Ms. LONGWELL. I believe they wanted to have McKesson put all open market items on contract and then, therefore, comply with all TAA requirements.

The CHAIRMAN. Can you give rationale behind their desire to do that?

Ms. LONGWELL. Their desire to do it, I think, was to no longer have any open market items, to have them all on contract.

The CHAIRMAN. Are similar pharmaceutical contracts in the private sector typically for the same length?

Ms. LONGWELL. Pardon me?

The CHAIRMAN. Are similar contracts like this out in the private sector typically for the same length of time as the PPV contract with VA?

Ms. LONGWELL. I would say in the private sector, sometimes they are shorter. However, you do have a base of 2 years and then three 2-year options. So in that case, they are very aligned with what the private sector does because you do have an option to cancel those and not take another option period.

The CHAIRMAN. Mr. Donnelly.

Mr. DONNELLY. Thank you, Mr. Chairman.

And your brother, Jim is a hero to us.

Ms. LONGWELL. Me, too.

Mr. DONNELLY. And we appreciate his service. And I just want to let you know that for Vietnam vets, at least back home in Indiana, every parade I am at, they get a standing ovation wherever they go. So they are held in extraordinary esteem by all of us.

What happens to cause the shortages and stock outs and, you know, what processes are you using to try to identify where the problems are so that the items will always be in stock?

Ms. LONGWELL. There are really two types of outages. There is "manufacturer unable to supply" and then what in our world we call "temporary outs." And that is where we did not buy enough of the product.

We are measured on our "temp out" and how much of that is caused by McKesson not ordering the right amount. And we have complied with the contract and have always exceeded the contract requirements.

The "manufacturer unable to supply" is where the manufacturer for whatever reason is not able to make enough of the product, had facility issues, have decided to get out of that market.

And we help provide on our Web site every week, we update any issues we are having with manufacturers and we try to put in there an estimated day when they will be released.

So that is really where the two types fall.

Mr. DONNELLY. For instance, with the manufacturer piece, do you have a way to detect here are the problem items that are out of stock all the time and, if so, here are the recommended backups or these are the products we really struggle getting? Is there a way for you to determine what are the problem products?

Ms. LONGWELL. Yes. In our purchasing facility, they work with manufacturers every day to try to obtain product. And when they find that one of the manufacturers has run into an issue on a product, we post this information and keep it posted weekly on our Web

site or our portal that the customers go through. That allows the customers to see when there is an issue.

We also ask the manufacturers can you please tell us when you think this item will be available. Is it, you know, April the 1st, April the 12th? And we are updating that every week.

Mr. DONNELLY. Okay. And when a product is not available and they have to purchase off of open contract, how do you determine the pricing for that?

Ms. LONGWELL. When they are not on contract in the private sector, sometimes they will have negotiated other contracts, maybe individual contracts. But at McKesson, our pricing department decides what we are going to price the product if it is on the open market.

I do not know how they price those, but it is going to be based on if there a shortage of the product. You heard them talk about WAC. That is a basis for it. But I cannot tell you specifically how they determine the price.

Mr. DONNELLY. Okay. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Stearns, any questions?

Mr. STEARNS. No, sir.

The CHAIRMAN. Mr. Roe.

Mr. ROE. First of all, welcome home to your brother.

Ms. LONGWELL. Thank you.

Mr. ROE. I am a Vietnam era Veteran myself.

So, anyway, I would like to know how big of a problem these shortages are for McKesson and other providers like you, are because we are hearing more and more about whether it is immunizations or chemotherapeutic agents.

Ms. LONGWELL. Uh-huh. I mean, shortages are a problem not only for McKesson but for myself, my family, your family. We all want to be able to get the right product when we can. McKesson only will buy from FDA approved manufacturers of product, but we do try to make sure that we have a wide breadth of product we can offer, especially in the generic world. If one generic vendor is having a problem with it, we will have backup generic equivalents.

Mr. ROE. Let me give you the old if it ain't broke don't fix it.

Ms. LONGWELL. Okay.

Mr. ROE. When you are out there as a doctor seeing a patient and you have taken months or a year to get them stabilized, you have no idea how disconcerting it is for that patient and that doctor when they cannot get the medication that they have finally gotten to work.

So these shortages are creating real problems in the real world out here for us and the health care system to provide the kind of care for our patients, especially a lot of folks that have had anxiety or mental problems, to finally get what works and then find out what works is not available anymore.

So I just wondered what kind of an issue it was for you all in providing and are you getting any blow back from your providers that this is a problem?

Ms. LONGWELL. I mean, we always hear from our customers if we are not able to provide something. We always try to make sure that any product that we cannot supply, we have gone back to the manufacturer time and time again, is there anything they can do,

please tell us what the expected date is, because I do not want to post on our portal that we expect release by Friday and then only to be able to tell them on Friday, no, that is not going to happen, it is not going to be until Monday.

Mr. ROE. Okay. Thank you. I yield back.

The CHAIRMAN. Mr. Stutzman, any comments?

Mr. STUTZMAN. I have just got one question. Thank you, Mr. Chairman. I just have one question.

Could you describe to us a little bit how you purchase from your manufacturers? I mean, there are so many pharmaceuticals out there and you obviously know what consumers or what your customers are needing. How fast can you react to that? Is that something that is within a computer system where you know the need and then do you—you talked a little bit about when you communicate to the manufacturers. How fast can they respond? What kind of flexibility do you have and do they have to provide the products? And then if you answer that question, that will kind of answer my second question, I believe.

Ms. LONGWELL. We have our standard product that our system is smart enough that it looks at demand that has been going on and helps build demand. When we bring on a new customer, we also will build in demand. So we never like to bring on a large customer more than 45 days before the start date because we want to be able to get that product, that demand built.

When we bring on new customers, we will go to the manufacturer and let everyone know we just got this new customer, please make that part of the allocation that you are giving us. And so we make sure that we are building up when we do bring on a new customer.

When we do find out there is an issue, if we still have product available, but we know we are not going to be able to get a lot of additional product, we will put customers on allocation. And what that does is that limits hoarding, if you will. We do not want anyone to grab all the market. We want to be able to provide it to everyone. So we will put allocations in our system to prevent them from doing that.

But our system goes in and it looks. Every week, it is doing updates of what our inventory should be. So we also look at when there are items that go off of patent. If we have a generic item come on and we know that generic item is going to be a big buy, we will buy up on that so that we will be able to have it.

Unfortunately, where we run into problems and where doctors' offices and hospitals run into a problem is where a facility shuts down or where they have a problem where they have shut down their facility. We are caught off guard and we are all having to struggle.

That is the time we go to the second manufacturer who may have the generic equivalent and say can you help us, how ramped up are you?

Where we run into problems are where the manufacturer that was shut down was doing 75 percent of the overall volume. The backup manufacturer was only doing, you know, 10. Now he has got to do all, you know, 80 percent. And so they have trouble gearing up as well.

We work with them as much as we can trying to make sure that we are getting the product we can get for our customers.

Mr. STUTZMAN. All right. Thank you. I will yield back.

The CHAIRMAN. Mr. McNerney, do you have any questions? You are recognized.

Mr. MCNERNEY. Thank you, Mr. Chairman.

Do you feel that there are safety and quality concerns when drugs are purchased on the open market?

Ms. LONGWELL. No, not from McKesson. I can only talk for McKesson. We only buy FDA approved drugs. We only buy them from their manufacturers. So we do not buy anything on what is called the secondary market. McKesson just does not buy from that.

Mr. MCNERNEY. Would you feel that pharmaceuticals purchased on the secondary market would be questionable or have safety concerns?

Ms. LONGWELL. I do not know if they would or would not. And since I do not know, we do not buy them.

Mr. MCNERNEY. All right. Thank you. I yield back.

The CHAIRMAN. Mr. Flores, you have any questions?

Mr. FLORES. Mr. Chairman, I have no questions or comments. Thank you.

The CHAIRMAN. Mr. Johnson, a question?

Mr. JOHNSON. I do, Mr. Chairman, and I thank you.

Before I ask my question, though, I would like to commend McKesson for contracting with over 100 Veteran-owned small businesses, suppliers, Veteran or minority-owned business overall.

There are 2,800 of those that you guys contract with and I appreciate that. And also in addition to sponsoring events focused on the Veteran community—Veteran-owned small business conferences you participate in. Those kinds of things. And I as a Veteran myself and all the Veterans really appreciate that.

I also understand that McKesson has rebid for the PPV contract that is coming up with the VA. And I certainly hope that this hearing will not negatively affect the VA's decision where McKesson is concerned because I am convinced that McKesson has delivered exactly what the VA asked them to do in compliance with the contract.

And we appreciate that. And we are going to be watching closely and asking the VA to do a cost benefit analysis of that contract award so that we can see the best option is pursued.

Ms. Longwell, can you explain to the Committee what happens when the VA attempts to purchase items off contract through your electronic system?

Ms. LONGWELL. In our electronic system, when you go to look for aspirin, I will use aspirin as the example, you can put in aspirin and it is going to pull up all the aspirin that we have. And it is going to show you what is on contract.

So in the VA system, it is going to show not only if it is in the FSS contract, it will show FSS in a column and it will show the contract number. It also is going to show the quantity, the DC quantity we have and it is going to show if it is zero, is that a "manufacturer unable to supply" or an MUS issue, that button will be checked. It will show all items that are on contract. So if they

have generic equivalents for that same item, it will be listed as well.

If the customer goes to place an order and they just put in aspirin, the system is going to show them all of those so they can drive to the right contract. And it will sort it so the lowest price contract item is sorted to the top.

It will, however, show if they do not have any on contract that is available, it will also show the open market equivalents of that same item.

Mr. JOHNSON. Okay. Thank you. Mr. Chairman, I have no further questions.

The CHAIRMAN. Mr. Denham, any questions?

Mr. DENHAM. No.

The CHAIRMAN. Mr. Runyan.

Mr. RUNYAN. No, sir.

The CHAIRMAN. Mr. Benishek.

Mr. BENISHEK. No.

The CHAIRMAN. Mr. Huelskamp.

Mr. HUELSKAMP. No.

The CHAIRMAN. Mr. Amodei.

Mr. AMODEI. No.

The CHAIRMAN. Any further questions?

[No response.]

The CHAIRMAN. If not, we thank McKesson for your testimony, Ms. Longwell.

Mr. JOHNSON. Mr. Chairman.

The CHAIRMAN. Mr. Johnson.

Mr. JOHNSON. Mr. Chairman, I make a motion under Rule 2—

The CHAIRMAN. Just a minute. We are going to excuse the witness first.

Mr. JOHNSON. Okay. Thank you.

The CHAIRMAN. And then I will make a statement and recognize you.

Ms. LONGWELL. Once again, thank you. Thank you for all you do.

The CHAIRMAN. Thank you very much. Thank you.

For the record, this hearing has adjourned.

[Whereupon, at 12:24 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.

I want to welcome everyone to today's hearing titled "Examining VA's Pharmaceutical Prime Vendor Contract."

This Committee started investigating VA's Pharmaceutical Prime Vendor, or "PPV", contract well before stories on the topic began running in the press, and the findings raised enough questions to warrant this hearing today.

The PPV contract, when written and executed correctly, is intended to ensure VA medical facilities receive needed pharmaceuticals at a competitive price and in a timely fashion.

Medical facilities throughout the Nation rely on this system to ensure the best care for our veteran patients.

The Committee's investigation began when discrepancies appeared in how VA ordering officials had been handling open market purchases of items not available on the PPV contract.

These purchases go back much further than just the last year or two: they span multiple administrations, showing many within VA chose to ignore rather than fix a known problem.

While Federal Acquisition Regulations outline clear procedures on how agencies can acquire items not on contract, VA officials for years have ignored those procedures when purchasing supplies that were either not available at the time or not on the PPV contract.

Instead of actually performing due diligence in its open market purchasing, VA officials took the easy route and requested the PPV to deliver the needed pharmaceuticals, or in some cases non-pharmaceutical items.

An open market purchase requires a degree of competition; VA's practices willfully ignored required competition, thereby compromising best value to taxpayers and potentially compromising patient safety.

In short, what VA has been doing is not mere bureaucratic oversight; it is illegal, with serious potential ramifications for veterans.

I am disheartened by VA's treatment of the matter. We know that senior officials at the Department have known of these practices for a long time, yet did little to address the issue, and certainly were not forthcoming about it to Congress.

In fact, VA has acknowledged knowing open market purchases through the PPV could be problematic as far back as December of 2010, but only in November of 2011 took formal action.

This action was little more than a re-statement of current law that employees should already have been following and leadership enforcing.

One thing we will get to the bottom of is who knew of VA's illegal buying and did nothing about it.

As has been the cause of several other problems identified by this Committee, weaknesses in contracting at VA are a major cause of the illegal purchases we are discussing today.

Instead of applying temporary bandages to cover up problems, VA needs to address the recurring causes within its own department and fix them.

Whether a complete contracting overhaul is needed or simply new leadership that can enforce existing law, it is my sincere desire that this Committee and the Department can resolve these issues and move forward.

My concern about the depth and duration of this illegal purchasing is serious enough that I have partnered with Chairman Issa of the Oversight and Government Reform Committee in requesting needed documents and information from VA to fix this problem.

I want to thank Chairman Issa for his help in investigating this matter, and look forward to VA's full and timely cooperation.

Lastly, I want to note VA's continuing habit of not providing requested information to this Committee.

One request is now a month overdue, and yet another is *five months* overdue.

I want to work with your Department to get our veterans the services and care they deserve, and that is going to require your Congressional Affairs team working with us to deliver solutions.

I now recognize the Ranking Member for an opening statement.

**Prepared Statement of Hon. Michael H. Michaud,
Acting Ranking Democratic Member**

Thank you, Mr. Chairman.

We have before us today some of the most senior level managers within the Department of Veterans Affairs—managers entrusted by the public to run the second largest agency in the Federal Government efficiently and effectively. We are here because VA has once again demonstrated an inability to perform at the level expected in managing procurement processes.

In testimony provided to the Committee, VA readily admits that violations took place. However, they are quick to assure us that changes have been implemented to fix the deficiencies at hand. Frankly, Mr. Chairman, I have heard it all before.

Today I have just three questions.

First, to quote a phrase made famous during the Watergate scandal—What did VA officials know, and when did they know it?

According to VA testimony, VA “did not follow all applicable law and regulation” for approximately \$1.2 billion in what are called “open market” pharmaceutical purchases since 2004.” The VA also states that “once these deficiencies were elevated to senior managers in 2011, VA worked to develop a solution.”

In December 2010, the VA decided to cease open market purchases in the future Pharmaceutical Prime Vendor (PPV) contract. What was the impetus behind this decision?

Was there an awareness in 2010 that there were serious problems with VA open market purchases, problems so severe that a decision was made not to include an open market clause in the new contract?

Yet nearly a year elapsed before VA took decisive action. At no time during the course of this period is there any indication that anyone in VA leadership simply insisted that open market purchases conform to VA policies, regulations and law. How much money was wasted?

Have these \$1.2 billion in purchases that were not in accordance with applicable laws and regulations been ratified by the VA?

Are there assurances that only warranted contract officers will be responsible for purchases above \$3,000 going forward?

After the VA Inspector General in 2009 found a litany of problems with improper open market purchases for medical equipment and supplies, VA management and leadership should have been put on notice that problems might exist in other prime vendor programs. The VA IG recommended that VA needed to revise its FSS waiver process, but VA responded that the waiver process in VA Handbook 7408.1 “provided sufficient controls and appropriate approval levels for open market purchases.” There is no evidence that VA paid any attention to the waiver process for buying drugs and pharmaceuticals in the open market.

I find it hard to believe that, as the VA states, “the process that was in place since 2004 had become routine.” I have to ask you, what is routine about the abject failure to follow established policies and procedures?

38 USC Section 8125 requires VA to submit a report every year to the Committee on the health care procurement experience. I look forward to receiving those reports from VA dating back to 2004.

My second question is who should be held accountable for this failure?

Time and time again, the VA comes to Capitol Hill and testifies that it has wonderful policies and procedures in place. Unfortunately, no one ever seems to follow these policies and procedures, and there seems to be no consequences for these failures. Time and time again, the VA OIG and GAO testify concerning serious problems with VA management and controls, and time and time again VA ignores these findings and fails to take pro-active action.

VA testimony includes an “illustrative example” of a GS-5 Pharmacy Specialist “confronted with the choice of ordering an open market item or doing without.” Let me offer a better example, how about the manager responsible for overseeing the GS-5 making sure the pharmacy specialist knew what VA policies and procedures were required and then ensuring they were followed?

However, what seems to be the actual case is that there was no management and no accountability all the way up the line and procedures and policies were not followed in purchasing \$1.2 billion worth of drugs and pharmaceuticals.

Third, how is this going to be fixed and how will these fixes improve the care we provide to our veterans?

I want to know how the absence of an open market clause in the new contract will affect veterans. I want to know if the VA is still making open market purchases of drugs and pharmaceuticals, either through the PPV or through other suppliers, and how can we be sure that proper processes are in place and, more importantly, being actively supervised by management. I want to be assured that VA open market purchases are from reliable suppliers and that all purchased drugs and pharmaceuticals meet all safety requirements.

The VA, in last year’s budget submission, claims \$355 million in savings in 2012 and 2013 due to “acquisition improvements.” But if the VA cannot follow its own policies and procedures, how much faith can we have in claims of acquisition savings?

I would like to see detailed documentation that VA has achieved savings and efficiencies while improving the procurement and acquisition process, a process that seems, in light of the serious breakdowns we are looking into today, to need much in the way of reform.

There is a saying that ignorance of the law is no excuse.

I hope that VA can help us understand today what accountability we should expect from failures that seem to arise not from ignorance, but from willful neglect of VA policies, procedures, and existing laws and regulations, and how this will change moving forward.

Prepared Statement of Hon. W. Scott 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 how we use the currently established contract to obtain pharmaceuticals for our Veterans.

Summary of Problem and Corrective Action:

VA acquires the majority of pharmaceutical products required through companies represented on the Federal Supply Schedule (FSS) and certified. Purchase and delivery of these pharmaceuticals is accomplished through a separate vehicle called the Pharmaceutical Prime Vendor or PPV contract. This two-tiered approach is an industry best practice—gaining economies of scale to set prices for drugs and then contracting for logistics services to deliver them at point and time of need. PPV provides a critical link in the supply chain among drug manufacturers, VA hospitals, and Veterans who need treatment. The PPV contract was awarded competitively to McKesson Company in 2003. VA’s first order under this contract was placed in May of 2004 and VA has used the contract continuously for the last 8 years.

VA has policies and procedures that govern how purchases are made from the PPV contract. Since 2004, approximately 96 percent of the \$30 billion has complied with all applicable law and regulation. However, approximately 4 percent occurred using an “open market” clause in the PPV contract, which was allowed under the contract, but which was to be used in accordance with all applicable procurement law and regulation. VA did not follow all applicable law and regulation for these transactions. These deficiencies were the responsibility of VA to identify and correct.

Once these deficiencies were elevated to senior managers in 2011, VA worked to develop a solution that would correct flaws in our internal processes and conform to regulation without preventing our Veterans from receiving necessary medications. On November 8, 2011, VA ordered its employees to end purchases being made through this flawed process and replaced it with a process that conforms to applicable regulations. Additionally, VA mandated training for employees authorized to place orders, placed qualified contracting officer representatives at the facility level to ensure compliance, and moved forward with a new Request For Proposal (RFP)

for a replacement PPV contract that will not allow the mistakes of the past to be repeated.

At no time were our Veterans put at risk. The pharmaceuticals purchased through PPV were FDA approved medications provided by McKesson Corporation, a distributor that provides these same pharmaceutical products to Wal-Mart, Target, RiteAid, Costco, CVS/Caremark, DukeHealth, Tenet, Omnicare, Aetna, and Cigna, among others. The result of these corrective actions preserves VA's access to necessary drugs and complies with all applicable law and regulation. In this way, we will continue to provide our Veterans with high quality care, with their unique medical needs as our first priority.

Acquisition Reform at VA

VA has improved the quality and cost of its acquisition system over the past 3 years. In October 2008, VA established the Office of Acquisition, Logistics and Construction (OALC) to better address the many challenges in acquisition identified through internal studies, as well as recommendations from VA's Office of Inspector General and the Government Accountability Office. This new Office, reporting to the Deputy Secretary, resulted in the appointment of an Acting Chief Acquisitions Officer (CAO) whose main focus is to improve acquisition in the Department as specified in the Services Acquisition Reform Act (SARA). Previously, the Department's Chief Financial Officer was responsible for both business lines, which was contrary to the SARA requirements.

The Secretary charged OALC to lead the Department's acquisition transformation efforts by focusing on management information, improving management of the acquisition life cycle, improving the acquisition workforce, and leveraging technology to improve contracting outcomes. VA has established the Senior Procurement Council and implemented metrics to measure critical contracting requirements, implemented an enterprise spend analysis process, established a risk management office to oversee the A-123 process, established a Supplier Relationship Management initiative to work with our suppliers to improve our contracting processes, provided training to ensure a professional acquisition workforce, and developed information technology (IT) systems to simplify and standardize how we implement contracting throughout the Department.

Additionally, the National Acquisition Center (NAC), a major component of the VA Acquisition landscape, has an extensive program of instruction for ordering officers on what their responsibilities are and the limits of their authority. The NAC provides this training to all ordering officers across VA and will provide refresher training to all personnel filling this role, since 2011.

VA is working to ensure that all its contracting officers meet Federal Acquisition Certification standards by the end of Fiscal year 2012. We are also focusing on institutionalizing program management practices across the Department. A new Acquisition Executive Council serves as the advisory body for developing VA's Acquisition Corps and will identify positions throughout the Department requiring program or project management certification.

Within VHA, procurement staffs were reorganized under a new management line that provides management and oversight dedicated to improving procurement operations. VHA completed its reorganization at the end of fiscal year (FY) 2011. VHA, in partnership with OALC, recently appointed a seasoned "Federal Acquisition Certification in Contracting" (FAC-C) Level III procurement executive to serve as the leader for VHA's procurement organization. VHA has additionally recruited and hired experienced senior executives within the procurement organization. Since February 2011, VHA has hired over 330 procurement professionals across the system, reducing the vacancy rate of 25 percent to 8 percent for trained and qualified procurement specialists. In FY 2011 these changes helped VA avoid \$1.1 billion in acquisition costs.

But despite these reforms, VA did not detect the problems with the PPV open market clause, in part because the process that was in place since 2004 had become routine. Moreover, when properly applied, the PPV program provided a reliable, cost-effective and safe source of pharmaceuticals. In the next section, we describe in greater detail how this happened.

Decision to Use PPV to Distribute Drugs More Efficiently and Effectively

In 1994, VA replaced its old "depot" distribution program with a new commercial distribution strategy to eliminate its warehousing system for storing and distributing drugs and supplies. Under the old VA drug distribution system, drugs were ordered in bulk from centralized depots. Orders could take up to 6 weeks for deliv-

ery, inventory management was difficult and time consuming, and many needed medications were nearing their expiration dates by the time they were actually in the hands of VA pharmacy personnel. In addition, there was as much as a 12 percent internal VA “up charge” for ordering and distributing these products. VA facilities also purchased from other supply sources to supplement their requirements for items not available from the depots.

The health care industry moved away from this model of supply for pharmaceuticals, medical, environmental, and virtually all other items used in patient care to distribution contracts that provided just-in-time acquisition and inventory processes and efficient online systems for placing orders. VA decided to do the same and entered into its first Pharmaceutical Prime Vendor contract in 1994.

This model has been adopted by virtually every other major health care provider in both the private and public sectors and is regarded as a best commercial practice. Other entities that use VA’s prime vendor contract include the Indian Health Service, the Bureau of Prisons, the U.S. State Department (Peace Corps), the U.S. Public Health Service, the Department of Homeland Security, and Howard University Hospital. Authorized State Veterans Homes that have sharing agreements with VA facilities also are eligible to use the contract.

The usual path a Federal agency uses to purchase supplies is to establish a contract that sets a fixed price for a particular good. The Federal Acquisition Regulation (FAR) implementing the Competition in Contracting Act (CICA) defines the process for awarding and administering the contract, including the establishment of a fair and reasonable price for goods purchased. VA is also required to comply with various other statutes, such as the Trade Agreements Act (TAA) and the Buy American Act (BAA). These required terms and conditions are outlined in applicable clauses in the contract. VA is required to follow these laws and regulations and did so in awarding the current PPV contract.

The PPV program remains the most cost-effective solution to providing timely, cost-efficient, high quality health care products across the country. It enables VA to get the medications VA provider’s need, when they need them. The pharmaceutical prime vendor is required to follow FDA standards for product quality and patient safety.

The Current PPV Contract

The current contract was competitively awarded to the McKesson Corporation on December 31, 2003, following the laws and regulations in the previous section. The initial period of performance for this contract was May 10, 2004, through May 9, 2006. The contract is currently in its last option period, and expires in May 2012.

The contract provides drugs and supplies to VA and other government customers via 750-plus 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 offers VA a discount on all purchases. Pricing for the majority of the pharmaceutical products distributed through the PPV is established through contracts (e.g., the Federal Supply Schedule (FSS), or national contracts) awarded by OALC as previously discussed.

The contract statement of work (SOW) requires the PPV to supply and distribute drugs, pharmaceuticals, and certain other items that are dispensed through pharmacies. The source of these items are labeled in a web portal provided by McKesson to denote the various contract vehicles under which the pharmaceuticals are offered including, for example, FSS, VA national contracts, Basic Ordering Agreements, and various other Federal contracts.

The current contract also enables VA to order, through the PPV distributor, supplies that are not identified on any Federal contract in order to avoid a disruption where a needed drug cannot be obtained for a Veteran. This is referred to as the “open market clause.” The current PPV contract states “. . . the PPV may be requested by the customer to supply and distribute open market drug/pharmaceutical products/items/units on their behalf.” The contract also stipulates that the appropriate user will have followed applicable procurement laws and regulations when using this clause. This enabled VA to establish additional contracts for drugs not currently under a Federal contract available through the PPV. These contracts were to be put in place by warranted contracting officers using Federal and Department regulations. The term “open market” means that the drug was not purchased under any existing Federal contracts currently available to the PPV. While the open market items that were acquired through the PPV were ordered through the same commercial online ordering system as contracted items and were sourced by the PPV contractor, these FDA-approved medications were not available on a VA contract.

This does not mean the medications purchased were unsafe or were purchased from unreliable sources; it means only that it was purchased without a valid contract in place. This is where the improper use of the PPV contract occurred and the ordering process broke down.

Illustrative Example

In an effort to explain how non-contract items were ordered in the past, the following exhibit provides a view of what the ordering officer sees on the McKesson ordering system. In this screenshot, a user has searched for Cisplatin, a chemotherapy drug used to treat carcinomas, sarcomas, lymphomas, and germ cell tumors. Cisplatin is administered intravenously and is considered a critical drug for cancer treatment. In the scenario shown below, the PPV ordering system returned all matching items in a list. This list displays whether stock is available for the item in the column called "DC_Qty." The search return also displays the unit cost for the item in the column called "Unit Price." The column identified as "Cust Cntrct Type" identifies whether an item is on contract. In the search results, the system shows that none of the contract quotes for Cisplatin that are available on an FSS contract have stock available to order. However, the item is clearly available from another source. It is understandable that for many years, a GS-5 pharmacy specialist, motivated by a desire to maintain a continuous supply of drugs for patients and when confronted with the choice of ordering an open market item or doing without, would have chosen the open market item.

Exhibit not available at time of print.

What is not readily apparent from the information presented in the PPV portal or adequately explained in the training that VA ordering officers received, is that in order for these orders to be fulfilled, they would have to be purchased off-contract. This expedient choice would have conformed with the FAR had the ordering officer held a valid warrant and established a contract using appropriate procurement and payment methods. The correct approach for performing the order above would have been to engage a warranted contracting officer to acquire the needed items under a contract and use the appropriate procurement methods.

Corrective Action

VA has implemented a process to make open market procurements in accordance with the FAR. 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. There will be no option for ordering officers to obtain non-contract supplies. In addition, improved training will be provided for ordering officers.

The new contract will preserve the ability to get needed drugs that the PPV has provided VA since its inception and the health and safety of Veterans will not be at risk. But it will be provided through a FAR-compliant mechanism to obtain medications not on a Federal contract.

We expect to have this new contract awarded by the end of March 2012. Because this contract has not yet been awarded, we are limited in the information we may discuss at this time. But we assure you, the new contract will address VA's requirements while conforming to the FAR. We will inform Congress of the details once we have awarded a new PPV contract.

Conclusion

The failure to properly use and oversee the administration of the open market clause of this contract represents a breakdown in our system of management and accountability. We emphasize that this was a procedural breakdown, that it in no way compromised Veterans safety and affected not more than 4 percent of total pharmaceutical purchases since 2004. We have taken steps to eliminate this possibility now, and we are working to reduce the potential for other errors in the future by more closely managing orders under the PPV contract, while still ensuring our Veterans and their families receive the medications they need.

Mr. Chairman, thank you for the opportunity to discuss this issue on the record. 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 Linda A. Halliday

Mr. Chairman and Members of the Committee, thank you for this opportunity to testify on the scope and methodology of the Office of Inspector General's (OIG) ongoing reviews of VA's administration of the Pharmaceutical Prime Vendor (PPV) contract and to also give a historical background on the OIG's work in contracting and open market purchases. I am accompanied by Michael Grivnovics, Director, Federal Supply Service Division, and Mark Myers, Director, Health care Resources Division, in the OIG's Office of Contract Review.

HISTORY

The OIG's Office of Contract Review (OCR) has conducted pre-award and post-award contract reviews and other pricing reviews of Federal Supply Schedule (FSS) and construction contracts since 1993. These reviews provide both the OIG and VA with unique insight into the commercial marketplace for pharmaceuticals; medical and surgical supplies and equipment; and health care services. In addition, the OIG's Office of Audits and Evaluations has conducted numerous audits addressing purchasing practices at VA medical facilities, with emphasis on open market, or non-contract, purchases. Based on this work, we have advised VA, Congress, and other Government entities on vulnerabilities in the Government's procurement practices and recommended changes needed to protect patients treated at VA and other Government medical facilities as well as the taxpayer.

Open market purchasing is not a new issue; over the past 12 years, the OIG has issued 49 public reports that identified concerns with open market purchases. In May 2001, we issued a report, *Evaluation of the Department of Veterans Affairs Purchasing Practices*, in which we reported that the "effectiveness and integrity of the Federal Supply Schedule (FSS) program has deteriorated." We noted that due to legislative changes requiring acquisition streamlining and reform, the FSS was no longer a mandatory source and there was an increase in open market sales. As a result, a growing number of vendors had cancelled existing contracts, decided not to submit proposals, removed high-dollar sales items from the contract, or simply refused to offer Most Favored Customer pricing. We noted that a "vendor's ability to sell open market in significant volumes effectively eliminates the Government's ability to leverage prices using its aggregate buying power." In response to the report, VA initiated a Procurement Reform Task Force to address the issues. One of the outcomes of the Task Force was to create a purchasing hierarchy that required VA to purchase pharmaceuticals and medical/surgical supplies and equipment from national contracts first before using alternative buying mechanisms such as local contracts or buying open market.

In the 1990s and since 2008, we have worked with VA, the Department of Justice, the Office of Management and Budget, the General Services Administration (GSA), and the GSA OIG to identify shortcomings in the FSS program that affect the Government's ability to leverage its aggregate buying power and to receive prices that are fair and reasonable at the time of award and remain so during the entire term of the contract.

Reporting to Congress

From 2002–2004 and again from 2008–2010, the OIG worked with staff from this Committee on two legislative initiatives focused on reforming VA's procurement practices. Our recommendations during this process addressed legislative initiatives that would improve VA's ability to get items on contract and thus reduce open market procurements.

In December 2009, in testimony before this Committee's Subcommittee on Oversight and Investigations, we testified about acquisition deficiencies including open market purchasing. At that hearing, we discussed reports issued in 2004, 2007, and 2009, that showed VA facilities were not complying with the purchasing hierarchy and were instead purchasing products open market.

In March 2011, in response to questions during a hearing before the House Committee on Appropriations' Subcommittee on Military Construction, Veterans Affairs, and Related Agencies, we testified about issues facing VA and other Government purchasers on leveraging the Government's buying power when contracting for pharmaceuticals. We recognized that open market purchases were a problem and stated that the causes included the fact that there was no requirement that manufacturers offer generic drugs on contract and that the *Trade Agreements Act* precluded some vendors from offering their products on contract. As a result VA and other Government entities were buying open market and possibly not complying with acquisition laws and regulations.

Contract Process

In 2007, OCR found that VA was purchasing covered or branded pharmaceuticals open market through the PPV even though the products were on FSS contracts at a Federal Ceiling Price (FCP) as mandated by statute. We determined that this occurred because of a loophole that allowed purchasers to buy products through the PPV even though the manufacturer declined to sell their products through the PPV. Because the items were purchased open market, the prices exceeded the contract's FCP. We reported the problem to VA's Pharmacy Benefits Management (PBM) Services, the National Acquisition Center (NAC), and VA's Office of General Counsel. As a result of our discussions, the PPV electronic ordering system was modified to block purchases of items from manufacturers who declined to sell through the PPV. However, in 2011, we found that the modification was ineffective because purchasers were still buying contract items at open market prices through the PPV. We determined that although the PPV's ordering system did block the purchase, the purchaser had the ability to override the system and make the purchase. We found no controls were in place to hold purchasers accountable. For one vendor's product line, we found \$5.7 million in open market purchases of which \$2.3 million represented overpayments because VA paid more than the FCP. In addition to issuing three letters to the NAC addressing our finding on open market purchases of products from three separate manufacturers, we discussed the issue with PBM, the NAC, and OGC.

Through pre-award and post-award reviews, which include extensive discussions with manufacturers, in 2011 OCR identified a growing number of issues relating to generic drugs including the inability and/or unwillingness of vendors to put these items on contract, sell through the PPV, or offer most favored customer pricing. This work also provided us with insight into contracting and buying practices of private health care providers and institutions. This information was shared with the Office of Acquisitions and Logistics and PBM for the purpose of finding solutions to this growing problem. In May 2011, OCR was invited to participate in a 2-day meeting with PBM, the NAC, and other VA officials to discuss open market purchasing through the PPV and possible solutions. This was the first indication we had that VA had concerns about the level of open market purchasing through the PPV. We attended the meeting, provided our insight, and have been working since October with VA's Integrated Product Team (IPT) to address immediate, short-term, and long-term solutions. Some short-term solutions proposed by the IPT resulted in amendments to the current PPV solicitation to establish negotiated prices for items not on national contracts and a requirement that these products comply with the *Trade Agreement Act*.

Long-Term Solutions

Identifying viable long-term solutions is a not an easy task because the causes, which are numerous and often complex, have never been quantified. For example, some products are not available on contract because vendors have chosen not to offer them on contract or cannot offer the products on contract because the products do not comply with the *Trade Agreements Act*. In other cases a non-contract item may be purchased because contract items are unavailable due to shortages. We also know that purchasers will buy open market when the contract price exceeds the price offered by non-contract vendors. This is particularly true when the brand name drug is on contract but the generic equivalents are not. In addition, patient care and safety concerns must be considered. Some solutions can be addressed through contract provisions and internal policies and processes but others may require legislation.

OIG'S CURRENT REVIEWS

At this time, we are conducting a review of PPV purchases for fiscal year 2011 to quantify the extent and cause of the problems. This includes quantifying the actual dollars spent on open market sales; what percentage of these purchases were pharmaceutical items versus medical/surgical items; and identifying patterns and trends of open market purchases of pharmaceuticals. We also will determine and quantify whether the pharmaceutical item purchased open market was on contract and, if so, why the sale was listed as open market. If the item purchased was not on contract, we will determine whether there was a comparable item on contract. If comparable items were available, we will try to determine why the contract item was not purchased. We also will select a sample to ascertain the extent that purchases may have violated existing procurement laws and regulations. We are attempting to determine whether open market purchases of pharmaceuticals violated

the *Trade Agreements Act*. In addition, we are reviewing whether changes made by VA in November 2011 to prevent or limit open market purchasing through the PPV were effective.

We are also conducting a review of the internal controls of VA's Fast Pay System, a system that expedites payments for goods received under contract and makes payments generally within 24 to 48 hours. This internal controls review will identify the risks and vulnerabilities associated with reliance on related payment and processing activities including whether items are received and correctly priced; payment errors are corrected in a timely manner; contract terms are met; and there is a segregation of duties to prevent fraud. The Fast Pay System is unique to the PPV. Under the PPV contract, VA facilities are required to use the Fast Pay process for PPV purchases.

We are conducting tests of sample invoices tracking from time of ordering, payment through the Fast Pay System, and receipt of goods from the ordering location. Further, we are examining the effectiveness of the VA's Financial Services Center's financial controls by comparing the payments made to the invoices at VA facilities. In addition, we are assessing whether VA received correct and timely reimbursements for purchases made on behalf of other Government agencies.

A longer-term review to be conducted by OCR is to review the prices charged for items that were not purchased open market in comparison to the contract price at the time of purchase to ensure that customers were not charged more than the contract price. If this review identifies overcharges, we will recommend that the contracting officer issue a bill of collection and that VA take other action if appropriate. If the current review shows that procurement laws and regulations were violated, the longer term review will determine the frequency and dollar value of such violations and make recommendations for appropriate corrective action.

CONCLUSION

Over the last 12 years, the OIG has continually reported on the issue of open market purchases and our concerns that the Government was not sufficiently aggregating its buying power to obtain fair and reasonable prices comparable to those paid by similar commercial customers for the purchase of pharmaceuticals, medical and surgical supplies, and health care resources. We will provide the Committee the results of our ongoing reviews when they are completed. We will continue to advise VA and Congress on issues related to VA procurement and contracting issues.

Mr. Chairman and other Members of the Committee, this concludes my statement and my colleagues and I would be pleased to answer any questions that you may have.

Prepared Statement of Sharon Longwell

Good morning, Chairman Miller, Ranking Member Filner and Members of the Committee. My name is Sharon Longwell and I am the Vice President of Health Systems, National Accounts, for McKesson Corporation. I appreciate the opportunity to appear before you today to discuss the Department of Veterans Affairs' Pharmaceutical Prime Vendor (PPV) contract.

I would like to begin by emphasizing four points:

- (1) McKesson has delivered excellent quality and service to the VA as the pharmaceutical prime vendor. Through the deep negative distribution fee in our contract with the VA, we have provided the Department with \$526 million in savings over the terms of the prior PPV contract.
- (2) McKesson has consistently exceeded the requirements of the contract and is providing state of the art technology and unparalleled quality and value to the Department, including 99.9 percent accuracy in fulfilling orders.
- (3) For 179 years, McKesson has had an unwavering commitment to the safe, rapid and cost effective delivery of FDA-approved pharmaceuticals to all of our customers, from the largest hospital system and chain drug store to the smallest neighborhood pharmacy and all government contracts. All pharmaceutical products purchased from McKesson by the VA, whether under VA "contract" or an "open market" item, have the required FDA approvals. McKesson complies with all Federal and state laws and regulations governing sourcing, pedigree, chain of custody and drug integrity.
- (4) We are a proud member of the Department's mentor-protégé program as we offer partnership opportunities to veteran-owned and disabled veteran-owned

small businesses, and we continue to actively recruit, hire and retain veterans as a vital part of our workforce.

For 179 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 15 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 system, McKesson delivers medicines to a significant number of 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.

The Role of the Pharmaceutical Prime Vendor: Service, Savings, Safety

Service

In our role 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), providing the highest quality service to more than five million veterans. We have invested an additional nine million dollars in dedicated software, hardware, facilities and staff for the PPV contract to improve service and drive down costs for the VA. As the prime vendor, McKesson is responsible for providing thousands of products at prices set under a Federal supply contract which the VA has secured through negotiations with 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 contract item. If the authorized buyer attempts to purchase product that is not on a VA negotiated contract with the manufacturer, our system directs them to the lowest priced contract item. If a product is out of stock, the system suggests the lowest priced generic equivalent product that is on contract. 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.

There are circumstances, however, when contracted pharmaceuticals are in short supply or where the VA may not have contracted with manufacturers for critical medicines, even though they are needed to treat patients in a timely manner. Among the very specific and detailed requirements of the Department's Statement of Work (SOW) for the pharmaceutical prime vendor, it states that, in addition to supplying the VA with products that the VA has secured with a Federal supply contract, *"the PPV may be requested by the customer to supply and distribute open market drug/pharmaceutical products/items/units on their behalf."* Under that provision, purchases of open market products from McKesson are permitted by this contract. It is important to note that, when the VA decided to purchase open market products from McKesson, it paid the same or less than our private sector hospital and institutional customers paid for the same products. Purchases of open market products are a standard practice in the private sector. Based on our experience, the VA's purchases of open market products, which are less than 5 percent of their total, are quite low. In the private sector, for instance, 30–40 percent of the purchases of hospital and institutional customers are of open market products.

McKesson has a dedicated "VA-only" customer service department. 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. Our accuracy in fulfilling orders is 99.9 percent. At any time, the VA can access a full listing of McKesson's current inventory for any one of our 31 distribution centers nationwide, many of which are strategically located near VA facilities in order to provide maximum coverage in instances of immediate need. 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 not only met the requirements of our contract, but we have, in fact, consistently exceeded its requirements for service and quality.

Savings

When McKesson was awarded the Pharmaceutical Prime Vendor contract for the Department of Veterans Affairs in 2004 after a highly competitive bidding process, the negative distribution fee that we offered the VA in our contract was so aggressive that we were publicly criticized within the industry. In fact, allegations were

made that we could not service the contract with such unprecedented and deep cuts in our distribution fee.

McKesson offered the best proposal on price and technology to win the award. The VA has had an opportunity to review the prime vendor relationship every 2 years, and has chosen to renew our contract at each option period as an endorsement of our continued savings and high level of performance. McKesson's performance with the VA has resulted in a Federal 'budget multiplier', saving the Department over half a billion in taxpayer dollars.

Safety

All pharmaceuticals purchased for the VA through McKesson, whether they are under VA negotiated contracts or open market products, have the required U.S. Food and Drug Administration (FDA) approvals. McKesson complies with Federal and state laws and regulations governing sourcing, pedigree, chain of custody and drug integrity. McKesson purchases pharmaceuticals directly from the manufacturer. Manufacturers, whether domestic or foreign, have facilities that are registered with and subject to inspection by the FDA. While manufacturers are ultimately responsible for the safety and efficacy of the prescription drugs they manufacture, the FDA enforces the applicable statutes and regulations to ensure that prescription drugs marketed in the United States are safe and effective, regardless of the point of manufacture.

McKesson's quality and safety standards are equally rigorous regardless of customer, contract, or any other factor. In fact, all of the products bought by the VA from McKesson, including open market products, come through the same secure supply chain that serves your local hospital, chain or neighborhood pharmacy. McKesson leads the industry in innovative solutions to make the Nation's pharmaceutical supply chain, already the best in the world, stronger and more secure.

In summary, McKesson has delivered significant, measurable value under the Pharmaceutical Prime Vendor contract.

- (1) McKesson has delivered excellent quality and service to the VA as the pharmaceutical prime vendor. Through the deep negative distribution fee in our contract with the VA, we have provided the Department with \$526 million in savings over the prior PPV contract.
- (2) McKesson has consistently exceeded the requirements of the contract and is providing state of the art technology and unparalleled quality and value to the Department, including 99.9 percent accuracy in fulfilling orders.
- (3) For 179 years, McKesson has had an unwavering commitment to the safe, rapid and cost effective delivery of FDA-approved pharmaceuticals to all of our customers, from the largest hospital system and chain drug store to the smallest neighborhood pharmacy and all government contracts. All pharmaceutical products purchased from McKesson by the VA, whether under VA "contract" or an "open market" item, have the required FDA approvals. McKesson complies with all Federal and state laws and regulations governing sourcing, pedigree, chain of custody and drug integrity.
- (4) We are a proud member of the Department's mentor-protégé program as we offer partnership opportunities to veteran-owned and disabled veteran-owned small businesses, and we continue to actively recruit, hire and retain veterans as a vital part of our workforce. Specifically:
 - McKesson has advanced veteran-owned small business goals. We currently contract with over 100 veteran-owned business suppliers and 2,800 small, veteran and minority-owned businesses overall.
 - McKesson is one of 20 prime vendors and the only health care company chosen to participate in the prestigious Department of Veterans Affairs mentor-protégé program.
 - RelayHealth, McKesson's connectivity business, won the Department of Veterans Affairs "Blue Button for All Americans" contest in 2011 by making a Blue Button personal health record system available to all patients, including veterans. We donated the \$50,000 award to the Wounded Warrior Project.
 - Missouri presented McKesson with a "Flag of Freedom" award in 2011 for our commitment to hiring veterans in the state.
 - The McKesson Military Resource Group, comprised of employees who are military veterans and military family members, advocate McKesson's efforts to respect, honor and partner with the military community. They are also engaged in supporting the company's focus on hiring and retaining veterans.
 - McKesson sponsors events focused on the veteran community, including San Francisco's Fleet Week, the National Veteran Small Business Conference, and

the California Disabled Veteran Business Alliance's annual *Keeping the Promise Exposition*.

- Our annual "Community Days" have brought together over 15,000 McKesson employees across the country in 2011 to assemble tens of thousands of care packages for active duty troops deployed around the world and wounded warriors recuperating stateside.

At McKesson, we take enormous pride in driving efficiencies that improve the quality and delivery of health care for our Nation's veterans. We have been and will always be committed to providing the highest levels of service as we safely and rapidly deliver cost-effective medications to the VA and the veterans they serve.

MATERIAL SUBMITTED FOR THE RECORD**Post-hearing Questions from Hon. Bob Filner, Ranking Democratic Member, Committee on Veterans' Affairs to Hon. Eric K. Shinseki, Secretary, U.S. Department of Veterans Affairs**

February 27, 2012

The Honorable Eric K. Shinseki
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Mr. Secretary:

In reference to our Full Committee hearing entitled, "Examining VA's Pharmaceutical Prime Vendor Contract" that took place on February 1, 2012, I would appreciate it if you could answer the enclosed hearing questions by the close of business on April 3, 2012.

In an effort to reduce printing costs, the Committee on Veterans' Affairs, in cooperation with the Joint Committee on Printing, is implementing some formatting changes for materials for all Full Committee and Subcommittee hearings. Therefore, it would be appreciated if you could provide your answers consecutively and single-spaced. In addition, please restate the question in its entirety before the answer.

Due to the delay in receiving mail, please provide your response to Carol Murray at Carol.Murray@mail.house.gov, and fax your responses to Carol at 202-225-2034. If you have any questions, please call 202-225-9756.

Sincerely,

BOB FILNER
Ranking Democratic Member

DMT:cm

Questions for the Record
Examining VA's Pharmaceutical Prime Vendor Contract
February 1, 2012
Department of Veterans' Affairs

1. Concerning the VA's open market drug and pharmaceutical purchases over the period of January 1, 2006 through December 31, 2011:
 - a. Please list the top 5 most purchased drugs in terms of volume, number of purchases, and dollar value.
 - b. What policies and procedures were in place to flag or identify items frequently purchased and then to seek to place these items on contract?
 - c. What percentage of overall open market purchases were made through the Prime Pharmaceutical Vendor (PPV)?
2. Since the November 8, 2011 memorandum prohibiting "improper purchase of all open market items through the PPV" how many open market purchases has VA made?
 - a. Of these purchases, how many have been made through the PPV?
 - b. Of these purchases, how many have required ratification after the purchase?
 - c. Of these purchases, how many have followed the waiver procedures found in VA Handbook 7408.1?
 - d. Of these purchases, what has VA done to ensure that prices paid were reasonable and that drugs and that all drugs and pharmaceuticals met all safety rules, regulations and laws?
 - e. Of these purchases, how many of these purchases involved so-called "gray market" drugs or suppliers?
3. Your November 8, 2011 memorandum states that "[s]pecial procedures have been developed to quickly purchase open-market pharmaceuticals to reduce the lead times for these procurements (attached)."

Attachment not available at time of print.

- a. Please provide a copy of these "special procedures."

- b. Do these “special procedures” deviate from the waiver procedures found in VA Handbook 7408.1? If so, please provide a detailed rationale for these deviations.
 - c. What safeguards are currently in effect to eliminate purchases made by non-warranted contract officers for amounts greater than \$3,000?
 - d. What safeguards are in effect to ensure that purchases made involving less than \$3,000 are made properly?
 - e. What policies and procedures are in place to ensure that fair prices are paid for open market purchases?
4. The OIG’s testimony indicated that there are no controls in place to hold purchasers accountable who “override the system” when purchases were blocked by the PPV’s ordering system.
 - a. Please explain to the Committee, in detail, what it takes for a purchaser to override the system and who is the person who has that authority, both prior to, and after November 8, 2011?
 - b. Is there a report that is required that would indicate how many times the override authority is used and why there is a need to override the system? If there is such a report, to whom is it forwarded and who receives copies?
 5. For 12 years the OIG has been reporting on the FSS and has issued no less than 49 reports that include concerns about open market purchases. That amounts to about 4 reports a year or one every 3 months.
 - a. How is it that this issue continues to grow seemingly unchecked with no effective controls or oversight in place?
 6. In testimony VA claims to have avoided \$1.1 billion in acquisition costs due to changes in FY 2011 such as hiring 330 procurement professionals. Can you please point to other specific changes where VA can demonstrate cost avoidance?
 7. As of February 8, 2012, in terms of open market purchases, is the VA in violation of the Federal Acquisition Regulations (FAR) or the Veterans Affairs Acquisition Regulations (VAAR)?
 - a. In your view, do all purchases, including those made in amounts greater than \$3,000 require a warranted contract official?
 8. With the admitted loss of control of the open market purchases, has there been any action taken to discipline and hold accountable the management who allowed this to happen?
 - a. What lessons has VA senior management learned from this failure and what steps has it taken to ensure that systemic problems and failures are identified at the earliest possible time and corrected in a speedy and timely fashion?
 9. In testimony you give an example of how a GS-5 pharmacy tech could choose the open market purchase and get the needed drug as opposed to going without.
 - a. Please give a detailed response on the purchasing hierarchy involved in open market purchases at the VA Medical Center level. Please include titles and timelines at each level of authority.
 10. Time and again the Government Accountability Office (GAO) and the VAOIG have reported lack of sufficient knowledge of policies and procedures by staff, confusion in the field and the need for more training.
 - a. What are you doing to ensure that the proper staff is trained and that follow-up measures are taken to ensure that the staff remains trained if and when there is a procedural change to the acquisition and procurement process?
 11. In testimony you state that senior management was first made aware of the open market purchase problem in 2011 VA developed a solution to correct the flaws in “our internal processes and conform to regulation.” Please provide a specific timeline of:
 - a. Who was first aware of the deficiencies, how did they become aware and when did they notify the next management level?
 - b. What specific actions were taken and when by each level of management?
 - c. If there were delays in informing the next level of management, what was the reason for the delay?

12. You indicated that VA had decided in December 2010 to take the “open market purchase” clause out of the next iteration of the PPV contract.
 - a. What led to that decision?
 - b. If the VA will no longer be making open market purchases through the PPV, how will the field be affected as far as obtaining a needed drug that is not on contract?
 - c. What safeguards are currently in place, or will be put in place, to ensure that drugs and pharmaceuticals purchased through suppliers other than the PPV meet all safety requirements and are purchased at a fair price?
13. Looking forward, what steps will VA take to ensure the open market drug and pharmaceutical purchases involve items for which there is a confirmed chain of custody between the manufacturer and supplier?
 - a. What steps will VA take under the new PPV contract to ensure that suppliers from which open market items are purchased are not charging exorbitant prices for items in short supply?
 - b. What steps will the VA take to govern its dealing with gray market suppliers?
14. Of the approximately \$1.2 billion in open market purchases:
 - a. How many of the purchases were made by warranted contract officials?
 - b. What steps is VA taking to ratify the improper purchases, or those that were made without a warranted contract official approval?
15. Do you have copies of existing waiver requests under VA Handbook 7408.1 for the \$1.2 billion in open market purchases dating back to 2004?
 - a. If you do not have the waiver requests, please explain why there are no waiver requests and when going forward, what enforcement measures are in place to ensure that appropriate employees are in compliance with VA Handbook 7408.1.
16. Please provide the Committee with the detailed steps, from initial prescription to purchase and delivery, needed to make open market purchases in compliance with your November 8, 2011 memorandum.
17. In last year's budget submission, VA claimed \$355 million in savings in 2012 and 2013 due to “acquisition improvements.” Please provide the Committee with an accounting of exactly where the \$355 million was saved and what improvements were made. Please include a timeline with this as well.

**Responses from Hon. Eric K. Shinseki, Secretary,
U.S. Department of Veterans Affairs to Hon. Bob Filner,
Ranking Democratic Member, Committee on Veterans' Affairs**

Department of Veterans' Affairs

1. Concerning the VA's open market drug and pharmaceutical purchases over the period of January 1, 2006 through December 31, 2011:
 - a. Please list the top 5 most purchased drugs in terms of volume, number of purchases, and dollar value.

Response:

Top 5 most purchased drugs in terms of volume (National Drug Code units):

- (1) Magnesium Citrate Liquid, Oral
- (2) Dextromethorphan 10mg/Guaifenesin 100mg/5ml Syrup
- (3) Lidocaine 5%Oint, Top
- (4) Oxycodone HCL 5mg Tab
- (5) OMEGA-3 (N-3) Polyunsaturated Fatty Acids 1gm Cap

Top 5 most purchased drugs in terms of number of purchases:

- (1) Magnesium Citrate Liquid, Oral
- (2) Lidocaine 5 percent Oint Top
- (3) Dextromethorphan 10mg/Guaifenesin 100mg/5ml Syrup
- (4) Bacitracin Zinc 500Unt/Polymyxin B S04 10000Unt/GM Oint,Top
- (5) Bacitracin 500Unt/gm Oint Top

Top 5 most purchased drugs in terms of dollar value:

- (1) Chondroitin NA 40mg/Hyaluronate NA 30mg/ml Inj,Oph.Syringe,0.5ml

- (2) Venlafaxine HCL 75mg Tab
- (3) Duovisc,Kit 0.5ML/0.55ML Inj,Oph
- (4) Nafcellin NA 2gm/VIL Inj
- (5) Nafcellin NA 10gm/VIL Inj

b. What policies and procedures were in place to flag or identify items frequently purchased and then to seek to place these items on contract?

Response: The majority of VA pharmaceutical expenditures (~95%) are for brand-ed pharmaceutical items that are under contract; either a Federal Supply Schedule Contract or a VA National Contract. While it is VA's desire to have the remaining, mostly generic, 5 percent of pharmaceutical expenditures made under contract, it is not always possible to do so.

The procedure VA uses to identify drugs that are frequently purchased but not under contract is simply to review the PPV purchasing data for items designated as non-contract. However, it is not uncommon for VA to review its purchasing data to identify a generic pharmaceutical item which is not available under contract, aggregate purchasing requirements and conduct a solicitation, but not receive any bids/offers. In these cases, VA's only alternative is to purchase these drugs via the streamlined acquisition procedures allowed by the Federal Acquisition Regulation or via a formal procurement request to a warranted contracting officer.

c. What percentage of overall open market purchases were made through the Prime Pharmaceutical Vendor (PPV)?

Response: For the period of November 8, 2011 through February 8, 2012, our data indicates that approximately 79 percent of VHA's open-market purchases in support of our pharmacy departments were purchased through the PPV vendor, but not through VA's PPV contract.

2. Since the November 8, 2011 memorandum prohibiting "improper purchase of all open market items through the PPV" how many open market purchases has VA made?

Response: From November 8, 2011 through February 8, 2012, there were approximately 73,000 open market line items purchased in support of Veterans' medication needs.

a. Of these purchases, how many have been made through the PPV?

Response: Of the approximately 73,000 open-market line items that were purchased from November 8, 2011 through February 8, 2012, approximately 57,760 (79 percent) were purchased *from* the VA's Pharmacy Prime Vendor, but not *under* the PPV contract.

b. Of these purchases, how many have required ratification after the purchase?

Response: Analysis of procurement data for the month of January 2012 is underway to determine what number of actions will require ratification. Data analysis has been completed for the period of November 8, 2011 through December 31, 2011, which resulted in 5,733 orders being ratified.

c. Of these purchases, how many have followed the waiver procedures found in VA Handbook 7408.1?

Response: None of the open-market purchases cited for the period of November 8, 2011 through December 31, 2011, followed the waiver procedures found in VA Handbook 7408.1. A waiver is not required for purchase of items that are not on contract.

d. Of these purchases, what has VA done to ensure that prices paid were reasonable and that all drugs and pharmaceuticals met all safety rules, regulations and laws?

Response: After November 8, 2011, all open market purchases at or above \$3,000 are being made by warranted contracting officers to ensure the prices paid were fair. For items less than \$3,000, VA uses streamlined acquisition procedures to ensure fair prices.

e. Of these purchases, how many of these purchases involved so-called "gray market" drugs or suppliers?

Response: As per McKesson's testimony at the February 1, 2012 hearing, McKesson assures VA that it does not purchase any drugs and pharmaceuticals from secondary or "gray" markets.

3. Your November 8, 2011 memorandum states that special procedures have been developed to quickly purchase open-market pharmaceuticals to reduce the lead times for these procurements (attached).

a. Please provide a copy of these “special procedures.”

Response: Please see Attachment VHA SOP 160-010-01, Attachment 13 for Pharm Procurements.

b. Do these “special procedures” deviate from the waiver procedures found in VA Handbook 7408.1? If so, please provide a detailed rationale for these deviations.

Response: No, the special procedures do not alter the requirements to obtain a waiver if the needed product is available on a Federal Supply Schedule (FSS) contract.

c. What safeguards are currently in effect to eliminate purchases made by non-warranted contract officers for amounts greater than \$3,000?

Response: A combination of training, data analysis, and progressive discipline is being used to address this issue. Procurements are being analyzed and letters of counseling issued to individuals that have made improper purchases. Currently letters have been issued for improper purchases made between November 8, 2011 and December 31, 2011. January data is currently being evaluated and appropriate action, where warranted.

Also, Pharmacy Ordering Officers have been directed that for all purchases above \$3,000, it must be directed to and made by a warranted contracting officer.

d. What safeguards are in effect to ensure that purchases made involving less than \$3,000 are made properly?

Response: Open-market purchases valued under \$3,000 fall under the Government Purchase Card Program. VHA’s Network Contracting Office Purchase Card Managers and Purchase Card coordinators are assuring that pharmacy staff have the required training and support to be purchase card holders. Purchases made through the purchase card program are subject to monthly, quarterly and random audits and reviews performed by oversight staff and finance office.

e. What policies and procedures are in place to ensure that fair prices are paid for open market purchases?

Response: After November 8, 2012, all open market purchases at or above \$3,000 are being made by warranted contracting officers to ensure the prices paid were fair in accordance with applicable laws and regulations. For items less than \$3,000, VA uses streamlined acquisition procedures to ensure fair prices in accordance with applicable laws and regulations.

4. The OIG’s testimony indicated that there are no controls in place to hold purchasers accountable who “override the system” when purchases were blocked by the PPV’s ordering system.

a. Please explain to the Committee, in detail, what it takes for a purchaser to override the system and who is the person who has that authority, both prior to, and after November 8, 2011?

Response: When a VA Pharmaceutical Prime Vendor ordering activity places an order for an item that is restricted or blocked, the Pharmaceutical Prime Vendor contractor-owned ordering system generates a message stating that the item is “restricted.” The ordering activity then can reorder the item and override the restriction or block by checking the “Do Not Substitute” button on the ordering system screen. No authorization is needed by ordering activities to override the system. The decision to order a restricted or blocked item is made at the VHA Field activity level and has been in effect prior to, and after November 8, 2011. What has changed since November 8, 2011, is that the Pharmaceutical Prime Vendor contractor was requested to, and has, separated open market items from the PPV contract items. The open market items were placed under a separate account making them no longer visible to VA Pharmaceutical Prime Vendor customers under their regular account or screen. Open market items are now only visible under a facility’s open market account and screen.

b. Is there a report that is required that would indicate how many times the override authority is used and why there is a need to override the system? If there is such as report, to whom is it forwarded and who receives copies?

Response: There is no such report that identifies “overrides.” However, there is a monthly “Do Not Sub Activity Report”, which details all the orders placed by facilities where the “Do Not Substitute” button was checked. The report is sent to VHA’s PBM Group located in Hines, Illinois, and to the National Acquisition Center’s Contracting Officer for review and analysis.

5. For 12 years the OIG has been reporting on the FSS and has issued no less than 49 reports that include concerns about open market purchases. That amounts to about 4 reports a year or one every 3 months.

a. How is it that this issue continues to grow seemingly unchecked with no effective controls or oversight in place?

Response: VA addressed these concerns at the time of each report, and each recommendation was addressed, corrective action identified with milestones, and eventually closed. In an effort to provide effective controls and oversight, VA developed a set of tools, over the last 3 years, which dramatically changed its ability to deal with these issues. These tools include a new management team; streamline authority; and the introduction of a new capability to deliver micro-purchases. VA has reduced the number of its Head of Contracting Activity (HCA) from 30 to six. VA also issued clear direction to the field to fortify its position regarding open market purchases.

6. In testimony VA claims to have avoided \$1.1 billion in acquisition costs due to changes in FY 2011 such as hiring 330 procurement professionals. Can you please point to other specific changes where VA can demonstrate cost avoidance?

Response: In FY 2011, VA pursued a variety of acquisition savings efforts across the Department, including improved market analysis, enhanced focus on competition, and pursuit of various strategic sourcing and other requirements consolidation initiatives. For example, the Department aggressively participated in the Federal Strategic Sourcing Initiatives (FSSI) program. In FY 2011, VA accounted for more than 44 percent of all usage related to the FSSI Domestic Delivery Services (DDS2) program. DDS2 savings in FY 2011 were \$149.6 million. Also in FY 2011, VA was a Federal leader in leveraging the FSSI Office Supplies Second Generation (FSSI OS2) program, resulting in \$11.8 million in office supply savings.

7. As of February 8, 2012, in terms of open market purchases, is the VA in violation of the Federal Acquisition Regulations (FAR) or the Veterans Affairs Acquisition Regulations (VAAR)?

Response: To the best of our knowledge, open market purchases are processed in accordance with the FAR, VAAR and acquisition policies.

a. In your view, do all purchases, including those made in amounts greater than \$3,000 require a warranted contract official?

Response: Yes. Only a warranted contracting officer may legally bind the government contractually in obligations above the micro-purchase level (>\$3,000). Ordering officers may be appointed by cognizant warranted contracting officers to place orders against existing contracts, but these ordering officers must be supervised by the contracting officer, who appointed them and limit their duties to placing orders against a specific contract.

8. With the admitted loss of control of the open market purchases, has there been any action taken to discipline and hold accountable the management who allowed this to happen?

Response: The failure to properly use and oversee the administration of the open market clause of the PPV contract represents a breakdown in our system of management and accountability. This was a common practice that dominated for 17 years. The situation evolved over time and the managers and leaders associated with that environment are no longer with the Department. As stated in testimony, VA has thought deeply about the issue of accountability and after extensive internal deliberations and analysis concluded that there is no one individual to hold accountable for the pervasive misuse of the open market clause.

We emphasize that this was a procedural breakdown, that it in no way compromised Veterans safety and affected not more than 4 percent of total pharmaceutical purchases. We have taken steps to eliminate this possibility now, and we are working to reduce the potential for other errors in the future by more closely managing orders under the VA’s PPV contract, while still ensuring our Veterans and their families receive the medications they need.

- a. What lessons has VA senior management learned from this failure and what steps has it taken to ensure that systemic problems and failures are identified at the earliest possible time and corrected in a speedy and timely fashion?

Response: In November 2011, VA implemented a process to make open market procurements in accordance with the FAR. VA will further improve the structure of the follow-on PPV contract to ensure upon full transition to the new contract that only medications available under Federal contract are viewable on the electronic catalogue from which ordering officers place their requirements. There will be no option for ordering officers to obtain non-contract supplies. However, there will be an option for ordering officers to purchase generic pharmaceuticals under the new VA PPV contract based upon a discount from the Wholesale Acquisition Cost (WAC) which has been competed among the offerors; thus making these generics now part of the PPV contract. The awarded PPV shall be required to provide FDA approved and Trade Agreement Act (TAA) products which are also WAC Based Priced Generics (WBPG); have National Drug Codes (NDC); and have a published WAC through the PPV contract. Order placement of WBPG through the PPV contract is optional and subject to periodic review by the Government.

9. In testimony you give an example of how a GS-5 pharmacy tech could choose the open market purchase and get the needed drug as opposed to going without.

- a. Please give a detailed response on the purchasing hierarchy involved in open market purchases at the VA Medical Center level. Please include titles and timelines at each level of authority.

Response: Open-market pharmaceutical procurements at the medical center level follow the following hierarchy—

- (1) Open-market procurements valued at \$3,000 or below are ordered by trained Government Purchase Card holders that work within the Pharmacy Department. This could be a GS-5 pharmacy tech or other departmental staff. Purchases valued less than \$3,000 are typically ordered the same day the requirement is identified.
 - (2) Open-market procurements valued above \$3,000 are procured by warranted contracting officers in the supporting Network Contracting Office. Using the expedited procedures identified in Attachment 13 of VHA SOP 160-010-01, awards are typically made within 5 to 7 business days if the value of the order is less than \$25,000. It does take longer for orders valued above \$25,000 due to the advertising requirements of FAR Part 5. However, the vast majority of orders are valued less than \$25,000.
10. Time and again the Government Accountability Office (GAO) and the VA OIG have reported lack of sufficient knowledge of policies and procedures by staff, confusion in the field and the need for more training.
- a. What are you doing to ensure that the proper staff is trained and that follow-up measures are taken to ensure that the staff remains trained if and when there is a procedural change to the acquisition and procurement process?

Response: In order to ensure that the proper staff is trained and that follow-up measures are taken to ensure that the staff remains trained, VA has taken several important steps. VA has identified a Contracting Officer Representative (COR) for each PPV ordering location. The CORs have a separation of duties, in that they are not the same individual that places orders against the PPV contract. The CORs were officially appointed in writing by the Administrative Contracting Officers (ACO) and completed Federal Acquisition Certification (FAC-COR) Level I training. The Office of Acquisition and Logistics (OAL) also has developed supplemental specialized COR training specific to the PPV contract. The PPV specific training will help ensure that the PPV CORs conduct their duties under the direction of the Procurement Contracting Officer (PCO) at the National Acquisition Center. ACOs were identified as prescribed under Federal Acquisition Regulations (FAR) Part 43.302 and in concert with policy. The ACOs will perform contract administration functions in support of the contracts under which the COR has been specified, will support program reviews, and provide ongoing status and performance reports to the PCO.

11. In testimony you state that senior management was first made aware of the open market purchase problem in 2011. VA developed a solution to correct the flaws in "our internal processes and conform to regulation." Please provide a specific timeline of:
 - a. Who was first aware of the deficiencies, how did they become aware and when did they notify the next management level?

- b. What specific actions were taken and when by each level of management?
- c. If there were delays in informing the next level of management, what was the reason for the delay?

Response: As stated in testimony, the first known recognition that open market purchases were not being executed appropriately was in January 2009. At that time, NAC officials worked with general counsel, acquisition review, IG and VHA to correct issues related to the CMOP. Recognition of more pervasive problems at the facility level was not collectively recognized by acquisition, general counsel and pharmacy management until March 2011. The goal at that time was to correct the open market deficiency in the next PPV contract while deliberations occurred to find an alternate mechanism to procure pharmaceutical products that comported with applicable laws and regulations. In September 2011, the issue was brought to the attention of VA's Chief of Staff and by November action was taken to stop all purchases that did not comply with applicable laws and regulations.

12. You indicated that VA had decided in December 2010 to take the "open market purchase" clause out of the next iteration of the PPV contract.

- a. What led to that decision?

Response: The National Acquisition Center National Contract Service Pharmaceuticals Chief discovered the open market clause was inconsistent with procurement regulations. The PPV workgroup (a workgroup comprised of VHA PBM, General Counsel, technical, other Federal Agencies, and contracting representatives) agreed to the exclusion of open market items in the new PPV solicitation.

The existence of the clause and recognition that it was inconsistent with procurement regulations was not an indication that open market purchases were not being executed in accordance with applicable laws and regulations. As stated in the previous response, recognition of more pervasive problems at the facility level was not collectively recognized by acquisition, general counsel and pharmacy management until March 2011. The goal at that time was to correct the open market deficiency in the next PPV contract while deliberations occurred to find an alternate mechanism to procure pharmaceutical products that comported with all applicable laws and regulations. In September 2011, the issue was brought to the attention of VA's Chief of Staff and by November action was taken to stop all purchases that did not comply with applicable laws and regulations.

- b. If the VA will no longer be making open market purchases through the PPV, how will the field be affected as far as obtaining a needed drug that is not on contract?

Response: The drugs VA previously purchased as open market through the Prime Vendor Fast Pay arrangement will now be part of the new ensuing VA PPV contract to ensure availability.

- c. What safeguards are currently in place, or will be put in place, to ensure that drugs and pharmaceuticals purchased through suppliers other than the PPV meet all safety requirements and are purchased at a fair price?

Response: All open market purchases at or above \$3,000 are being made by warranted contracting officers to ensure any item procured meets all safety requirements and that prices paid are fair. For items less than \$3,000, VA purchase card holders use the streamlined acquisition procedures and adhere to policy to determine a fair price.

13. Looking forward, what steps will VA take to ensure the open market drug and pharmaceutical purchases involve items for which there is a confirmed chain of custody between the manufacturer and supplier?

Response: In addition to drugs purchased through the PPV that are under contract, the follow-on PPV contract also includes items previously considered open market PPV items. Bringing all of these products under a single PPV contract umbrella will ensure there is a confirmed chain of custody or pedigree for all drugs purchased. As stated by VA's PPV in its testimony, it only purchases drugs either directly from the manufacturer or from the manufacturer's authorized distributor. In addition to this assurance, drug pedigree information is available to VA from McKesson whenever it is needed.

- a. What steps will VA take under the new PPV contract to ensure that suppliers from which open market items are purchased are not charging exorbitant prices for items in short supply?

Response: Under the new PPV contract, items previously considered open market are now considered contract items. All items purchased under the new contract will be made: (1) at prices VA negotiates with the manufacturer of the drug, minus the PPV discount, or (2) at the Wholesale Acquisition Cost or WAC, again, minus the PPV discount. Adherence to the terms and conditions of the contract, which will be monitored by the VA contracting officer will ensure that fair and reasonable prices are being charged.

- b. What steps will the VA take to govern its dealing with gray market suppliers?

Response: As per McKesson's testimony at the February 1, 2012 hearing, McKesson assures VA that it does not purchase any drugs and pharmaceuticals from secondary or "gray" markets."

14. Of the approximately \$1.2 billion in open market purchases:

- a. How many of the purchases were made by warranted contract officials?

Response: Of the approximately \$1.2 billion in open market purchases, it is not possible to determine which individuals made which purchases for the purpose of calculating how many of the purchases were made by warranted contracting officers. VA is aware that there was a potential for improper purchasing through VA's PPV; however, as explained in 14(b), VHA has evaluated improper open-market purchases made between November 8, 2011 and December 31, 2011 and processed the paperwork to ratify those actions. The same process will continue to be used going forward. VA will continue to closely monitor and oversee open-market purchases to ensure that improper purchases have ceased.

- b. What steps is VA taking to ratify the improper purchases, or those that were made without a warranted contract official approval?

Response: VHA has evaluated improper open-market purchases made between November 8, 2011 and December 31, 2011, and processed the paperwork to ratify those actions. January data is still being evaluated, but the same process will continue to be used. VA will continue to closely monitor and oversee open-market purchases to ensure that improper purchases have ceased.

15. Do you have copies of existing waiver requests under VA Handbook 7408.1 for the \$1.2 billion in open market purchases dating back to 2004?

- a. If you do not have the waiver requests, please explain why there are no waiver requests and when going forward, what enforcement measures are in place to ensure that appropriate employees are in compliance with VA Handbook 7408.1.

Response: A waiver request is only required when an item is not available under any existing VA Federal Supply Schedule, national contract or national blanket purchase agreement. Thus a waiver request was not warranted as the open market items procured were not covered by any of the above contracts. VHA Procurement and Logistics Office and VHA PBM will provide oversight and ensure compliance with the waiver process as outlined in VA Handbook 7408.1.

16. Please provide the Committee with the detailed steps, from initial prescription to purchase and delivery, needed to make open market purchases in compliance with your November 8, 2011 memorandum.

Response: Please see attached PPV Ordering Procedures, Ordering Process; PPV Ordering Procedures Memo; SOP 160-030-01.

17. In last year's budget submission, VA claimed \$355 million in savings in 2012 and 2013 due to "acquisition improvements." Please provide the Committee with an accounting of exactly where the \$355 million was saved and what improvements were made. Please include a timeline with this as well.

Response: In its FY 2012 budget submission, VHA identified \$1.2 billion in operational improvements, of which \$355 million was identified as savings resulting from acquisition improvements. To address concerns raised by OIG and GAO, VHA convened an interdisciplinary team late in the first quarter of FY 2012 to review and revise the VHA-specific acquisition savings initiatives. This team consisted of staff from VHA procurement and logistics at both the Central Office and field levels, as well as representatives from the Office of Management (OM), the Office of the VHA Chief Financial Officer (CFO), the VA Office of Acquisition and Logistics (OAL). Representatives from the Veterans Benefit Administration (VBA) were also

invited in an observational capacity to ensure that any best practices learned were shared among the administrations.

The team was chartered with the following objectives: (1) identify areas of opportunity for increased rigor and stricter criteria for defining cost savings (specific areas of focus included validation of savings calculation methodologies; documentation requirements; establishment of an ongoing audit process to ensure reporting is accurate; and additional savings initiatives not identified in previous program iterations. (2) Review external best practices and audit findings to inform the above issues and to identify additional areas of opportunity in VA acquisition savings practices.

In its recommendations, the interdisciplinary review team provided a list of new, retained, or revised initiatives from which VISNs and program offices can identify savings towards FY 2012 goals. These recommended initiatives, as well as the requested timeline, have been provided as a separate attachment.

