VENDORS IN THE OR—VA'S FAILED OVERSIGHT OF SURGICAL IMPLANTS

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BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

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Wednesday, January 15, 2014

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:02 a.m., in Room 334, Cannon House Office Building, Hon. Mike Coffman [chairman of the subcommittee] presiding.

Present: Representatives Coffman, Lamborn, Roe, Huelskamp, Benishek, Walorski, Kirkpatrick, and Kuster.

OPENING STATEMENT OF THE CHAIRMAN MIKE COFFMAN

Mr. COFFMAN. Good morning. This hearing will come to order. I want to welcome everyone to today's hearing titled, "Vendors in the OR—VA's Failed Oversight of Surgical Implants." This hearing examines serious problems with the tracking and handling of surgical implants within the VA and follows through on procurement issues revealed in a previous hearing by this subcommittee.

According to multiple sources VA medical centers have allowed surgical implant vendors to participate in hands on treatment administered to veterans. Based on my staff's initial findings I asked GAO to investigate these allegations regarding veteran healthcare and to determine what policies are currently in place. GAO substantiated that several veterans had received skin grafts that had been applied directly by skin graft vendors. GAO found that VHA requires each medical facility to develop its own policy on vendor access resulting in varying degrees of specificity regarding their participation in patient care.

These findings raise serious questions about the extent of vendor involvement in patient care at VA facilities and the lack of clear guidance regarding vendor access. VA's own consent form as well as industry best practices state that vendor representatives may be present to provide technical advice but may not physically participate in the procedure. However, GAO's investigation confirms that these policies are being unevenly applied or unenforced. Clearly, national guidance and oversight is necessary to protect veterans who undergo surgical implant procedures.

There are also significant problems with how VA handles and tracks surgical implants in veterans. Previous VA OIG audits criticized the VHA for weak internal controls that jeopardize VA's ability to identify and notify patients in the event of FDA product re-

call. According to GAO's report released on Monday these concerns remain and have not been remedied. For some clinical specialties, including gastroenterology, interventional radiology, and pulmonary, identifying information on implants was not tracked in any system. It is troubling to consider that for these specialties VHA was unable to verify that the items purchased were actually implanted in the patients for whom they were intended.

In 2008 VA began developing the Veterans Implant Tracking and Alert System, VITAS, to track and retrieve identifying information including the lot and serial number of surgical implants placed in patients VHA-wide. Unfortunately according to GAO this system's development was suspended at the end of the fiscal year 2012 due to data reliability challenges and as of December, 2013 development of VITAS has not resumed limiting VHA's ability to identify and locate patients who have received implants.

Additionally GAO's report shows that VA has failed to make sufficient progress with prosthetic procurement reform. In a May 30, 2012 hearing this subcommittee revealed that VA medical centers and VHA regional network contract officers misused waiving authority to spend nearly $3 billion on open market purchases of prosthetics, including surgical implants, rather than procure them through competitive contracts including those with businesses on the federal supply schedule. As a result of the hearing VA acknowledged that there are often several options available for implants and that disadvantaged veteran owned small businesses and others offering these products were being unfairly excluded from consideration. VA indicated that it would implement reforms so that noncompetitive and sole source purchases would require justification on a case by case basis.

GAO's report does contain some good news. VA has made some progress with obtaining national committed use contracts for nonbiological implants, such as artificial joints, cardiac pacemakers, heart valves, and coronary stints. Use of these national committed use contracts is the most favored method of procurement for implants under the Federal Acquisition Regulations. However GAO also reported that no such contracts have been negotiated for biological implants, such as skin and bone grafts. Moreover contrary to a memorandum dated May 23, 2012 from Assistant Deputy Under Secretary Matkovsky GAO found biological implants were rarely ordered from the federal supply schedule at each VA medical center it visited. According to GAO overuse of the waiver process continues. It reported that none of the medical centers it visited procured surgical implants in compliance with waiver requirements for open market purchases.

Finally it is most disappointing to note that while VA and VHA now have procurement oversight components, GAO reported that they have failed to impose corrective actions for these deficiencies.

In conclusion, VA must continue to implement reforms so that medical centers procure surgical implants that meet patient needs while also ensuring best value. More importantly VA and VHA must pay much better attention to patient safety concerns regarding surgical implants. It is way past time for VA to develop national policies that set forth the parameters for vendor access to treatment facilities and that implement sufficient oversight con-

trols. Additionally proper tracking of surgical implants is a problem that has been unresolved for far too long and it must be remedied post haste.

[THE PREPARED STATEMENT OF CHAIRMAN MIKE COFFMAN APPEARS IN THE APPENDIX]

With that, I now recognize Ranking Member Kirkpatrick for her opening statement.

OPENING STATEMENT OF HON. ANN KIRKPATRICK, RANKING MINORITY MEMBER

Mrs. KIRKPATRICK. Thank you, Mr. Chairman. I really appreciate having this hearing on the purchase and use of surgical implants. As we know, it is common for the vendors of medical devices to be in the operating room during surgery. But it is very uncommon for them to scrub and to touch a patient. So I am really interested in the testimony today and in whether or not we need to actually, you know, beef up our policies on this.

On Monday the Government Accountability Office released a reported entitled, "VA Surgical Implants—Purchase Requirements were not Always Followed at Selected Medical Centers and Oversight Needs to be Improved." So that is what we are concerned about today. The GAO looked at four VA medical centers and found that these hospitals did not always follow VHA policy regarding documenting open market purchases of surgical implants, including obtaining the necessary waivers to purchase items not covered by a VA negotiated contract. Last year VA instituted a new policy regarding purchases above the Federal Acquisition Regulations, FAR, micro purchase threshold of $3,000 and below the simplified acquisition threshold of $150,000. Medical facility and regional office officials attributed noncompliance mainly to insufficient VHA guidance and VA staff's inexperience in completing the new requirements.

This is a familiar litany to members serving on this subcommittee. It has been noted before that it does not matter how good and thorough the policy and standards are if no one follows them and there are seemingly no consequences for noncompliance. This is what I would like to explore today, in addition to looking at the specific allegations and looking at ways to improve the process.

Surgical implants and the larger issue of medical procurement provides us with the classic balancing act of patient and provider choice on one hand, and efficiency and savings on the other. These are not in my view mutually exclusive concepts. But also there are ultimately very few easy answers. Should there be a greater level of centralization on procurement? Or should we provide greater local autonomy while ensuring that the policies are followed? Indeed, how do we ensure that VA employees are provided the tools to do their job and help our veterans, but are also held accountable if they do not comply with established policies?

On the issue of surgical implants, what policies and structures are in place to ensure that VA staff is kept fully up to date on advances in the field of surgical implants and the availability of different options? While also ensuring that VA's contracting efforts

are directed toward items that are clinically advantageous and necessary for patient care.

Our decisions regarding which items to include in a VA negotiated committed use contract made from the top down or the bottom up? And more importantly, are these decisions made rigorously and systematically? How effective is the recently instituted program executive office and does this effort have the staffing level and financial resources to make a difference and improve the process?

GAO reported that VHA spent approximately $563 million on surgical implants in fiscal year 2012. That is an increase of 28 percent over the 2008 levels. I would like to hear from our witnesses today regarding the factors that led to this increase. It is not clear to me whether the increase is primarily due to the practice of open market purchases or to an increase in either the costs of surgical implants or an increase in their use.

Patient care and safety is our number one concern. That is why I am concerned over allegations that surgical implant vendor representatives participated in direct patient care. I want to ensure that the VA policies are fully followed in this regard while also recognizing that at times vendor representatives can have an important role in providing technical assistance and education to VA care providers.

So let us begin the conversation on how best to fix the problems before us today and work to improve the VA healthcare system and the healthcare it provides to our veterans. Spending taxpayer dollars wisely is essential but providing the healthcare that veterans have earned and deserve is critical. I look forward to hearing from our witnesses today and I yield back. Thank you, Mr. Chairman.

[THE PREPARED STATEMENT OF HON. ANN KIRKPATRICK APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick. I ask that all members waive their opening remarks as per this committee's custom. With that I invite the first panel who are now at the witness table. On this panel we will hear from Mr. Randall Williamson, Director of the healthcare team at the Government Accountability Office. He will be accompanied by Mr. Wayne McElrath, Director of GAO's Forensic Audit and Investigative Services Team. We will also hear from Mr. Roscoe Butler, Assistant Director for Healthcare with the National Veterans Affairs and Rehabilitation Commission at the American Legion. Your complete written statements will be made part of the hearing record. Mr. Williamson, you are now recognized for five minutes.

STATEMENTS OF MR. RANDALL WILLIAMSON, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE; ACCOMPANIED BY MR. WAYNE MCELRATH, DIRECTOR, FORENSIC AUDIT AND INVESTIGATIVE SERVICES, GOVERNMENT ACCOUNTABILITY OFFICE; AND MR. ROSCOE BUTLER, ASSISTANT DIRECTOR FOR HEALTH CARE, NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION, THE AMERICAN LEGION

STATEMENT OF RANDALL WILLIAMSON

Mr. WILLIAMSON. Thank you. Good morning Mr. Chairman, Ranking Member Kirkpatrick, and members of the subcommittee. I am pleased to be here today to discuss GAO's recent report on VA's purchasing of surgical implants. Surgical implants include biological implants, such as skin and bone grafts, and non-biological implants, such as cardiac pacemakers and artificial joints. Today I will address three areas of our work. First, VA's compliance with federal purchasing requirements and its oversight of surgical implant purchasing; second, VA's ability to identify veterans who have had surgical implants that are recalled by the manufacturer or the Food and Drug Administration; and third, allegations that surgical implant vendor representatives participated in direct patient care at VAMCs.

With me today is Wayne McElrath, who directed our investigative work on vendor participation in surgical procedures at three VAMCs.

Regarding VA's compliance with purchasing requirements, we found through our work at selected VAMCs that VA's surgical implant purchase requirements were not always followed. For example, when surgical implants are purchased on the open market and not through established VA and government negotiated contracts where prices have been specifically established, VAMCs are required to file a waiver justifying why the item is being purchased on the open market. We found that in many cases such waivers were not being obtained or had incomplete documentation. We also found that in justifying open market purchases of surgical implants over $3,000, VAMCs are not always preparing a written determination that prices are fair and reasonable and/or citing an appropriate rationale for sole source award. We found that oversight over surgical implant purchases was not robust and allowed these conditions to persist at VAMCs.

Turning now to VA's ability to identify veterans who have received recalled surgical implants, we found that VA is limited in its ability to systematically identify and locate all patients who receive surgical implants, which could be a critical factor if an implant is recalled by the manufacturer or the FDA because of safety concerns. For example, VA through its own studies has found instances at numerous VAMCs where data on lot and serial numbers for surgical implants were not entered into VA's computerized system for tracking such purchases. This limits the VAMC's ability to match veterans to implants that they received. Absent the ability to accurately track implants to veterans receiving them, VA may be putting some veterans at risk in the event that surgical implants are recalled.

In 2008 VA began developing a new tracking system to remedy this problem. But VA's efforts to develop such a system are currently stalled due to technical challenges and a lack of funding.

Finally, our investigations of allegations received by the subcommittee disclosed that in some instances a vendor representative supplying surgical implants to one of the three VAMCs we investigated was participating in direct patient care at that facility. Specifically, at least as recently as August 2013, a vendor was assisting VA clinicians in applying skin grafts or was himself applying skin grafts to several veterans. Without proper precautions, allowing a vendor representative to participate in direct patient care could compromise veteran safety.

While VA allows vendors to provide technical assistance and advice during procedures involving surgical implants, national VA policies do not adequately define the degree that vendors are allowed to participate in patient care. Rather, VA relies on VAMCs themselves to develop their own procedures in this regard. Absent definitive national guidelines VAMCs acting alone may develop different and inconsistent guidelines and controls over vendors, which is exactly what we found at the three locations we investigated. For example, two VAMCs required background screening for vendors accessing the facilities, while the third VAMC did not. Also, at one VAMC, written procedures covering vendor access and involvement in clinical procedures expressly prohibits vendors from physically performing any part of a clinical procedure, whereas written procedures for the other two hospitals are silent in this regard. Also we found instances where some VAMCs were not following their own written procedures.

While the results of our findings cannot be generalized to VA as a whole, they raise serious questions about the extent that consistent procedures and controls exist with respect to both vendor access to VA facilities and vendor involvement in patient care at facilities nationwide. This concludes my opening remarks.

[THE PREPARED STATEMENT OF RANDALL WILLIAMSON APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you, Mr. Williamson. Mr. Butler, you are now recognized for five minutes.

STATEMENT OF ROSCOE BUTLER

Mr. BUTLER. Chairman Coffman, Ranking Member Kirkpatrick, and members of the subcommittee, on behalf of our National Commander Dan Dellinger and the 2.4 million members of The American Legion, I want to thank you for inviting our organization here today to this hearing to address our concerns with aspects of how VA implements their prosthetic and implant medicine program.

As a member of The American Legion's System Worth Saving Task Force, I have been privileged to travel to many VA healthcare facilities and see firsthand how programs really work in the field. In both my experience working for VA for many years and in my travel on behalf of The American Legion, I have seen that conditions in the field do not always match what the folks inside the Beltway think they are. There are several problems with VHA policies and implementation of implant medicine healthcare. Most of

these problems could be fixed with clear written direction from central office and better oversight and consequences to enforce compliance.

First, VA still has a problem tracking surgical implants that places veterans at risk. An OIG audit from two years ago identified that there are expired surgical devices on VA's supply shelves. Further, GAO report and testimony today indicated that VA has an inaccurate tracking capability in recording the serial numbers of the implant surgical devices. The grave concern of The American Legion is that in addition to having expired products on the shelves veterans potentially could be walking around today with expired surgical implants. The American Legion urges Congress to require VA to implement an automated tracking system that addresses vulnerabilities by, one, initially recording the serial number of a surgical implant device when procured and placed into VA's inventory; two, record the expiration date; and three, that a record tracking flag be put into place to alert VA staff when the product is near its expiration date.

As there remain limitations to VA's current supply inventory system and uncertainty surrounding the safety and well-being of veterans currently with implantable devices, The American Legion urges VA to verify that there are no veterans with expired surgical implants and accelerate its timeline for implementing a new prosthetic inventory system that includes these recommendations.

Secondly, The American Legion remains concerned that VA does not have an official policy on vendors in operating rooms. While having vendors in the OR to provide technical advice may be medically necessary, it needs to be made crystal clear that veterans have consented and received full disclosure that strictly adheres to a clear, delineated VA policy. VA has admitted that they do not have a specific policy but indicated the National Center for Ethics in Healthcare noted that the presence of vendors in the operating room is a common practice in U.S. healthcare. And when there are broadly accepted professional ethics standards pertaining to a particular practice VA does not particular reiterate those standards in VA policy. Rather it was buried in VA's consent form under the number 15, additional information, which states in part the representative may provide technical advice but not participate in the procedure. The foundation of VA policy should be based on and consistent with statutory and regulatory authorities.

Third, The American Legion has concern about VA making a regular practice of circumventing the supply schedule. The federal supply schedule exists for a reason and the vendors on the schedule have been carefully vetted. Many of them are important contracts with veterans and/or small disabled veteran-owned business owners. While The American Legion recognizes and applauds the need to go off schedule in rare circumstances for the medical interests of the patient, it is becoming increasingly disturbing that off schedule purchases seem to be more the norm than the exception.

Let us be clear: the medical health of the veteran is the single most important factor in any decision about healthcare in the system. System Worth Saving visits uncovered doctors who choose to go off schedule to order stints for heart surgery because they were uncomfortable with the durability of the stints on the schedule. In

that circumstance you would hope that the doctors err on the side of the patient's safety 100 percent of the time. That said, if doctors are consistently going off schedule then either the schedule needs to be reformed or the process reformed. No system that is raised on circumventing its own process can be considered in anyone's best interest.

Again, thank you for the invitation to speak today and keeping a close focus on ensuring veterans get the most out of their healthcare system. We would be happy to answer any questions you might have.

[THE PREPARED STATEMENT OF MR. ROSCOE BUTLER APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you for your testimony. Mr. McElrath, was GAO able to determine why vendor representatives were allowed to provide potentially inappropriate patient care at the VAMC where the allegations were substantiated?

Mr. MCELRATH. We were not able to identify one specific reason. But some of the rationales that were given were lack of staffing, the difficulty of placing grafts on patients without having some assistance, and also a lack of knowledge relative to the particular VAMC's policies and procedures.

Mr. COFFMAN. Mr. Williamson, based on your report please elaborate on the challenges in trying to identify veterans who may have received a recalled surgical implant?

Mr. WILLIAMSON. Well, currently VA has a prosthetic purchasing system, which is used to track surgical implants and match them with veterans. VA has done a study of that system and found that lot and serial numbers were oftentimes were not entered correctly, or not entered at all. And that really is a detraction in trying to match veterans with implants.

Also, clinical services within VA have their own systems. Oftentimes, VAMCs or clinical services themselves will design systems. They may use spreadsheets, perhaps, kept on a computer. The difficulty with those systems is they are not standardized, and that information is not shared among VAMCs. Have augmenting systems. VA is developing a new system called the Veteran Implant Tracking and Alert System, VITAS. And that system is designed to centralize tracking of implants.

The difficulty is it still relies on manual input, and the chance of human error is still there. VITAS will have the same kind of difficulty in the sense that it is inputted by people. A way to get around that is to have a bar coding system where you scan the bar code in, and it is put in automatically. And that would solve the problem. VITAS is not going that route right now.

Mr. COFFMAN. Okay.

Mr. WILLIAMSON. So those are the challenges.

Mr. COFFMAN. Thank you. Mr. Butler, did you find that VHA had clear and consistent policy set forth to ensure a proper and ethical procedure when vendors were present during surgery?

Mr. BUTLER. We asked VA if they could provide us a copy of their policy and their response was that they did not have a specific policy. However, the consent was included, the authorization was included in their consent form. So that, this concerns us that they

are using guidance from the National Office of Ethics but they themselves have not promulgated a standard policy that can be applied consistently across the board throughout VA, or VHA.

Mr. COFFMAN. Thank you. Ranking Member Kirkpatrick.

Mrs. KIRKPATRICK. Thank you, Mr. Chairman. Mr. Williamson, you probably do not know, but the committee knows, that I have over 20 years experience in a hospital and I am really interested in hearing from our physician members of the committee about this. But it is highly unusual for a rep to scrub in the OR. And in the instances that you mentioned, did the reps scrub?

Mr. MCELRATH. The instance that we identified was the application of biologics, or skin grafts. The interviews that we conducted did not mention the words specifically "scrubbing in." But the wound care nurse and the vendor representative actually performed the procedure.

Mrs. KIRKPATRICK. So the nurse actually, the clinician actually performed the procedure, not the rep?

Mr. MCELRATH. No. From the patient care record the wound care nurse indicated that the vendor actually applied the skin graft.

Mrs. KIRKPATRICK. Okay, that is very disturbing. Can you tell us what vendor that was?

Mr. MCELRATH. Out of respect for the investigative process and the fact that we may be making a referral to the VA Office of the Inspector General for further investigation, we would respectfully request that we provide that information to your committee staff after the hearing.

Mrs. KIRKPATRICK. Thank you, please do. You know, looking at the overall goal of cost saving and clinician choice, Mr. Williamson, again I would like to know how effective is the VHA's Program Executive Office? And do you have ideas for us about how to strengthen and utilize that office?

Mr. WILLIAMSON. We did not look at that specific thing in general. I know in the past the subcommittee was very concerned about the use of Section 81–23 and whether that is being overused. And that is certainly something we looked at in our examination of the purchases, during our review. We see that the use of 81–23 justification is going down. And used prudently 81–23 is a good avenue for a physician or a clinician to use to provide treatment, the best treatment that he or she sees fit for a veteran. But we noted when we looked at the justifications for sole source procurement that there is a much greater use of emergent and compelling need as the basis of sole source purchases as opposed to 81–23 saw a flip flop. The 81–23, box is not being checked anymore, but rather urgent and compelling need is.

Mrs. KIRKPATRICK. You know, and those of us who have experience in healthcare know that the medical device industry changes quickly. There are always new devices coming out. And did you look at the training that the clinicians have in terms of educating them on the best products, the best use? Did you look at all about adequacy of training?

Mr. WILLIAMSON. Are you talking about the clinicians or the vendors?

Mrs. KIRKPATRICK. The clinicians, yes.

Mr. WILLIAMSON. We did not. We have in the past done some fairly thorough studies of credentialing and privileging systems that both VA and DoD have. We did not look at that training during this review.

Mrs. KIRKPATRICK. Mr. Butler, did you look at that at all?

Mr. BUTLER. We did not.

Mrs. KIRKPATRICK. You did not. Okay. Mr. Chairman, I am going to yield back. I really want to hear from our physicians on the committee.

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick. Dr. Huelskamp.

Dr. HUELSKAMP. Thank you, Mr. Chairman. I am a doctor but not a physician, so there will be no confusion here. But I do have some questions, particular of the GAO and I apologize for my voice this morning. You made some mention to the issue of urgency and perhaps timeliness as far as the purchases on the open market versus those through the VA purchasing requirements? Did you compare cost or quality, or any other characteristics? I see you looked at a certain percentage of those. I did not know if you had compared the outcomes and the cost and such?

Mr. WILLIAMSON. Could you repeat the last part of the question again?

Dr. HUELSKAMP. You mentioned you compared a few purchases, about I believe six percent of a certain subset. Did you look at the cost? Was it more or less expensive? Did you look at the quality? Was there any timeliness? As far as comparing those purchases in those two environments?

Mr. WILLIAMSON. Yes, we did not look at whether they got the best price. What we did was rather to focus on the documentation and see whether that existed. And in many cases, it did not exist to our satisfaction.

Dr. HUELSKAMP. Okay. Yeah, and I did not see that in the report. That is why I wanted to ask. The follow-up question would be, what is the penalty for failing to comply with the VHA purchasing requirements?

Mr. WILLIAMSON. Well agencies are also governed by the Federal Acquisition Requirements. It is certainly something that can cause a reprimand within the agency.

Dr. HUELSKAMP. Any evidence that there was any reprimand or any penalties for failing to follow up?

Mr. WILLIAMSON. No. A lot of times when waivers are not obtained, when the documentation is not obtained, it was not followed up on by VA and there was no action plan by VA to correct those kind of weaknesses.

Dr. HUELSKAMP. Sure. Okay. The next question would be I see you are experience at working with the health systems in the Department of Defense as well. Could you give a broad comparison between VA and the DoD? Do they have these similar problems, and are you familiar with that enough to answer?

Mr. WILLIAMSON. We have not looked at similar issues like surgical implants in DoD, if that is what you are talking about. No, we have not. We did look at how some large healthcare systems like Kaiser in the private sector surgical are purchasing implants

under their contracts. And they are much more aggressive than VA in trying to get items under contract.

Dr. HUELSKAMP. Mm-hmm. But you did not look at the cost comparison there?

Mr. WILLIAMSON. No.

Dr. HUELSKAMP. Okay. The last question will be for Mr. Butler, and I am very concerned about the patient privacy and the instances that were repeated here, and it is occurring. But what are your suggestions? What should be able to be authorized by a patient? If I understood correctly, you believe the language that was used probably authorized the vendor to be in the care situation. Is that your understanding of what——

Mr. BUTLER. No, it does not authorize, the language in their consent form does not authorize the vendor to provide hands-on care. It authorizes the vendor to provide technical advice. But that is a contract between the vendor and the patient, it is not a national policy. So we advocate that the VA establish a national policy that articulates all of the requirements for allowing vendors in the OR. And then use the consent form as the agreement between the vendor and the patient. We believe that if they have a national policy, as I stated, the foundation of VA is predicated upon the statute, the regulations, and the policy that VA adopts. And without a policy there is no requirement that facilities operate in a consistent manner or fashion.

Dr. HUELSKAMP. Well thank you, Mr. Butler. I agree as well. And I yield back my time, Mr. Chairman.

Mr. COFFMAN. Dr. Benishek.

Dr. BENISHEK. Thank you, Mr. Chairman. I am a general surgeon and I have been in the operating room, you know, lots of times. I have never actually seen a vendor, you know, do a case. So Mr. McElrath, can you, was this a couple instances of some vendor putting on a skin graft? Is that what you are saying? Is there any other episodes that you encountered that the vendor was involved with a case? Or is it a couple——

Mr. MCELRATH. We found two cases where vendors were actually involved but there were several instances over a period of time. By speaking to clinicians that we interviewed during the course of this investigation, we were able to identify those records. If the clinicians had not input that information directly into that patient record, all we would have is witness testimonies. It made it easier for us to corroborate their statements because they actually entered into the patient record who placed the skin graft.

Dr. BENISHEK. Well, you know, it is frankly shocking to me that this actually happened. You know, I am a little concerned about, you know, standards that come from Washington to every VA because all that stuff gets messed with. But it seems to me that each hospital should have rules, like the Joint Commission on Hospital Accreditation would not go for this. I mean, this would not fulfill the accreditation needs of any hospital that I know of. And, you know, I think that rule should be developed at the hospital. They should be, you know, reasonable rules. And I cannot believe that a, you know, something must have been wrong. I mean, Mr. Williamson, you said that some of the hospitals had no rules about——

Mr. WILLIAMSON. The three we looked at had written procedures, but those procedures were inconsistent and they left out some of the things that——

Dr. BENISHEK. Well in my experience, you know, which is in the private sector mostly, but I have had some experience in the VA system as well, you know, each hospital is required to have a set of rules and procedures, you know, to be accredited by the Joint Commission.

Mr. WILLIAMSON. Right.

Dr. BENISHEK. You know, which, you know, sets a standard for not only the VA but for, you know, private sector hospitals which I hope that the VA would be in the same boat. And the VA that I worked at, you know, we were inspected. And this type of stuff I think would fall out of an inspection, you know, immediately if they were aware of it. What can we do? I guess really the problem to me is accountability. I mean, nobody at the, you know, the problem I come up with again and again in this committee is that when errors like this are found, nobody seems responsible. There is not one individual that you could point to and say this is your responsibility and you need to be reprimanded or change your ways, put it in your performance review. Has any of that occurred in any of these circumstances that you know of?

Mr. WILLIAMSON. You are talking about the vendor?

Dr. BENISHEK. Well, no. I am talking about the hospital people that allowed this to happen. I mean, you know, you never get to a person whose responsibility it was, then they could identify, you know, report this place in their performance review saying that, you know, they did not comply with the rules of the hospital.

Mr. WILLIAMSON. Mm-hmm.

Dr. BENISHEK. And, you know, you may be subject to termination, you may be subject to disciplinary action. The accountability of the administration of the hospital or, you know, the upper echelon is always of importance to me. Because it seems to never happen where one person gets identified as being a problem. And you know, a culture of lackadaisical performance seems to be allowed a lot of the time within the VA. So as far as you know, has anybody been disciplined or had a report placed in their——

Mr. WILLIAMSON. No.

Dr. BENISHEK. Well we will ask the VA, too. But I just was hoping that maybe you guys could. Let me also ask about this vendor, or the purchase of materials. You know, as a surgeon I want to work with the materials and the devices that I am familiar with.

Mr. WILLIAMSON. Right.

Dr. BENISHEK. Okay? So sometimes I would be upset that the VA, you know, really want to use this thing which I never used——

Mr. WILLIAMSON. Mm-hmm.

Dr. BENISHEK.—and I am not comfortable with it. So I want to have the implant or, you know, the device that I am comfortable with and used to using. And I think that many surgeons have that same, you know, preference.

Mr. WILLIAMSON. You are correct.

Dr. BENISHEK. But there is no reason why when you come to the hospital and set up you can tell them all of what you are going to use.

Mr. WILLIAMSON. Mm-hmm.

Dr. BENISHEK. And they should be able to set up a plan to purchase that, you know, in a price advantageous. And I think that is a problem. And I think that is a problem related to how this is working here. Because the surgeon comes in, the VA will not put it on their formulary for whatever reason, and the guy says, "Well I am not doing the case unless I get the stuff that I am familiar with." So is there any evidence of that happening?

Mr. WILLIAMSON. Well when we went to four different VA hospitals across the country to look at this we interviewed 28 clinicians, and we asked them that very question. Why do you choose surgical implants from the open market in many cases when these are on contract? And it comes down to, number one, the best interest of the patient. In other words, veterans sometimes have unique needs and they have implants that best suit their treatment needs. The other reason is like you say, "what are you comfortable in using?" "What have you been trained on in terms of the surgical implants?" Also, other reasons include the literature searches that they might have access to in terms of the effectiveness of implants and contacts with surgical implant vendors.

Dr. BENISHEK. Well that does not preclude the ability of the VA to enter into contracts with people that provide a myriad of different devices. I mean, there are lots of VAs across the country. You know, there may be ten different devices and, you know, a hundred different surgeons may use each one of those differently.

Mr. WILLIAMSON. Right.

Dr. BENISHEK. So I do not see how that, that does not preclude the ability for the VA to contract with multiple providers for the same type of——

Mr. WILLIAMSON. Right.

Dr. BENISHEK [continuing]. Implant. And that does not seem to happening.

Mr. WILLIAMSON. The key is for VA to get more items under contract to get a good price.

Dr. BENISHEK. Right.

Mr. WILLIAMSON. And right now we only have nine types of items under national committee use contracts that VA has with vendors. And one of the things that we recommended was that VA take a more aggressive posture in——

Dr. BENISHEK. There are only nine?

Mr. WILLIAMSON. There are only nine, all non-biological implants.

Dr. BENISHEK. Out of the thousands of implants, different types of implants available?

Mr. WILLIAMSON. Yes. They are the highest——

Dr. BENISHEK. That is a shocking number——

Mr. WILLIAMSON [continuing]. High volume and high cost items.

Dr. BENISHEK [continuing]. Because that is a very small number of the different implants that it happens.

Mr. WILLIAMSON. Right.

Dr. BENISHEK. That is a major deficiency that I think you have identified here at a high level within the VA. Because there should be a thousand different implants on the VA formulary. You know——

Mr. WILLIAMSON. Now there are, in addition to the national committed use contracts, there are the federal supply schedule contracts. And there are a number of both biological and non-biological surgical implants on the FSS. So there are other lists to choose from. But the first choice would be the national committed use contracts because those give VA the best prices.

Dr. BENISHEK. My time is expired. Thank you.

Mr. COFFMAN. Congresswoman Walorski.

Mrs. WALORSKI. Thank you, Mr. Chairman. Mr. Williamson, I just, the information is just shocking. And every time we sit in these Oversight Committee hearings with these reports, which I very much appreciate, it is just shocking I think to the American taxpayers and to all of us who sit here who want to provide the absolute finest services to our best and brightest servicemen and women and to hear these kind of reports. And I guess, you know, one question I have is it just is shocking to me that there are national medical device tracking efforts already. Would it not behoove the VA to look at something that is already in place like the UDI if they obviously have not been able to successfully track implants?

Mr. WILLIAMSON. I do not think there is any, I do not think that it necessarily would provide the information VA needs on surgical implants. I think that the trouble is there is no centralized system right now. The prosthetics purchasing system has some weaknesses, as I reiterated in my opening remarks. And VA is trying to develop a centralized system in addition to a number of systems that the surgical services are using on their own. So there are two sets of books here.

Mrs. WALORSKI. Is there a bar code system set up——

Mr. WILLIAMSON. No.

Mrs. WALORSKI [continuing]. In the VA where those implants are just bar coded before they——

Mr. WILLIAMSON. Not to my knowledge, no. That would take away the human error and that would probably be the best system. A system based on bar coding would be a better system.

Mrs. WALORSKI. And what about the FDA's UDI system? Or what about the American Joint Replacement Registry, AJRR? Or something as simple as just having some kind of a standardized policy of a scanner where it is literally just scanned into a system that tracks?

Mr. WILLIAMSON. Yes, that would be, something that could be considered. Again, it is a scanning system. It alleviates——

Mrs. WALORSKI. But what happens when, what happens when, you know, we see a recall of some specific device that has been implanted and it has affected X amount of people? How do they know if that is implanted in a veteran?

Mr. WILLIAMSON. Well, you have got to rely on your systems that you have already in place and identify through serial numbers, lot numbers, medical records, other kinds of things——

Mrs. WALORSKI. But when human error puts a wrong code or wrong——

Mr. WILLIAMSON. I am not saying it is impossible because if there was a recall there are existing ways to trace it. Certainly going through the medical records. But that is a long, laborious

project. And it is also subject to human error. Would somebody detect it as they are going through all that?

Mrs. WALORSKI. Thank you, Mr. Chairman. I yield back my time.

Mr. COFFMAN. Thank you. Dr. Roe.

Dr. ROE. I thank the chairman for yielding and thank you for this testimony. Let me just, having been involved in a lot of devices and having an implantable device in my eye right now, and I actually can read your name, something I could not do before my device was implanted. I would like to go about how the procedure, how this actually works in the private sector. And Dr. Benishek alluded to it. Let us say a uterine ablation or any other new procedure that comes out, as a surgeon you have to go and be trained. There are standards in your hospital that require a certain number of hours of training before you can do that. And there may be some technical assistance in the operating room if you are operating a piece of machinery or whatever that you need a vendor there for.

Mr. WILLIAMSON. Mm-hmm.

Dr. ROE. I completely agree that the vendor has no place in actually doing the procedure. You as the surgeon are trained to do that procedure. And the technical advice are there are just things that come up that happen during the procedure. So I certainly understand the need for, and Ms. Kirkpatrick clearly pointed it out, these changes are happening at light speed.

Now I would be very uneasy if I knew that this device in my left eye could not be kept up with. If we did not know, that there was some reason it could not be tracked. Because as you know, and mostly in orthopaedic, that is where most of the implants are, that sometimes these fail. And if you find a behavior of failure throughout these you would like to be able to track down the patients and tell them that, hey, this device has some risk to you or could do this. Look out for these symptoms. As a physician I would want to be able to inform my patients that that happened.

So the way it worked in our hospital is when the new procedure came out you had to have a certain amount of training, be certified in that procedure, and then carry out that procedure a number of times. And then many times I would mentor other people, teach them how to do the procedure. And the old saying in years gone by, see one, do one, teach one, that has sort of gone by the wayside now.

You are absolutely right, a system, whether it is bar coding, that is the simplest thing in the world. I mean, Walmart can tell you how many bars of soap went out of Walmart in Tennessee. You ought to be able to keep up with a lens implant or a knee implant and find out who they are. That is fair, technology is there, it is not new. So I think those kinds of things are fairly simple. And I do not believe that we have a problem here that can be easily solved with the systems that are in place. And maybe it will require a new IT, I do not know, Mr. Williamson, whether it will or will not, or whether those current systems are available. But this is not new. I mean, we have been doing this for 25 years. And we are going to continue to do it. And especially as our population ages and more and more implantable procedures are done. I mean, how many people have you met now that cannot go through an airport because they set off a metal detector they have had so many de-

vices implanted in them? And we have to have a way to track those. Because not all of them are perfect, there is no question about it. And the reason it is important to be able to track those is because when you find out what those defects are it gives the manufacturer and the engineers a chance to improve those and make them better for future patients. So I mean, I think, Ms. Kirkpatrick, I have learned, I know your background, and I certainly believe what we have got here, and I agree with Dr. Benishek, I am not sure we need a national policy. But each hospital, that is fairly simple stuff. And I will yield to anyone who wants to respond. Mr. Butler, I read your testimony and agree with much of it. But again, this is not reinventing the wheel.

Mr. BUTLER. If I may?

Dr. ROE. Yes, sir?

Mr. BUTLER. With regard to your comment about the national policy, the local hospitals develop their local policies based upon the national guidance from the central office. So if they do not have national guidance from central office, their local policies may be inconsistent from one facility to the next. So there needs to be consistency across all the VA healthcare system. And that consistency comes from the national guidance provided by the program office out of DC.

Dr. ROE. I certainly, I cannot argue with that, some consistency. The other thing that I think we get into is surgeons. And I get this. You know, I like a certain type of suture. Is it vicryl? Is it chromic? Is it whatever? Do I like staples? Do I like this particular staple? I mean, those things change so fast and there needs to be some consistency because error rates go down when you have, there is no question, when you have a policy and a procedure that you go through just like taking an airplane off. We learned that in our operating room, that the more consistent that you could do it and the more frequently you did it the same way, the less errors there were. But there ought to be some latitude because not everybody falls under the bell-shaped curve, as Dr. Benishek clearly pointed out. And what you are familiar and used well and had good success with. So procuring that, and I understand if you have got ten surgeons the procurement officer in a VA cannot procure ten different types of suture for that when it really does not make any difference on the long term outcomes and the data will prove that. And this should be data driven and not just cost driven. And I think unfortunately what happens a lot of times these things are cost driven and not data driven.

I would yield back my time.

Mr. COFFMAN. Thank you, Dr. Roe. Mr. Lamborn from Colorado.

Mr. LAMBORN. Thank you, Mr. Chairman. And I want to thank you for having this important hearing and for your work on this issue. So I appreciate that.

Mr. Williamson, your report noted that the fair and reasonable price determination was not completed for a number of open market purchases that you reviewed and not properly documented in other cases. Does this mean that the VHA was overpaying for surgical implant purchases from the open market?

Mr. WILLIAMSON. Not necessarily. We did not look at, the cost itself. Rather we just looked at the documentation that existed to

support that. But it does certainly make it more likely that the fair and reasonable price was not obtained. Even when we looked and examined documentation when there was an explanation, sometimes the explanation was not too good. For example the language might say that it was based on prior prices. And yet the prior prices were not delineated. So, it is just a statement and nothing more. Another case we found for example, was a case of a bone graft that was supposed to cost $6,000 and the fair and reasonable price determination was based on a price range of other bone grafts that ranged from $3,000 to $20,000. And, on the basis of that range, the VA staff person determined that the $6,000 bone graft was fair and reasonable. That is probably not the precision that you would want in determining the reasonableness of that $6,000 bone graft. So even when the documentation was there, it was not very good in many cases.

Mr. LAMBORN. Okay, thank you. And Mr. Butler, I have a question for you. In your testimony you indicated that the American Legion is utilizing a System Worth Saving Task Force. Can you please elaborate on the task force and what it found regarding implant tracking?

Mr. BUTLER. Well in 2003 our Past National Commander Ron Connelly, when he was the Commander, went out and visited over 60 VA healthcare facilities looking at the quality of care and access within the VA healthcare system. As a result of that at our national convention a resolution was adopted that the System Worth Saving Task Force continue those site visits. So every year the American Legion System Worth Saving Task Force identifies a theme. This year our theme is a ten-year look back at the VA healthcare where we are visiting 15 VA healthcare facilities and we are looking at the access, the quality of care that is provided to America's veterans.

So with regard to your question about what findings we found as it relates to implants, we have not really focused, that has not been the focus of our attention. But we are beginning to, since this was a part of the hearing, as we go out on our site visits we are beginning to ask those questions in terms of procurement and so forth to see what systems and what concerns veterans have. When we go out to a site visit we have a town hall meeting with veterans and we bring those veterans in so that they can tell us what are the concerns and the issues they have. So we are asking veterans what concerns, issues they might have so that we can when we meet with the medical centers we can address those intelligently to find what, to get their response to those issues. So as we are continuing our site visits we are beginning to focus on those questions.

Mr. LAMBORN. Okay. I appreciate your work and the American Legion's work on that. And Mr. Williamson, I have a follow up question. Does "open market" mean the possibility that items are not Trade Agreement Act compliant?

Mr. WILLIAMSON. Not necessarily. No, I do not think so on that one. If I understand your question right.

Mr. LAMBORN. Yeah, what I am trying to get at is there potential that there are gray market products that the VA is using?

Mr. WILLIAMSON. There is always that potential, although we did not, notice that when we did our work.

Mr. LAMBORN. Okay. I appreciate that. Mr. Chairman, I yield back.

Mr. COFFMAN. Thank you, Mr. Lamborn. Mr. Williamson, what are the implications of low compliance with waiver requirements for purchasing surgical implants from the open market?

Mr. WILLIAMS. Two things come to mind here. One is an accountability factor. The waiver requirements are there for a reason, to make sure that people go through a thoughtful process, that clinicians go through a thoughtful process when they choose open market items. And that is one factor. The other factor is that the information that VA can glean from a waiver, has a connection to national contracts, establishing more national contracts. For example, VA gets information on high volume, high use items, through the waiver process, that are being purchased on the open market. VA can use that data to identify items that they should pursue under a national contract. So that is a very important part of having good solid waiver information.

Mr. COFFMAN. Okay. And Mr. Williamson, your report identified shortcomings in VA and VHA oversight of surgical implant purchasing. How do you think that oversight could be improved?

Mr. WILLIAMSON. Well, one of the things that both VA and VHA have done is to perform separate studies looking at surgical implant purchasing they came up with basically a number of the same findings that we did. The difficulty was that when they identified areas of noncompliance and talked to VAMCs about them it was more in an advisory capacity, a disclosure category, as opposed to doing something about it. And one would expect, and what we expect when we recommend something to somebody, is that they come back with an action plan or something of that nature to make sure it happens.

Mr. COFFMAN. And Mr. Williamson, you know, finally your report discussed low compliance with waiver requirements for purchasing surgical implants from the open market. Why were facilities not fully compliant?

Mr. WILLIAMSON. There were a couple of reasons. As you know, VA is implementing a new system for surgical implants and purchases over $3,000. Over the last year or so it has been a major effort with VAMCs across the country. People that we asked in the VAMCs about why they did you not prepare waivers or why are these not on file told us that the higher priority was to get this new system in place. And that was one of the reasons. Also as other members have alluded, to physicians who practice in VA facilities often have outside practices. They may be working at VA part-time. And so they are not always as familiar with the waiver rules. And those are basically the two reasons that we heard when we asked that question.

Mr. COFFMAN. Thank you, Mr. Williamson. Ranking Member Kirkpatrick.

Mrs. KIRKPATRICK. Thank you, Mr. Chairman. Dr. Roe, I agree with you that we should try to solve this problem within the existing policies that we have. However, Mr. Chairman and the committee, if it is the consensus of the committee that we need a new

policy I think we need to be very careful that we protect that local control. Because doctors, as you stated and Dr. Benishek as well, we want our physicians to have the tools that they are comfortable with because ultimately our goal is the best patient care possible for our veterans. So I think we have to be careful and keep that in mind and give our physicians, men and women, the best tools that are available so that they can deliver the best patient care.

That said I would like the panel's thought about this idea. When a vendor's rep crosses the line and actually touches a patient in the OR, would it not be more effective just to terminate the contract with the vendor? Terminate the contract?

Mr. WILLIAMSON. That is certainly a possibility. And again, if you really want to enforce the idea that vendors, have no hands on treatment ability in VA hospitals, there have got to be some fairly stringent requirements and penalties in place. I can probably think of a number of things in terms of improving the whole access process for vendors in VAMCs. It starts with getting them to sign in at the police office when they arrive. We found, for example, that at one facility we looked at the log in the police office that vendors were supposed to complete in had not had an entry since 2011. And we knew that vendors had been in there many times. So there are a number of things in the whole access process that need to be addressed, it is not just in the operating room or during procedures it is the whole access that needs to be changed.

Mrs. KIRKPATRICK. And maybe the procurement process, making sure that those contracts have some clause in there that if a rep actually touches the patient their contract is terminated. Mr. Butler, do you have any opinion on that?

Mr. BUTLER. Well, you know, there may be provisions already in the contract that covers that. They have to look back at the contracts and see specifically what the contract states. And I would agree that if there are not any particular provisions that allow that, that there needs to be something. Because that is a violation of what the veteran consented. The veteran, based upon the current consent form the veteran did not consent for the vendor to participate in the surgery. So clearly that is a violation of the agreement between the veteran and the clinician.

Mrs. KIRKPATRICK. Right. You know, and my interest is not, you know, again, it is making sure we have got the best patient care possible for our veterans. But let us do not make the physician's job more difficult. You know, let us look at the vendor who actually violated that consent form.

Back to the bar code and the tracking, Mr. Williamson, does not the VA track medication by bar code already? I mean, is there not a system——

Mr. WILLIAMSON. I believe so, but I am not sure of that.

Mrs. KIRKPATRICK. Okay. Again, I think we should look at what is working within the VA system. I am pretty sure they track medications. I do not know why they cannot track medical devices. Thank you, Mr. Chairman.

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick. Dr. Benishek.

Dr. BENISHEK. Thank you, Mr. Chairman. I did not really touch upon the other issue that we are talking about and that is the

tracking. Some of the other members did. But frankly I just cannot believe that that does not happen either. I mean, like Dr. Roe mentioned it has been going on in the private sector for 25 years. And you know, you know, constantly with every device that I know of comes with a sticker with a bar code on it. And you put it in the chart, you know, so that it is thoroughly documented, you know, what device is in which patient. And I just cannot believe that this goes on. And it brings me back to my same question I had, and that is the accountability of when these errors occur. What can we do better to identify, you know, the people who manage this system and to make them accountable for these errors? Do any of you have an idea about that?

Mr. WILLIAMSON. Well, keep in mind that people, are looking at a surgical implant package and there are numbers all over the package. Given that, there can be a very innocent transposition of numbers. It is not something intentional, it may not be done a lot, but it does happen and there are enough cases happening that it leads one to have concern if a recall occurs.

Dr. BENISHEK. Oh, I understand that errors can occur, you know, among the OR scrub nurse, or the circulating nurse. But, you know, that is uncommon. I mean, and I think, you know, a procedure like with a sticker where there is not going to be a transposition of numbers because you are going to be placing the sticker that came with the device in the patient's chart——

Mr. WILLIAMSON. Right.

Dr. BENISHEK [continuing]. And in some kind of a hospital tracking system and scanned into the computer, that happens all the time. But making sure that that system is in place is somebody's job. And that is what concerns me about, you know, the VA in general, that nobody seems to be accountable for things like this when we bring them up in these committees. I mean, we have issues like this that come up with in the VA all the time and we never get down to, you know, whose job it was to do that? And, you know, are they being, getting the right oversight?

Mr. WILLIAMSON. That is probably a good question for VA. I would think that the IT people should be all over that. But again, I think that is a question that you should address to VA.

Dr. BENISHEK. Well I am going to let Dr. Roe talk as well. Thank you.

Mr. COFFMAN. Thank you, Dr. Benishek. Ms. Walorski. Dr. Roe.

Dr. ROE. I guess the question that I have now is we have identified the problem. It is pretty simple, really. And the question is what recommendations would you all have? And I agree with Ranking Member Kirkpatrick. You want to make sure that the job I have when I go in the operating room is as easy as possible. I think some of the, Dr. Benishek, who is a general surgeon, touching this about who is accountable is that he knows who is accountable when they put the knife in his hand, it is him.

Mr. WILLIAMSON. Right.

Dr. ROE. And he does not have to look anyplace but the mirror. And with the VA system we continually try to find out well whose job was it that was to prevent this? I think that is a little bit of your frustration as I, and mine also. But I guess very simply what recommendation would you all have for us? This is a fairly simple

problem to solve. And we do need these folks. And Ms. Kirkpatrick may have hit on something. If you cannot go back in the OR, that is the death penalty. I mean, for a vendor that is the death penalty for them. And that company cannot do that. And you do need, when you get these new devices many of them are, procedures I mean, are highly technical. And until you have a real sense of familiarity with them, you know, everybody is going to do their first procedure at some point in time, whether it is, it may be some variation of what you have been doing. But when new techniques come out, you are going to learn those techniques, but somebody has got to be the first one. And you know, hopefully it goes well, and you need assistance with that. So we do not want to stop that certainly. But there is, I do not see any reason to ever have a vendor having any hands on with a patient. I just cannot conceive of a situation where you would need to do that. Can you, Dan?

Dr. BENISHEK. No.

Dr. ROE. Okay, I do not either. And so let me yield to you all. And give us two or three things that we need to do, and let us get this done.

Mr. WILLIAMSON. Well with regard to that, a national policy governing the hands on treatment of veterans I think, is important, as Mr. Butler has said, a national policy or national procedure as a template is needed for the VAMCs so they are not all going out and doing their own thing. And as I said in my opening remarks, we found variation and inconsistency in that regard. Now, you have heard throughout the questions and answers and in my opening remarks the word "accountability." And accountability for oversight and accountability for properly preparing a waiver and other requirements that go into purchasing. That word is important throughout any of the recommendations we make. There has got to establish accountability people to do what they are supposed to do. And it varies as far as where accountability lies. Sometimes it is the clinician, sometimes it is the procurement folks. In other cases, it is people in Washington, DC.

Dr. ROE. So the policies would be a reliable, repeatable tracking system for any implantable device.

Mr. WILLIAMSON. Mm-hmm.

Dr. ROE. Fairly simple technology now, should be able to take care of that easily. Number two, there should not be any vendor contact with, direct patient care, I should say. To advise you about how to use a particular piece of technical equipment, that is what they are there for. To turn this device this way, you have seen other surgeons do that. I certainly have used them very successfully in the operating room. But no direct patient contact. And then I think thirdly the procurement is a little different issue because it does get into, and I do see, like I said if you have got ten different surgeons, and we all think we are absolutely right every time. You know that. And that our way is the best way. And so I do understand some standardization. But I think at least those two things we could agree on today and implement those things and I think would solve most of these problems.

Mr. WILLIAMSON. That makes sense.

Dr. ROE. Okay. I yield back.

Mr. COFFMAN. Thank you, Dr. Roe. Mr. Lamborn of Colorado.

Mr. LAMBORN. Thank you. Just a quick comment, I have a plant in my district and I toured it recently and they do marvelous work creating these amazing implantable devices, everything from little pins and screws to large bone grafts, apparatuses, and things like that. And it is just amazing the amount of work and engineering and experience that goes into one of those. And I just think that they have been a wonderful partner in working with the VA and the medical field at large to improve the lives and the prognosis of patients who have all kinds of, and veterans who have all kinds of medical difficulties. So I just want to make sure that no one ends up blaming them or in case the VA has procedures that need to be improved. So let us not lose our focus. I mean, this is the VA that we need to have in front of us. And we are really making sure their procedures are up to speed and that the accountability with the VA is what it should be. So I just wanted to make that clarification. Mr. Chairman, I yield back.

Mr. COFFMAN. Thank you, Mr. Lamborn. And I want to thank the panel so much for your testimony. And let us see, you are now excused. I now invite the second panel to the witness table. Our second panel, we will hear from Mr. Philip Matkovsky, Assistant Deputy Under Secretary for Health for Administrative Operations at the Veterans Health Administration. He will be accompanied by Dr. Thomas Lynch, Assistant Deputy Under Secretary for Health Clinical Operations at the Veterans Health Administration. Your complete written testimony will be made part of the hearing record. Mr. Matkovsky, you are now recognized for five minutes.

STATEMENT OF MR. PHILIP MATKOVSKY, ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH FOR ADMINISTRATIVE OPERATIONS, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY DR. THOMAS LYNCH, ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH CLINICAL OPERATIONS, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF PHILIP MATKOVSKY

Mr. MATKOVSKY. Mr. Chairman, Ranking Member Kirkpatrick, and members of the committee, thank you for the opportunity to appear before you this morning to discuss the Department of Veterans Affairs' practices regarding the use, tracking, and procurement of surgical implants at VA medical centers. I am accompanied today by Dr. Thomas Lynch——

Mr. COFFMAN. Make sure that your microphone is on, could you do that? Is it on?

Mr. MATKOVSKY. I believe it is. Perhaps it is not functioning? Can you hear me now?

Mr. COFFMAN. The light is on now.

Mr. MATKOVSKY. All right. I am sorry about that.

Mr. COFFMAN. That is all right.

Mr. MATKOVSKY. I am accompanied today by Dr. Thomas Lynch, Assistant Deputy Under Secretary for Health for Clinical Operations. The Veterans Health Administration has made significant changes in the last three years to the way we procure surgical implants and prosthetic appliances for veterans. These changes are intended to improve procurement, performance, and accountability

while ensuring effective healthcare delivery for veterans. Beginning in fiscal year 2012 and concluding at the end of fiscal year 2013, we transitioned purchasing of surgical implants and prosthetic appliances valued at greater than $3,000 to warranted contracting officers in our procurement organization. VHA's procurement—sorry about that. Sorry about that again. VHA's procurement organization hired and provided specialized training to contracting staff to ensure procurements are properly executed consistent with both clinical requirements and federal and VA policies and regulations. We believe these changes strengthened our procurement performance.

Throughout the transition our main focus was ensuring orders were completed timely and in concert with clinicians' prescriptions. With the transition now complete we continue to monitor timeliness and accuracy and we are now auditing procurement quality and increasing our use of negotiated contracts for sourcing implants and prosthetic appliances. As a result of the transition our acquisitions above micro purchase limits are now recorded in ECMS, our contract managing system, and the federal procurement data system.

Our quality audits of these procurements have led to changes in procedures and ordering templates as well. Continuous QA reviews will begin in this fiscal quarter to provide detailed oversight of our ordering process. These reviews will focus on sourcing practices and will be used to improve our utilization of existing national contracts, improve training, and identify further opportunities to place biologics and implants on additional contracts. In fiscal year 2014 we will evaluate establishment of competed additional national contracts that will be directly informed by our clinical leadership to ensure we are emphasizing clinical quality, patient safety, and value.

VHA is currently updating and finalizing our policy for prosthetics procurement. Once promulgated this new directive will provide comprehensive and clear guidance to VA medical center staff on how to order prosthetics.

We are still reviewing the recently released GAO report on surgical implants. Prior to receiving the GAO report VA had initiated a number of reforms to acquisition. Any further opportunities identified by GAO to enhance our acquisition procedures will be considered in our ongoing process.

The presence of vendors in the operating room is a common practice in healthcare settings. There are broadly accepted professional standards pertaining to the presence of vendors in operating rooms from the American College of Surgeons and the American Medical Association. Physicians use professional judgment to determine when the presence of a vendor in the clinical setting improves the safety and effectiveness of patient care. Currently VA is working however to develop overarching policy regarding the role of vendors. VHA Handbook 1004.02, entitled Improved Consent for Clinical Treatments and Procedures, requires physicians obtain patient signature on a consent form before undertaking specific procedures such as surgery. This policy requires physicians to discuss the contents of this form with patients. The form also states that under certain circumstances the presence of a vendor is important to the

success of the procedure; that prior to the procedure the vendor will sign an agreement to strictly adhere to the privacy rules; that the vendor may provide technical advice but will not physically participate in the procedures; and that the vendor will be closely monitored by the VA treatment team.

VHA additionally has a comprehensive recall process that is triggered both by our own facilities as well as external notices such as the FDA. This process is overseen by our National Center for Patient Safety, which monitors all recall actions requiring product removal from inventory and coordination with patients. At the facility level all surgical implants are required to be tracked. Further for certain implantable devices such as pacemakers vendors are additionally required to ensure medical device tracking to the patient level so that individuals may be contacted in the event of a recall or a problem with the device they received.

When a recall is initiated VHA follows a step by step process that begins with removing affected products from our inventory and that further ensures all mandated actions are closed out to 100 percent complete. This process then moves to identifying process, notifying patients, monitoring patients, and in certain cases performing clinical follow up with patients. When recalls do occur we also work with vendors to ensure all VA patients involved have been identified.

Mr. Chairman, we appreciate your support and encouragement in identifying and addressing issues regarding the procurement of surgical implants at VA medical centers. My colleague Dr. Lynch and I are prepared to respond to any questions you may have.

[THE PREPARED STATEMENT OF PHILIP MATKOVSKY APPEARS IN THE APPENDIX]

Mr. COFFMAN. Thank you for your testimony. Dr. Lynch, was VHA aware of vendor representatives providing direct patient care at VAMCs?

Dr. LYNCH. We were not aware until the GAO report was issued.

Mr. COFFMAN. Okay. Mr. Matkovsky, what does VA see as an appropriate role for vendor representatives in the procedure area, be it in the OR, wound care clinic, or any other setting?

Mr. MATKOVSKY. We do not see it as providing direct patient treatment. I would indicate that in this one case, after we found out from the GAO report, we did refer this case to our Office of Inspector General ourselves. Consultation, support, particularly technical advice regarding new technical implants is permissible. But direct patient engagement is not.

Mr. COFFMAN. Mr. Matkovsky, what percent of biologic contracts are made on the federal supply schedule and the open market?

Mr. MATKOVSKY. We looked at a couple of these, sir. One of them looking at the below threshold, so contract actions below $3,000, about 70 percent of those actions are on contract, so national contracts, regional contracts. In addition for the biologics, I believe there were about $75 million of acquisitions in fiscal year 2013. We have not broken out separately those that were on contract, not on contract. But I believe in the first quarter of fiscal year 2014, our number is roughly about 40 percent on national contract, sir.

Mr. COFFMAN. Okay. I would very much like you to provide that break down to the committee within two weeks. Thank you. Ranking Member Kirkpatrick.

Mrs. KIRKPATRICK. Mr. Matkovsky, I appreciate that VA is working on policies regarding vendors in the OR. I think the concern of this committee is always what is the consequence of violating a policy of the VA? What is your thought about terminating the contract with the vendor whose rep actually touches a patient?

Mr. MATKOVSKY. Not to be evasive, Congresswoman, but in this case we would have to look at it. If they violated the terms of a contract, then an appropriate action would be to terminate their contract with the VA. But at a minimum they would have performed something in violation of our policy. The difference there would be if it is a quality product or a product that we have on a committed use contract would we want to terminate a contract nationally for the actions of one vendor? But it is something we would want to monitor very closely.

Mrs. KIRKPATRICK. And I just want to reiterate the concern of the committee is that a lack of consequences, good policies, but a lack of consequence if the policy is breached. But let me go on to the second point. The GAO report states that the program executive office identifies items that are frequently used and high cost. This implies that that is the only mechanism for identifying items to be included in these contracts. Is that in fact the case?

Mr. MATKOVSKY. That is not the only mechanism, it is one of the mechanisms. And I have some numbers from our program executive office. It really took effect in fiscal year 2013. By the end of fiscal year 2013, I was directly involved in setting some of the performance goals for that organization and had tied my accountability directly to that success. By the end of the fiscal year, in fiscal year 2013, there were roughly 110, 113 packages developed by that group, the total life cycle value of those packages in excess of $2.1 billion estimated. What they do is they look at our procurement spend in something we called MEDPDB, the medical product database that we share with DoD. And we look at the things we buy. And where we do not have items on national contract we identify them as opportunities. That is one mechanism. It is not the only mechanism. Another mechanism we use as we transitioned away, I just want to emphasize in a period of about 18 months, we removed 1,100 contracting officer warrants from prosthetic staff and transitioned that to procurement staff. We now have about 378 prosthetics contracts at a regional and local level that we did not have before. Those total in a value annual of $323 million. So that is a mechanism that allows us to do bottom up.

I believe you had made the comment about top down versus bottom up. Where clinician preference is indicated and we can find it in buying patterns, we had hoped that this transition would allow us to identify those spend patterns as it moves into contracting. And then contracting would establish local and regional contracts, and then subsequently we would establish national contracts. We are evaluating a biologics contract. It is going to be a complex contract but that would be a national committed use contract like we have with.

Mrs. KIRKPATRICK. Could you—oh, excuse me.

Mr. COFFMAN. I am sorry, Mr. Matkovsky? Could you please speak a little closer into the microphone? Thank you.

Mr. MATKOVSKY. Okay. Sorry.

Mrs. KIRKPATRICK. And could you provide the committee with the performance goals and metrics for that system?

Mr. MATKOVSKY. I will.

Mrs. KIRKPATRICK. Last question is, you know, you heard Dr. Roe say that the medical devices are changing at light speed. And what is your system for testing new devices and then introducing them to the VA system at large?

Mr. MATKOVSKY. I am going to defer to Dr. Lynch for some of this. But part of our evaluation process that we run with the program executive office, frankly the OAL National Acquisition Center for a number of years, had helped VHA in some of this work. We get product samples from the vendor community. So clinicians who are a member of our selection team are literally evaluating products as part of that process. That is different than the federal supply schedule mechanism, which is a much more top down approach. Not negating the value of either, but it would be direct testing of the product offering on the part of clinicians and then I will defer to Dr. Lynch for the research and evaluation of new technologies.

Dr. LYNCH. Let me just try and comment a little bit about the introduction of new technology and the process. I think Congressman Roe and Congressman Benishek discussed that earlier. The VA does in fact have a very rigid process of credentialing providers and introducing new products into the VA. Physicians are expected to undergo specific training. This is actually specified in our credentialing process. When they actually begin to do the process, if appropriate, they will do it under supervision for a period of time before they are credentialed to perform it widely without supervision. So I think we have a process that is very similar to that discussed by Congressman Roe in terms of introducing new procedures and assuring that there is competence on the part of the physician to perform that procedure.

Mrs. KIRKPATRICK. Thank you, and I yield back, Mr. Chairman.

Mr. COFFMAN. Thank you, Ranking Member Kirkpatrick. Dr. Benishek.

Dr. BENISHEK. Well that is a great statement there you made, Dr. Lynch, about, you know, rigorous rules for credentialing. But something is wrong, right? Because I mean, some vendors were doing cases. So there is obviously these guys were not credentialed to be doing cases in the OR. So there is a failure there somewhere, right?

Dr. LYNCH. Let me——

Dr. BENISHEK. You would agree that there has been a failure if this actually occurred like has been described?

Dr. LYNCH. I absolutely agree that a vendor should not be touching a patient. The GAO did not share the specifics of this case with us. We have done some background. We think we understand what happened and where it happened. It did not happen in the operating room. It happened outside of the operating room. It happened during the course of a dressing change. It was not a skin graft, it was a skin substitute, one of the cryopreserved skin covers that are used for wound care. And it did not involve a physician. We believe

it involved a mid-level provider. We have asked our Office of Medical Inspector to go in and evaluate that. Regardless of where it occurred and regardless of the circumstances let me be very clear it should not have occurred. But we do not believe that it occurred in the operating room at this time.

Dr. BENISHEK. I see. Okay. Well I do not have, I am not privy to the details either. So I mean obviously we need to get that done.

Dr. LYNCH. But I just wanted to be very clear that this does not appear to have been an event that occurred in the OR while a patient was asleep or while a patient was under anesthesia.

Dr. BENISHEK. All right. Well I guess those facts have yet to come out. It is just that I want to touch again on the accountability part. You know what I mean? How many people are in your department, Mr. Lynch? I mean, you are the, or Dr. Lynch? You are the Assistant Deputy Under Secretary for Health Clinical Operations. So either, I mean, how many people do you have working for you?

Dr. LYNCH. Directly I have about 15. Indirectly because of the 151 care centers that I oversee, approximately 400 people working for us, sir.

Dr. BENISHEK. You know that to me is, I am trying to get to, I mean I think we have identified the fact that there is problems here that should not have happened. My issue is that, and you have heard me say it if you listened to the previous testimony, I have difficulty with the fact that we never seem to identify a person who is responsible for the follow up. And I am going to tout my legislation. You know, I have got this VA Accountability Act which would actually make the VA identify somebody within the VA who is responsible for something that did not occur, for example, to an Inspector General report. Okay? So that there is actual accountability by a manager if they did not comply with a, you know, an IG report. So do you ever write performance reviews on any of these people that work for you?

Dr. LYNCH. I write the performance reviews for the people who report to me directly, yes sir.

Dr. BENISHEK. So every year then you write, everybody gets a performance review written out?

Dr. LYNCH. My direct reports. Not for everybody across VHA, but——

Dr. BENISHEK. No, no, but I mean those 15 people that you talked about?

Dr. LYNCH. Yes. Yes.

Dr. BENISHEK. And those 15 people each have 15 people until you get to the 150,000——

Dr. LYNCH. Actually 400. I mispoke when I said 100,000 to 150,000.

Dr. BENISHEK [continuing]. You are talking about?

Dr. LYNCH. Correct.

Dr. BENISHEK. From my position here it is tough to get, you know, the bureaucracy initial number provided corrected in this document of the size that you are talking about with 150,000 people somewhere below you in the chain of command, to get those individuals' performance to improve. Because whenever we ask for the name of the person who is responsible for fixing this, we do not get the name of a person. We get, you know, a vague answer. We

can never get down to improving people's performance within the bureaucracy. Do you understand what I am kind of getting to?

Dr. LYNCH. I understand your frustration. I think though you have practiced medicine as I have, and I think you also appreciate the complexity of medicine and the interaction between individuals, processes, and policies that sometimes make it difficult to separate accountability from the person and the process. And I think that is the challenge that we face. We need to identify people who need to have remediation of some form. We also need to be able to identify where our processes and our policies interfere with our people performing good services.

Dr. BENISHEK. Have you ever written a review that recommended remediation or performance improvement?

Dr. LYNCH. I have put several individuals on a performance improvement plan, yes sir.

Dr. BENISHEK. But nobody has ever lost their job, or been transferred in that circumstance of those 15 people?

Dr. LYNCH. I have not fired anybody or transferred anybody, no sir.

Dr. BENISHEK. And how long have been in the position?

Dr. LYNCH. I have been in this position for about a year.

Dr. BENISHEK. Okay.

Dr. LYNCH. I have worked in the VA for about 35 years, sir.

Dr. BENISHEK. Well, you know, well I admire your service to our veterans. I really have a problem with this and I hope that the remainder of the staff, we got this VA Accountability Act through the committee but I was hoping that you all will tell our colleagues on the floor to consider voting for this VA Accountability Act so we can improve the accountability of people in the VA. I find it very frustrating, Dr. Lynch, about, you know, how the performance is. I guess I am way over my time, sorry.

Mr. COFFMAN. Mrs. Walorski of Indiana.

Mrs. WALORSKI. Thank you, Mr. Chairman. Mr. Matkovsky, we have learned in the testimony from the previous panel and then also just here each VA hospital has its own healthcare industry representative credentialing program; We know that; and requirements, often creating discrepancies in both the requirements and the enforcement from hospital to hospital. And you may have alluded to this in your opening remarks but I could not hear you real well, where, could you give us an update on where you are, where the VA is in establishing a single standardized credentialing program for use across the system? And I would direct your attention to what is being considered right now in my state, the State of Indiana, with the Indiana Hospital Association. It has the potential to create more consistent enforcement and compliance. After that GAO report, could you just give us an update? Where are you in coming up with a centralized program?

Mr. MATKOVSKY. Sure. I would separate the credentialing and privileging question with the vendor policy.

Mrs. WALORSKI. Mm-hmm.

Mr. MATKOVSKY. And quite frankly we agree with Mr. Williamson and Mr. Butler that a national policy would help here and that policy sets the guideline and then from that the local policies would be derived. We have just begun so I cannot give you a

specific timeline. But at the direction of the Under Secretary, he wants us to look at this and establish some form of national guidance.

Mrs. WALORSKI. Okay. And then also, as Mr. Lamborn alluded to, the VA is a very important customer, partner for the medical device industry. Since the implementation of the medical device tax a year ago has the VA seen any negative impact in terms of VA patient access? Or access to existing or any new technologies? And is there a concern going forward about access or new technologies as it pertains to the cost of the medical device tax?

Mr. MATKOVSKY. I do not know that I have the specifics on that cost factor. Some of the costs would probably be built into the actual provided price to us. But I do not have those details. I can get those and come back. We have not seen any negative effect at this point to access to medical devices?

Mrs. WALORSKI. Could you provide that to the committee?

Mr. MATKOVSKY. We will.

Mrs. WALORSKI. Thank you. Thank you, Mr. Chairman.

Mr. COFFMAN. Mr. Lamborn, Colorado.

Mr. LAMBORN. Thank you, Mr. Chairman. And this question is for either one of you. According to the GAO report that we just heard from, and I quote, "a physician who stated that vendor representatives were present during the application of skin grafts at this VA medical center told us that he did not know what the official vendor policy was at the VA medical center, and that he was not aware of a VA medical center policy that addresses vendor roles." It sounds to me like the oversight by VA is lacking when physicians have not been informed and made aware of VA policy. What are you doing as an overseer within the VA to make sure this never happens again.

Mr. MATKOVSKY. I think we can do this as a two-part. First of all, we went back and looked at all of the medical centers to verify that we have policy. We do have policy across the board. In this instance this is an individual who, the one that we are looking at, there was in fact a policy and it was a violation of local policy. I would further, with Congresswoman Walorski's comment in my response there, that we will be looking at a national policy. Part of the benefit of a national policy is that it has certain enforcement authority that gets carried with that as well. So the national policy will set the frame, local policies will derive from that, training will be associated with those policies. I agree wholeheartedly with Mr. Butler that that actually is a sound practice. That is what we are doing at this point.

Mr. LAMBORN. And doctor, do you have anything to add to that?

Dr. LYNCH. I would reinforce what Mr. Matkovsky said. I would also emphasize that we have asked our Office of Medical Inspector to go in to help us understand why the failure occurred so that we can prevent it from happening again.

Mr. LAMBORN. Thank you. And Mr. Chairman, I yield back.

Mr. COFFMAN. Thank you, Mr. Lamborn. Dr. Roe, Tennessee.

Dr. ROE. And Dr. Lynch, thank you for your 35 years of medical service to our veterans. I think this is, at least I hope that this situation is just an outlier that occurred. And at least I am beginning to think that it is. I was reading, it is very clear in the VA policy

where VA hospitals are teaching facilities, which is great, and trainees may participate in or observe in treatment/procedures. In certain circumstances the presence of a vendor representative or a company representative is important to the success of the procedure. That is true. Prior to the procedure the representative will sign an agreement to strictly adhere to VA privacy rules. And obviously that policy was not followed in this circumstance that Mr. Lamborn talked about. The representative may provide technical advice but will not physically participate in the procedure. That is very clear. The representative will be closely monitored by the VA treatment team. I mean, that is pretty clear policy to me. That is not hard to understand.

Dr. LYNCH. I think VA's position is very clear. I think the AMA and the American College of Surgeons have reinforced that position. And like Congressman Benishek, I have spent many years in the operating room. I have never seen a vendor representative scrub on a case. I have seen them there for technical information. I have seen them there for calibration of the device that is placed. I have never witnessed a vendor representative scrub. I think this was an outlier. But I think it emphasizes the importance of understanding why it occurred so we can assure it does not happen again.

Dr. ROE. I 100 percent agree with that. And I think your evaluation, Dr. Lynch, is correct. Secondly, the tracking system I think is something that is not a major obstacle with today's technology. It should be fairly simple. Could you elaborate on that? Or would you elaborate on that?

Dr. LYNCH. I can tell you what we are doing and what I think are several best practices in VA right now. For any implant that is placed in the operating room in a VA hospital not only is there a sticker placed in the chart, as Congressman Benishek recommended or noted, but that information is also placed in the patient's electronic medical record by the circulating nurse at the time of the procedure. So there is in fact a redundant system. Not only do we have information in the prosthetic database but, we have information in CPRS, the patient information system.

Dr. ROE. If you had a, as you know some, a number of years ago there was a new ceramic hip that fractured. One of my, he did not think it was so funny and neither did his mother. He put it in his own mother. I would have never done that. I would not touch my mother with a ten-foot pole, but anyway he did. And well she——

Dr. LYNCH. Would she be too demanding for you, Congressman?

Dr. ROE. But anyway, it fractured and he had a way because of the tracking system to be able to get this out and replace it.

Dr. LYNCH. We actually——

Dr. ROE. The system, do you have that available now? Is that up and running and we just do not know about it?

Dr. LYNCH. We have a process in place that is run through our National Center for Patient Safety. Any recalls that are issued are processed by the National Center for Patient Safety. They have representatives at the VISN and facility level that they contact when there is a recall. Two steps happen depending upon the nature of the recall. The material is removed from the shelf so it cannot be placed in a patient. And if it is, necessary, we identify the

patients through the prosthetics database and the operative record and notify the patients of the recall and what steps need to be taken to follow them with that implant. In most cases, a hip or a pace maker, for instance it is usually not removed but the patient is followed more closely?

Dr. ROE. How long does that take?

Dr. LYNCH. I cannot tell you——

Dr. ROE. And are, because I know the VA dropped the ball big time on four or five years, I guess it was almost five years ago we talked about the colonoscopies and identifying patients, and the VA records. There was a huge dropped ball there. Are we sure, do you have systems in place to be sure that my lens implant does not, that is recalled, that I am notified?

Dr. LYNCH. I am comfortable that we have good systems, Congressman. I cannot guarantee you that there might not be exceptions. There are always exceptions in healthcare. But I am confident that we have good systems. I also feel that we can improve those systems. We can make them better by using some of the technology that we have developed, as the ranking member mentioned, in terms of bar coding for medication. We also bar code for transfusions. We need to look at some of the newer technology associated with RTLS and bar coding to see if we can improve the efficiency of that system. But I am confident that in the majority of cases we can identify the individual and assure the provider and the patient that they have appropriate information regarding the recall.

Dr. ROE. There have been some whopping failures that I have observed since I have been there. One, if you will indulge me just a minute, one final question. The procedures and techniques, or new devices I should say, that are tested by our VA physicians, are they being added to the federal supply schedule or not? Or are they purchased on open market purchases?

Mr. MATKOVSKY. Two answers to that. They would be more likely to go into a national contract or a committed use contract right now than an FSS. The FSS is somewhat vendor driven so the vendor will come and get itself on the schedule listing for the most part. But we have a team. I mentioned it before. It is broken into a number of different domains, a prosthetics domain, a surgery domain, nursing, you name it, and looks at our spend pattern and then moves things into committed use contracts through that process.

Dr. ROE. Okay. Thank you, and I yield back. I thank you for indulging me.

Mr. COFFMAN. Thank you, Dr. Roe. Mr. Matkovsky, recently VA unilaterally deleted biologics from VA's federal supply schedule contracts, then did an immediate about face by putting them back on the schedule. Was this related to the lawsuit filed against VA on this issue?

Mr. MATKOVSKY. Mr. Chairman, I do not have information on that. If I can take that one for the record?

Mr. COFFMAN. Very well. Dr. Lynch, vendors performing operations on veterans is not only a serious breach of VA protocol but also violates the veteran's privacy and thereby HIPAA. In accord-

ance with VA's table of penalties at a minimum will VA be holding anyone accountable for these failures?

Dr. LYNCH. Mr. Chairman, I cannot comment on that right now. It is under investigation. I think we will have a better idea of the nature of the accountability once we understand what happened. But if appropriate, people will be held accountable.

Mr. COFFMAN. Mr. Matkovsky, you issued a memorandum on May 23, 2012 underscoring VHA policy on the purchase of biologics that for the last year and a half has been blatantly disregarded by VHA employees. Are you concerned that your guidance is completely ignored without any repercussions? Or was the memo just a hollow attempt to say that you did something to address this continued failure to follow the law from our hearing in 2012?

Mr. MATKOVSKY. No sir, I do not believe it was a hollow attempt. I thought we had started at the same time from May 23, 2012 to September 30, 2013. We removed all of the warrants from our prosthetics staff to be able to purchase above the $3,000 level. That was a significant transition for us. Much of our energy went into making sure we got that right. One of the big concerns we had at the time, and when we testified at that hearing, the hearing before that, and then the subsequent hearing, my big concern frankly was the timeliness effect of that transition. We would be transitioning the purchasing of a prosthetic appliance with a vendor waiting on the other side of the transaction. So to complete that most of our energy went into that.

Now we are looking at the procurement compliance. Our audits are looking at the appropriate determination of the justification for other than full and open. If we are using 8123 incorrectly our audits will pick that up now. And we will make sure we are compliant, sir.

Mr. COFFMAN. Ranking Member Kirkpatrick.

Mrs. KIRKPATRICK. Dr. Lynch, Mr. Matkovsky. Thank you for being here. I appreciate your efforts in crafting a national policy. But I just want to remind you that my district in Arizona is a huge rural district. It is bigger than the State of Pennsylvania and covers over half the state. And it is unique in that we do have a lot of rural veterans. We also have 25 percent of the population Native American. And you know, I am always concerned about a one size fits all policy. And I would just like to know how you are addressing the unique challenges and needs of our rural veterans and our Native American veterans.

Dr. LYNCH. Let me take a first crack at that. We are a little bit off topic because I think once we move into rural areas we are not talking about surgical procedures, or probably not even the involvement of vendors. But we are talking about providing services to veterans. And I think the VA has taken the lead in telehealth as a means for delivering care, what I would term to be point of residence, where the patient is. And I think we have made great strides in developing mechanisms by which we can treat and interact with patients remotely and provide rural veterans the same quality of service that veterans are getting in our larger facilities. It began in primary care. I think we are now able to deliver specialty care services. We have the ability to use stethoscopes and

other remote monitoring equipment. So that I think we are being concerned about the rural veteran.

I came from Omaha, Nebraska. Our area covered about 70,000 to 80,000 square miles of Western Iowa and Nebraska. We faced some of the same challenges, and we found the use of telehealth very effective in delivering that care. The VA is actually now looking at newer models which will deliver care directly into the patients' homes by connecting physician and patient across the internet, so that they can interface directly in the home.

So I think we are concerned about the rural veteran. We are concerned about the veteran that cannot make the trip to our facilities. And I think we do have some tools to provide that care.

Mrs. KIRKPATRICK. Let me just say I applaud your efforts in my district. You know one of my concerns is, though, communication between the VA hospitals and those rural veterans and Native American veterans. Especially if you have got a device recall. So I just hope that you will keep that in the forefront of your minds as you go through the development of the policy.

My other question is really process. The GAO report indicated that in 2011 the VHA established a program management office for prosthetics to identify additional surgical implants that could be made available through a national committed use contract. However an official told the GAO that the office was unable to focus on developing national committed use contracts because of staffing constraints. So would you explain to the committee how the office is supposed to function? Where in the organization structure of VA is it located, VHA? Does it have the necessary staffing and financial resources to make a difference and improve the process? And do you believe this office is capable of performing the duties you have assigned to it?

Mr. MATKOVSKY. That office is located in VHA's corporate office in what we call patient care services. The national program director is on board. I think that program is running very well. There is a really strong collaboration between prosthetics now, logistics, and contracting. We attend concurrent meetings every Friday afternoon where we are reviewing the prosthetics order timeliness and accuracy. The committed use contracts, I gave a number very quickly, but at the below $3,000 threshold, these are the transactions that are micropurchases typically done on a purchase card by prosthetics staff, 70 percent of those transactions are against contracts, in excess of the dollar value of those contracts. Those will increase.

Mr. Chairman in further response to your comment about the memo from 2012, we have seen an increase, although not where we would like it to be, in the use of waivers. And we have to do a better job communicating that requirement to the clinical community. Also just to make sure people do not think of it as a punitive action but as an informative action, to let us know what else we need to get on contract.

I think it is actually a really functioning partnership at this point and the leadership team is doing a great job.

Mrs. KIRKPATRICK. Thank you. Thank you very much. I yield back.

Mr. COFFMAN. Dr. Benishek.

Dr. BENISHEK. Thank you, Mr. Chairman. Dr. Lynch, I have just a couple more questions about, I know you responded to Dr. Roe's question about the tracking. And you know we were informed about this VITAS system, the Veterans Implant Tracking and Alert System, apparently, which was in the process of development. I mean, can you elaborate on what that was? And what is the mechanism, are you not using that? Or what is the mechanism that you are using that you answered Dr. Roe's question in the affirmative. How does that work?

Dr. LYNCH. First of all, VITAS was an attempt to integrate the systems we currently have to track implants. It was developed and during initial implementation evaluation was not found to be functioning properly. So at the moment we have pulled VITAS back. We are relying on the National Center for Patient Safety (NCPS), who tracks recalls. We are relying on their interface with our networks and facilities. We have recall coordinators at each of our facilities who work with the National Center for Patient Safety to receive the recall, assure that any shelf product is immediately removed. The NCPS then works with subject matter experts in VA Central Office, who will work with the facility and its databases to identify any patients who may have had a particular implant placed so that we can inform the patient and the provider and be sure appropriate actions are being taken.

Dr. BENISHEK. Has this actually occurred under your tenure there? Have you seen anything that happened that you are aware of?

Dr. LYNCH. It has occurred seamlessly. There have been I think about 46 recalls over the past year that have been mediated by the National Center for Patient Safety. I cannot itemize those for you. Thirteen of those involved biologics. They were all biologics that were placed in the OR so we should have record of the implantation.

Dr. BENISHEK. So then that information goes to each individual medical center and then they from their list of patients figure out if they have done any of those implants? Is that how it works?

Dr. LYNCH. What they would do is go back and review the appropriate record to see if any of those were implanted in a patient and then link that implant to a patient, yes.

Dr. BENISHEK. So do you know how, does that take a long time then? Or, I mean, is it done on computers? Is that——

Dr. LYNCH. The search is done by computers, yes.

Dr. BENISHEK. All right.

Mr. MATKOVSKY. And it is also tracked on a web site. So you know, an internal system. National Center for Patient Safety will issue an alert. It goes to a patient safety officer at the VISN who oversees the patient safety officer at the facility. And depending on the criticality of the alert notice, there is a requirement to have 100 percent compliance by a given date. And that date is set by the criticality of the alert.

Dr. LYNCH. And there is a requirement that the medical center communicate with the National Center for Patient Safety to indicate that the appropriate action has been taken.

Dr. BENISHEK. All right. Well I do not know, I just got this answer here in response to your answer. Apparently there was a

source saying that the National Center for Patient Safety does not track biologics.

Dr. LYNCH. The National Center for Patient Safety does not specifically track the product, the facility does. The National Center for Patient Safety, however, does track the recall notices for biologics and does pass them through to Central Office, the Network, and the facility when appropriate.

Dr. BENISHEK. All right. Well I am just——

Dr. LYNCH. In fact there were 13 recalls within I believe the past year that did relate to biologics that were managed by the National Center for Patient Safety.

Dr. BENISHEK. All right. Well that is contradictory to somebody else's answer at a previous date, apparently. So——

Mr. MATKOVSKY. I think the distinction is that at the National Center for Patient Safety they are not keeping the list of the individual patient and the implant of that patient. That is not NCPS's charge. It is their charge to link to the FDR, find an incident from a medical center, and then trigger the recall action, set the goal, measure compliance. The tracking is done both in CPRS and in the prosthetics that will track that. So there are policies that require us to record the serial number and associate that with the individual patient.

Mr. COFFMAN. Right. And I think, and just to interject for a second, I mean, what we have had is testimony and certainly evidence in the GAO analysis is that you are not effectively tracking this information and that is a problem for patient safety. Dr. Benishek, please proceed.

Dr. BENISHEK. Actually I am pretty much out of time here, so thank you.

Mr. COFFMAN. Mrs. Walorski, Indiana.

Mrs. WALORSKI. Thank you, Mr. Chairman. Mr. Matkovsky, I just wanted to ask a follow up on the issue of the medical device tax. The reason I am asking that question and the reason I am concerned about it, and I have repeatedly asked the question of the VA, is because we have had complaints in my district, which is in Northern Indiana, of long waits for medical devices, hips, knees. Veterans even asking if they can, you know, why the VA cannot refer them to private hospitals, refer them to somebody else, get them the treatment because of enduring pain. And I posed the question to the VA way back in April of last year, of saying, you know, what is this impact going to be? Is there going to be an access issue? Which I have never received an answer on. But from what I am hearing in my district, in my district there is potentially an access issue.

And the other question I have was on this issue of funding. And I reasked the question to the VA back in November on the committee and somebody was here representing the VA and they said they would get back to us and they never did. I have never had an answer in 60 days. And the reason I am reposing the question to you today, especially because you are here testifying on this specific issue that we are talking about, when can you give me, even if the VA's answer is that the dollar value is minimal, all I want is the dollar figure the VA assigns to the medical device impact. When can I get that dollar figure that you guys are assessing to

the medical device impact? Can you tell me? Because my fear is that if I walk out of here today and I do not have some kind of an agreement with the VA today, I have waited 60 days, even put the request in writing, and we still do not have an answer. When can you provide me the answer?

Mr. MATKOVSKY. I would say roughly within 30 days. We do a forecast out for the prosthetics spend that we perform. And we are getting better at forecasting that amount. It is going to be somewhat challenging. I mean, we will have to look at how much the device tax costs and then do some extrapolation on that. But I would say give us 30 days and——

Mrs. WALORSKI. So I guess my response to that is I have given the VA 60 days, and no response both verbally and in writing. Can you provide me with that information by the end of the week? By tomorrow, 5:00?

Mr. MATKOVSKY. I want to do a good job and make sure we get it done right——

Mrs. WALORSKI. But my concern is nobody has answered the question. We have done everything here. And the complaints that I am receiving from veterans who are waiting for these products has to lead me to believe if there is an access problem in my district is there also a dollar value problem with funds available to the VA? And is there a economic impact? So my concern is because of the fact that veterans are complaining, and the pain that they are in in the meantime, and the issue of asking to even go to private hospitals, to go elsewhere, ask me if the VA will reassign them?

Mr. MATKOVSKY. I will personally commit to you that I will make sure we get this answer to you. I would say 30 days. We have some concurrence processes and other things that I need to go through. So I cannot necessarily commit to those timelines. But I will make sure we get it done.

Mrs. WALORSKI. Thank you. Thank you, Mr. Chairman.

Mr. COFFMAN. Our thanks to the panel. You are now excused. Today we have had a chance to hear about many deficiencies present in VA's handling, tracking, and procurement of surgical implants. I am not convinced that VA has taken the appropriate steps to correct these problems, especially considering how many of them were addressed in similar hearings this subcommittee held nearly two years ago. This lack of progress on the part of VA is unacceptable. As such, this hearing was necessary to accomplish a number of items. Number one, to discover the extent of VA inappropriately allowing vendors to participate in hands on surgical procedures. Two, to address the absence of an operational tracking system that would VA to determine what implants were administered to veterans in case of an emergency. Three, to identify the reasoning and effects of VA's failure to procure biological implants on the federal supply schedule as well as its rampant and incorrect use of waivers. Four, to require VA officials to explain their inadequate response to these serious problems and determine what steps if any are being taken to correct them.

I ask unanimous consent that all members have five legislative days to revise and extend their remarks and include extraneous material. Without objection, I would like to thank again all of our

witnesses and audience members for joining in today's conversation. With that, this hearing is adjourned.

[Whereupon, at 12:03 p.m., the subcommittees were adjourned.]

APPENDIX

PREPARED STATEMENT OF MIKE COFFMAN, CHAIRMAN

OVERSIGHT AND INVESTIGATIONS

REMARKS—VENDORS IN THE OR—VA'S FAILED OVERSIGHT OF SURGICAL IMPLANTS

JANUARY 15, 2014

Good morning. This hearing will come to order.

I want to welcome everyone to today's hearing titled, "Vendors in the OR—VA's Failed Oversight of Surgical Implants."

This hearing examines serious problems with the tracking and handling of surgical implants within the VA and follows through on procurement issues revealed in a previous hearing by this subcommittee.

According to multiple sources, VA medical centers have allowed surgical implant vendors to participate in hands-on treatment administered to veterans. Based on my staff's initial findings, I asked GAO to investigate these allegations regarding veteran health care and to determine what policies are currently in place.

GAO substantiated that several veterans had received skin grafts that had been applied directly by skin graft vendors. GAO found that VHA requires each medical facility to develop its own policy on vendor access, resulting in varying degrees of specificity regarding their participation in patient care.

These findings raise serious questions about the extent of vendor involvement in patient care at VA facilities and the lack of clear guidance regarding vendor access. VA's own consent form as well as industry best practices state that vendor representatives may be present to provide technical advice but may not physically participate in the procedure. However, GAO's investigation confirms that these policies are being unevenly applied or unenforced. Clearly, national guidance and oversight is necessary to protect veterans who undergo surgical implant procedures.

There are also significant problems with how VA handles and tracks surgical implants in veterans. Previous VA OIG audits criticized the VHA for weak internal controls that jeopardize VA's ability to identify and notify patients in the event of FDA product recall. According to GAO's report, released on Monday, these concerns remain and have not been remedied. For some clinical specialties, including gastroenterology, interventional radiology, and pulmonary, identifying information on implants was not tracked in any system. It is troubling to consider that for these specialties, VHA was unable to verify that the items purchased were actually implanted in the patients for whom they were intended.

In 2008, VA began developing the Veterans Implant Tracking and Alert System (VITAS) to track and retrieve identifying information—including the lot and serial number—of surgical implants placed in patients VHA-wide. Unfortunately, according to GAO, this system's development was suspended at the end of fiscal year 2012 due to data-reliability challenges, and as of December 2013, development of VITAS has not resumed, limiting VHA's ability to identify and locate patients who have received implants.

Additionally, GAO's report shows that VA has failed to make sufficient progress with prosthetic procurement reform. In a May 30, 2012 hearing, this subcommittee revealed that VA medical centers and VHA regional network contracting officers misused waiver authority to spend nearly 3 billion dollars on open market purchases of prosthetics, including surgical implants, rather than procure them through competitive contracts, including those with businesses on the Federal Supply Schedule.

As a result of the hearing, VA acknowledged that there are often several options available for implants and that disadvantaged veteran owned small businesses and others offering these products were being unfairly excluded from consideration. VA indicated that it would implement reforms so that non-competitive and sole source purchases would require justification on a case by case basis.

GAO's report does contain some good news: VA has made some progress with obtaining national committed use contracts for non-biological implants, such as artificial joints, cardiac pacemakers, heart valves, and coronary stents. Use of these national committed use contracts is the most favored method of procurement for implants under the Federal Acquisition Regulations. However, GAO also reported that no such contracts have been negotiated for biological implants such as skin and bone grafts. Moreover, contrary to a memorandum, dated May 23, 2012, from Assistant Deputy Under Secretary Matkovsky, GAO found biological implants were rarely ordered from the Federal Supply Schedule at each VA medical center it visited. According to GAO, over-use of the waiver process continues. It reported that none of the medical centers it visited procure surgical implants in compliance with waiver requirements for open market purchases. Finally, it is most disappointing to note that while VA and VHA now have procurement oversight components, GAO reported that they have failed to impose corrective action for these deficiencies.

In conclusion, VA must continue to implement reforms so that medical centers procure surgical implants that meet patient needs while also ensuring best value. More importantly, VA and VHA must pay much better attention to patient safety concerns regarding surgical implants. It is way past time for VA to develop national policies that set forth the parameters for vendor access to treatment facilities and that implement sufficient oversight controls. Additionally, proper tracking of surgical implants is a problem that has been unresolved for far too long and it must be remedied post haste.

PREPARED STATEMENT OF ANN KIRKPATRICK, RANKING MINORITY MEMBER

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING

VENDORS IN THE OR—VA'S FAILED OVERSIGHT OF SURGICAL IMPLANTS

JANUARY 15, 2014

Statement of Rep. Ann Kirkpatrick, Ranking Member, Subcommittee on Oversight and Investigations

Thank you Mr. Chairman.

This morning, the Subcommittee on Oversight and Investigations will be looking into VA practices regarding purchasing surgical implants. In addition, the Subcommittee will be looking into allegations that surgical implant vendor representatives had participated in direct patient care.

On Monday, the Government Accountability Office (GAO) released a report entitled VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement.

The GAO looked at four VA medical Centers and found that these hospitals did not always follow VHA policy regarding documenting open market purchases of surgical implants, including obtaining the necessary waivers to purchase items not covered by a VA-negotiated contract. Last year, VA instituted a new policy regarding purchases above the Federal Acquisitions Regulation's (FAR) micro-purchase threshold of $3,000 and below the simplified acquisition threshold of $150,000. Medical facility and regional office officials "attributed noncompliance mainly to insufficient VHA guidance and VA staff's inexperience" in completing the new requirements.

This is a familiar litany to members serving on this subcommittee. It has been noted before that it does not matter how good and thorough the policy and standards are if no one follows them and there are seemingly no consequences for noncompliance. And this is what I would like to explore today in addition to looking at the specific allegations and looking at ways to improve the process.

Surgical implants, and the larger issue of medical procurement, provides us with a classic balancing act of patient and provider choice on one hand, and efficiency and savings on the other. These are not, in my view, mutually exclusive concepts, but also, there are, ultimately, very few easy answers.

Should there be a greater level of centralization on procurement matters, or should we provide greater local autonomy while ensuring that policies are followed? Indeed, how do we ensure that VA employees are provided the tools to do their jobs and help our veterans but are also held accountable if they do not comply with established policies.

On the issue of surgical implants, what policies and structures are in place to ensure that VA staff is kept fully-up-to-date on advances in the field of surgical implants, and the availability of dif-

ferent options, while also ensuring that VA's contracting efforts are directed toward items that are clinically advantageous and necessary for patient care. Are decisions regarding which items to include in a VA-negotiated committed-use contract made from the top down, or the bottom up, and more importantly, are these decisions made rigorously and systematically? How effective is the recently instituted program executive office and does this effort have the staffing level and financial resources to make a difference and improve the process?

GAO reported that VHA spent approximately $563 million on surgical implants in fiscal year 2012, an increase of 28 percent over fiscal year 2008 levels. I would like to hear from our witnesses today regarding the factors that led to this increase. It is not clear to me whether the increase is primarily due to the practice of open market purchases, or to an increase in either the costs of surgical implants or an increase in their use.

Patient safety is our number one concern. That is why I am concerned over allegations that surgical implant vendor representatives participated in direct patient care. I want to ensure that VA policies are fully followed in this regard while also recognizing that at times vendor representatives can have an important role in providing technical assistance and education to VA care providers.

So let us begin the conversation on how best to fix the problems before us today and work to improve the VA health care system and the health care it provides to our veterans. Spending taxpayer dollars wisely is essential, but providing the health care that veterans have earned and deserve is critical.

I look forward to hearing from our witnesses today, and I yield back the balance of my time.

PREPARED STATEMENT OF RANDALL B. WILLIAMSON

GAO

Testimony
Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

VA SURGICAL IMPLANTS

Shortcomings in Implant Purchasing and Tracking

For Release on Delivery
Expected at 10:00 a.m. EST
Wednesday, January 15, 2014

Statement of Randall B. Williamson
Director, Health Care

GAO-14-271T

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee:

We are pleased to be here today to discuss our work on the purchase and tracking of surgical implants at Department of Veterans Affairs (VA) facilities. VA's Veterans Health Administration (VHA) is one of the largest purchasers of surgical implants, which include biological implants, such as skin and bone grafts, and non-biological implants, such as cardiac pacemakers and artificial joints. VHA spent about $563 million on surgical implants in fiscal year 2012, an increase of 28 percent since fiscal year 2008. Surgeons and other clinicians at VA medical centers (VAMC) determine veterans' needs for surgical implants, request the implant of their choice for purchase, and perform the clinical procedures to implant the items. While VA has negotiated competitive contracts for a variety of implants, VAMCs or VHA's regional network contracting offices (NCO) can purchase a specific surgical implant requested by a clinician from the open market with appropriate clinical justification, rather than purchasing a similar item through a VA-negotiated competitive contract.[1] Upon purchase, identifying information is recorded, such as the serial and lot numbers of the item, which can be used later to identify veterans who received a particular implant if one is recalled by a manufacturer or the Food and Drug Administration due to safety concerns.

At a May 2012 hearing of this subcommittee, concerns were raised about the extent to which VAMCs and NCOs purchase surgical implants from the open market without appropriate justification, as well as VHA's oversight of surgical implant purchases.[2] More recently, members of Congress raised concerns about VHA's ability to identify patients who received a surgical implant that was subjected to a recall and raised allegations about vendor representatives providing direct patient care to veterans at three VAMCs. My remarks today will address the following two areas: (1) VAMC compliance with VHA requirements for documenting

[1]VA negotiates national, regional, and local competitive contracts with vendors for all types of items—including surgical implants. Items that are not purchased from these contracts are referred to as open-market purchases. There are 21 NCOs throughout VHA's health care system that manage the contracting activities of the VAMCs within each of VHA's 21 Veterans Integrated Service Networks. These networks oversee the day-to-day functions of VAMCs that are within their network.

[2]*Purchasing Perspective: VA's Prosthetics Paradox, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Veterans' Affairs*, 112th Cong. (2012).

surgical implants purchased from the open market, and VA and VHA oversight of compliance with these requirements; and (2) VHA's ability to identify veterans who received an implant that is being recalled by the manufacturer or the Food and Drug Administration. My remarks on surgical implant purchasing and VHA's ability to identify veterans who received recalled implants are based on our report, released earlier this week, entitled *VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement.*[3] For this report, we visited four VAMCs that serve large veteran populations and assessed compliance with VHA requirements by reviewing a diverse selection of 257 surgical implant purchases from different vendors. The purchases we reviewed represented from about 6 percent to about 83 percent of the applicable purchases at each VAMC in the first 6 months of fiscal year 2013.[4] While these results cannot be generalized to all VAMCs, they provide insight into VAMC and NCO compliance. We also interviewed officials from VA, VHA, and from four networks, which oversee VAMCs, and reviewed pertinent statutes, regulations, and VA and VHA documents. Furthermore, we reviewed agency documents and interviewed VA and VHA officials on VHA's processes for tracking surgical implants placed in patients. Our work was performed in accordance with generally accepted government auditing standards. Further details on our scope and methodology are included in our report.

GAO also investigated an allegation that surgical implant vendor representatives had participated in direct patient care at three VAMCs. The results of our investigation are summarized in appendix I. Our investigative work was conducted from February 2013 to January 2014 in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency, as further detailed in appendix I. During our investigation, we conducted field interviews, performed document reviews, and reviewed relevant policies and procedures relative to the allegations presented.

[3]*GAO, VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement*, GAO-14-146 (Washington, D.C.: Jan. 13, 2014).

[4]The range in percentages is the result of large differences in the number of open-market purchases at each VAMC.

We provided VA with a draft of this statement. VA provided one technical commented, which we incorporated.

Surgical Implant Purchase Requirements Were Not Always Followed at Selected VAMCs, and VA and VHA Oversight Needs Improvement

Our work at four VAMCs found that these VAMCs did not always follow VHA requirements for documenting open-market purchases of surgical implants. Specifically:

- None of the four VAMCs fully complied with VHA requirements for obtaining waivers required for open-market purchases of surgical implants because they were focusing on other priorities or lacked awareness of the requirements, among other factors.[5]
- None of the four VAMCs fully complied with additional VHA requirements for documenting open-market purchases that are part of a new process VHA implemented in fiscal year 2013 for surgical implant purchases above the Federal Acquisitions Regulation's micro-purchase threshold of $3,000 and below its simplified acquisition threshold of $150,000.[6] VAMC and regional office officials attributed noncompliance mainly to insufficient VHA guidance and VA staff's inexperience in completing these requirements.[7]
- Three of the four VAMCs did not comply with a VHA requirement pertaining to agreements with vendors that provided surgical implants

[5]VHA policy stipulates that all open-market purchases of non-biological implants require a waiver approved by the VAMC Chief of Staff when a comparable item would have been available through a VA-negotiated national committed-use contract. At two of the VAMCs we visited, VHA data indicated that waivers were not being completed for open-market purchases of non-biological implants when a comparable item would have been available through a national committed-use contract. At the other two VAMCs, we selected 20 and 30 purchases for which VHA data indicated that such waivers were on file and reviewed whether those waivers were on file and whether they were complete. All open-market purchases of biological implants require a waiver by VHA's Procurement and Logistics Office when a decision is made to purchase an item from the open market rather than from a Federal Supply Schedule contract. At each VAMC, we selected 20 to 30 purchases of biological implants that, based on VHA data, appeared to have been purchased from the open market for review. For the open-market purchases, we assessed whether a waiver was obtained for those purchases, and if so, whether the waiver was complete.

[6]We reviewed between 15 and 28 purchases over $3,000 at each VAMC we visited.

[7]If a clinician requests a surgical implant over $3,000 from the open market, the following are required: (1) a statement affirming that the vendor's price was fair and reasonable and the basis for this determination; and (2) a justification for other than full and open competition that cites the legal authority for purchasing a surgical implant where the VAMC solicited only one source in making the open-market purchase.

to them on consignment. Under a consignment agreement, the vendor maintains vendor-owned items at the VAMC, and the VAMC purchases only the items actually used. A consignment agreement may be useful when the requirement for a surgical implant is immediate and it is not possible to predetermine which of several types or models are required. These agreements, which clinicians likely established to ensure timely access to implants, did not comply with a VHA requirement that consignment agreements must be authorized by a VHA contracting officer.

The lack of full compliance with these requirements limits VHA's ability to determine why VAMCs are purchasing surgical implants from the open market and VHA's ability to ensure that it is paying a fair and reasonable price for surgical implants. To improve compliance with VHA requirements, in our report, we recommended that the Secretary of Veterans Affairs take several actions, including providing clear guidance to VAMCs on when and how to complete required waivers, establishing internal controls to ensure VAMCs' compliance with waiver requirements, and providing additional training on how to properly document open-market purchases over $3000.[8] VA concurred with our recommendations and noted that VHA's Procurement and Logistics Office will emphasize the waiver process through webinar trainings and standard operating procedures guidance, and it will develop a checklist for documentation of open-market surgical implant purchases over $3,000.

In addition, we found that VA and VHA's oversight of surgical implant purchases to detect and correct instances of noncompliance needs improvement. Specifically:

- Although VA and VHA have recently begun conducting oversight of surgical implant purchases over $3,000 to assess compliance with VHA's new requirements, VHA officials told us that they have not ensured that corrective action has been taken to address identified noncompliance because of poor communication between VA and VHA and insufficient staffing to follow up on identified issues. VA's Office of Acquisition and Logistics did not provide VHA with information on the VAMCs at which noncompliance was identified, according to a senior VHA official. The official also explained that VHA's policy is largely intended to be consultative in nature and that

[8]GAO-14-146.

VHA's Procurement and Logistics Office is not sufficiently staffed to ensure that corrective action is taken.

- Moreover, VHA assesses each VAMC's performance on metrics established for surgical implant purchasing, such as the extent to which VAMCs purchased surgical implants from a national committed-use contract or obtained a waiver allowing clinicians to use an alternative item. However, as of November 2013, VHA did not have a policy governing how any identified deficiencies should be addressed and the corrective actions necessary for VAMCs and VHA's regional networks to take. Absent such a policy, the degree of monitoring and corrective actions taken varied among the four networks we visited. Network prosthetics officials at two of the four networks told us that they regularly monitored the results from VHA's assessments and took steps to ensure that VAMCs address identified deficiencies, such as correcting data-entry errors. In the other two networks that did not ensure that VAMCs address deficiencies, VHA's metrics identified a relatively high rate of noncompliance with surgical implant purchases from VA-negotiated national committed-use contracts. In one of these networks, this noncompliance included a high percentage of purchases missing serial numbers or lot numbers, which has potentially significant patient safety and cost implications.

Without ensuring that noncompliance with purchasing requirements or deficiencies in performance measures are appropriately addressed, VA and VHA run the risk of these issues recurring or continuing. To address this shortcoming, our report recommended that VHA revise existing guidelines to require that VAMCs and NCOs document the measures they are taking to address noncompliance and report their progress (via corrective action plans) in achieving those measures through the VHA and VA management chains of command.[9] VA concurred with our recommendation and stated that VHA will require documentation of measures taken to address noncompliance identified in audits.

[9]GAO-14-146.

VHA Is Limited in Its Ability to Identify and Locate Patients Who Receive a Surgical Implant

We also noted that VHA is limited in its ability to identify and locate patients who receive an implant, which is particularly important in the event of a recall by the manufacturer or the Food and Drug Administration because of safety concerns. For example, VA has noted instances across its health care system where lot numbers and serial numbers for such purchases were not entered into the prosthetics purchasing system and has initiated corrective actions, although these actions appear stalled as of December 2013.[10]

Specifically, in 2008, VA's Office of Information Technology began developing the Veterans Implant Tracking and Alert System (VITAS), which was designed to track and retrieve identifying information—including the lot and serial number—of surgical implants placed in patients VHA-wide. VITAS was developed to address identified shortcomings in VHA's existing ability to track surgical implants. According to VHA, these shortcomings include the following:

- The lot number and serial number of items implanted in patients is not always entered into the prosthetics purchasing system by purchasing and procurement staff, as required.
- While VHA clinicians from most specialties track identifying information of items implanted in their patients using standalone systems or spreadsheets that are particular to the clinicians' specialties, VA found that information on surgical implants recorded in these systems is neither standardized nor is it shared across VAMCs. Furthermore, VA found that identifying information on surgical implants used in certain clinical specialties, including gastroenterology, interventional radiology, and pulmonary, is not tracked in any system.[11]

According to VA and VHA officials involved in the development of VITAS, this system's development was suspended as of the end of fiscal year 2012 due to data-reliability challenges stemming from inaccurate or missing entries in the prosthetics purchasing system and interoperability

[10]The prosthetics purchasing system is used to record the purchase of all prosthetics, including surgical implants.

[11]According to VA, for these clinical specialties VHA was unable to verify that the items purchased by the prosthetics department were actually implanted in the patients for which they were purchased.

challenges between VITAS and other VHA systems that store information on surgical implants. VA and VHA are in the process of reevaluating VITAS; however, as of December 2013, VA and VHA had not decided whether to resume the development of VITAS. As a result, VHA's ability to identify and locate patients who received an implant remains limited.

Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions that you may have.

For questions about this statement, please contact Randall B. Williamson at (202) 512-7114 (williamsonr@gao.gov). Individuals making key contributions to this testimony and the report on which it is based include Wayne McElrath, Director; Gary Bianchi, Assistant Director; Kim Yamane, Assistant Director; Ashley Dixon; Cathleen Hamann; Julie Spetz; and Michael Zose.

Appendix I: Patient Care Provided by Vendor Representatives at Department of Veterans Affairs Medical Centers (VAMC)

This appendix summarizes the results of the investigative work we conducted to review an allegation that surgical implant vendor representatives had participated in direct patient care at three VAMCs by applying skin grafts to patients or debriding patients' wounds. We visited the three VAMCs at which the alleged actions had occurred and interviewed clinical staff, such as physicians, and nonclinical staff, including hospital administrators, to determine whether vendor representatives had participated in direct patient care, and, if so, the circumstances under which the direct patient care occurred. At each of the three VAMCs, we also reviewed documentation, such as VAMC vendor policies and clinical progress notes, which document patient care episodes. Furthermore, we interviewed vendor representatives who provided skin graft products to these VAMCs. The findings from these three VAMCs are not generalizable to other types of surgical implants, to other clinicians, or to other VAMCs. We did not identify the frequency of vendor representatives participating in the provision of direct patient care for all types of surgical implants at the VAMCs we visited, or for the Veterans Health Administration (VHA) as a whole. We conducted this investigative work from February 2013 to January 2014 in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency.

Results of Investigation

We were able to affirm that, in some instances, vendors were participating in direct patient care at one of the three VAMCs we investigated, as recently as August 2013. At the two other VAMCs, we were unable to affirm these allegations. Specifically, several clinicians at one VAMC stated that vendor representatives applied skin grafts to patients or assisted Department of Veterans Affairs (VA) clinicians with the application of skin grafts on multiple occasions. Patients' clinical progress notes we obtained from this VAMC confirmed that a vendor representative had applied skin grafts to several patients or assisted in the application of the grafts. One physician assistant who disclosed that a vendor representative had occasionally assisted in the application of skin grafts stated that vendor representatives may have assisted with this procedure because the VAMC lacked available clinical staff to provide such assistance. A physician who stated that vendor representatives were present during the application of skin grafts at this VAMC told us that he did not know what the official vendor policy was at the VAMC, and he was not aware of a VAMC policy that addressed vendor roles.

Our review indicates that VA allows vendor representatives who supply an implant to be present during a surgical procedure—in which an implant is placed in a veteran—and to provide technical assistance to the clinical staff. We also found that VHA's policy governing vendor access to VAMCs and involvement during clinical procedures is broad in nature. It requires each VAMC to develop its own procedures on vendor access and does not provide guidance on what these procedures should entail. Based on the written procedures we reviewed and interviews with officials at the three VAMCs we visited, we found varying degrees of specificity in current local procedures governing vendor access and participation in patient care. For example:

- At two VAMCs, officials stated that the local procedures require background screening (for possible criminal history) for vendor representatives who are present in clinical areas; the third VAMC had no such requirement.
- At one VAMC, written procedures also prohibited vendors from providing direct patient care, specifying that "vendors will not 'scrub in' or physically perform any part of a procedure"; the other two VAMCs had no such prohibition.

Moreover, we found that the VAMC where we affirmed that vendors were participating in direct patient care was not in compliance with its written procedures covering vendor access to the facility. According to an official from the VAMC director's office, no documentation was on file regarding vendor qualifications, training, and other certifications and competencies for the vendor representatives who are present in clinical areas at this VAMC. This is not in compliance with the VAMC's procedures that require that such information must be maintained on file for all vendor representatives who are present in clinical areas at the VAMC.

Our findings on vendor involvement in patient care at the three VAMCs we visited cannot be generalized to VHA as a whole. However, our findings raise questions about the extent of vendor involvement in patient care at other VA facilities. Accordingly, we plan to refer the specific cases we found on vendor involvement in direct patient care to the VA Office of the Inspector General for further investigation if deemed appropriate.

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STATEMENT OF
ROSCOE BUTLER, ASSISTANT DIRECTOR FOR HEALTH CARE
NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATION
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
ON
"VENDORS IN THE OR – VA'S FAILED OVERSIGHT OF SURGICAL IMPLANTS"

JANUARY 15, 2014

In January 2011 the Veterans Health Administration (VHA) issued a statement regarding the DePuy Orthopaedics Inc. ASR™ Hip Resurfacing System and the voluntary recall of the product that company initiated in August of 2010[1]. On the surface, the document outlines the process of taking existing stock off the inventory shelves of VHA facilities; however, despite the assurances of the missive, questions remain for veterans who may already have had the surgery. Although VHA claims to be able to prevent future use of the implants, what about veterans who have already received the implants? Is there a tracking system in place to identify veterans who have received faulty surgical implants? How are they contacted? How are the serial numbers of defective products tracked? Is the system in place at VHA robust enough to serve the best interests of the veteran patients?

The indications The American Legion has discovered in answer to these questions, and others, is that flaws still exist with the tracking and implementation of surgical implants in VHA. Through the work of our research through such tools as the System Worth Saving Task Force, which conducts nationwide, on-site investigations of VHA facilities, The American Legion has concerns about three key areas of VHA surgical implant policy, or lack thereof.

1. Lack of a robust system for tracking surgical implants.
2. Questions surrounding patient consent to vendor participation in implant surgery.
3. Possible circumvention of regulations and use of the supply schedule when making decisions about surgical implants.

Tracking Surgical Implants

The Department of Veterans Affairs (VA) Office of the Inspector General (OIG) conducted an audit in 2012 and made recommendations regarding VA's management of their prosthetics supply inventory[2]. In VHA's response, they indicated that they would work to develop a plan to replace the Prosthetic Inventory Package (PIP) and the Generic Inventory Package (GIP) with a more comprehensive system. The target completion date is March 30, 2015. In the interim,

[1] VHA Notice 2011-01 ASR™ HIP SYSTEM RECALL, January 11, 2011
[2] VAOIG Report 11-00312-127 "Audit of Prosthetics Supply Inventory Management

VHA indicated they were working on a VA OI&T patch (VistA Prosthetics patch 101) which was 95% completed.

While reaching this goal by 2015 is indeed laudable, and 2015 is rapidly becoming a critical year for VA to meet strategic goals including the elimination of veteran homelessness and the disability claims backlog, The American Legion would like to see a more detailed timeline implementing these changes and improvements for veterans. Reports through System Worth Saving Task Force visits and contact with VHA employees indicate responsibility for entering serial numbers of implant devices is manual, not automated, and is inconsistently implemented.

Although VHA claims to work to a standard of "removing recalled products from inventory within 24 hours of a recall", there is still no clear policy on how veterans who have already received implants are tracked. It is not enough to cut off the problem at the source, attention must be paid to veterans who are already downstream in the process. Without consistent tracking of implants, including positive identification by serial number and other identifying factors, uncertainty remains as to how veterans are served in the case of recalls. The American Legion would like to see a more comprehensive procedure and policy clearly delineated by Central Office to ensure consistency in all Veterans Integrated Service Networks (VISNs).

Patient Consent to Vendor Presence in the Operating Room

The American Legion recognizes that there may be circumstances when it would be beneficial to have qualified and certified personnel from a vendor present during implant surgeries. Hopefully, in such circumstances the veteran patient would receive a detailed briefing from the medical team serving their needs, and a clear and consistent policy, delineated in regulations, would be followed to ensure this is handled in a proper and ethical manner. Unfortunately, as The American Legion has researched policies regarding this practice, the opposite is true.

Consent to such a procedure, rather than being a separate and important step in the veteran's care plan, is buried in a three page form under the vague heading "**15. Additional Information**[3]" with a paragraph that reads in total:

> *VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.*

It would be easier to determine if this paragraph is given special attention during pre-surgical briefings; however no clear policy regulations exist, so it is not surprising that informed consent on this aspect is inconsistent. When questioned regarding the policy, VA responded not with their own policy, but referencing the National Center for Ethics in Healthcare. VHA recognized:

1. The presence of vendors in the operating room is a common practice in U.S. health care.

[3] VA Form 10-0431a APR 2008

2. There are broadly accepted professional ethics standards pertaining to the presence of vendors in operating rooms. VA does not have a specific policy pertaining to this practice, but VA providers are expected to follow the professional ethics standards of their profession. When there are broadly accepted professional ethics standards pertaining to a particular practice, VA does not typically reiterate those standards in VA policy.

3. Professional ethics standards explaining the presence of vendors in operating rooms include the following:

    1) http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8047.page
    2) http://www.ama-assn.org/resources/doc/code-medical-ethics/8047a.pdf
    3) http://www.facs.org/fellows_info/statements/st-33.html

4. Consistent with these standards, the consent form that VA uses for all treatments and procedures (VA Form 10-0431a), and that patients (or their surrogate) must sign prior to undergoing operative procedures, contains the following language:

    VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team.

While adherence to the National Center for Ethics in Healthcare is laudable, the lack of a clearly defined VHA regulation can lead to inconsistent application. Though the above response notes specifically, "The representative may provide technical advice but will not physically participate in the procedure" this is inconsistent with anecdotal accounts specifically noting instances where vendors directly participated in the surgeries. In those cases, even *IF* the veteran was properly briefed pre-surgery about vendor participation, direct participation would be outside the bounds of what the veteran had agreed to. This is disingenuous at best and deceitful at worst.

The American Legion believes VHA must delineate a policy with more clarity and ensure staff in all locations are complying with a clearly directed procedure for informed consent.

Circumventing the Supply Schedule

In 1958, title 38 U.S.C. § 8123 Procurement of Prosthetic Appliances was enacted, which authorized the Secretary to procure prosthetic appliances and necessary services without regard to any other provisions of law. Since then, improvements have been made to the Federal Acquisition Regulations (FAR), and the new FAR is intended to provide an acquisition schedule of prosthetic appliances from approved vendors. Many of those vendors represent Veteran Owned Small Businesses (VOSBs) and Service Disabled Veteran Owned Small Businesses

(SDVOSBs). While the provisions of section 8123 still exist in law and are important in certain circumstances, there is a growing concern that this circumvention is becoming the standard practice, rather than the exception and that raises multiple questions and problems.

The American Legion recognizes there is sometimes a need to go outside the schedule. On a System Worth Saving visit in the past year, American Legion Task Force members spoke to a VA physician who related a story in which he wanted to go outside the schedule to utilize a particular type of stent in a heart surgery. When questioned as to why he did not want to use the stents currently on the supply schedule, the physician cited concerns about the durability of the stents, and stated the choice was made to offer a better long term health prognosis for the veteran.

Obviously, the best health interest of the veterans in the healthcare system is always of paramount importance.

While there may be occasional reasons why a physician would need to operate outside the FAR, The American Legion notes this is increasingly becoming the rule rather than the exception, as noted in the testimony for Federal Supply Schedule (FSS) vendors such as Daniel Shaw, a VOSB participant in a hearing before this subcommittee entitled "Purchasing Perspective: VA's Prosthetics Paradox" in May of 2012.

The American Legion urges VHA to examine further how the interaction with the FSS takes place, and ensure that it is being utilized with the proper balance.

Clearly, this subcommittee has been focused on challenges within the prosthetics arena for some time, and will continue to maintain that focus in the future. On behalf of our National Commander Daniel M. Dellinger, and our 2.4 million members, The American Legion thanks this subcommittee for their diligent attention to the veterans' healthcare system. The American Legion will be watching closely, and hopes to work closely with both VA and Congress to ensure the ultimate outcome is in the veterans' best interest.

For any questions regarding this testimony please contact Ian de Planque, Deputy Legislative Director of The American Legion at (202) 861-2700 or ideplanque@legion.org

The data below identify the number of waivers from FSS orders processed through local contracts:

FY 2012: 10 Waivers approved
FY 2013: 21 Waivers approved

Through the first quarter of FY 2014, there are eight waivers approved or under review. Waiver requests are typically for multiple items on a local contract. VHA is identifying improvements to further improve the level of adherence to waiver processes. As VHA has transitioned procurements above the micro-purchase threshold from prosthetics staff to procurement staff, it will be more feasible to improve adherence with internal VA policies.

Purchases from FSS Biologics Vendors:
It is difficult to track specific biologics vendors due to limitations in VA FSS tracking systems. The data below identify general trends for purchases from FSS vendors.

FY 2013: Total: $23.2 Million

Top 5 Federal Supply Schedule Vendors:	
Avkare	$14.7 Million
Shire Regenerative	$4.5 Million
Academy Medical	$2.4 Million
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Cotton Medical Group	$309,000

Transition of Warrants:
Beginning in FY 2012 and concluding at the end of FY 2014, VHA removed procurement authority above the micro-purchase from over 1,000 for facility prosthetics staff. These duties were transitioned to approximately 200 warranted Contracting Officers.

Question 8: The GAO report states that VHA has a number of policy documents and trainings under development that are designed to improve compliance with the new purchasing process for surgical implants over $3,000. Please give us an overview of what these documents and trainings will entail and when you expect them to be in place. Also, please describe what steps VHA is taking to monitor the timeliness of orders and to make the process more efficient.

VA Response: The VHA Procurement Policy Office has drafted VHA Directive 1081, *Procurement Process for Individual Prosthetic Appliances*, which establishes procedures for procuring prosthetic appliances and sensory aids including surgical implants over the $3,000 micro-purchase threshold. This directive is undergoing VA's coordination, concurrence, and approval process and has obtained almost all required concurrences. The directive defines and standardizes the processes and policies that

PREPARED STATEMENT OF PHILIP MATKOVSKY

Mr. Chairman, Ranking Member Kirkpatrick, and members of the Committee, thank you for the opportunity to appear before you this morning to discuss the Department of Veterans Affairs' (VA) practices regarding the use, tracking, and procurement of surgical implants at VA medical centers.

The Veterans Health Administration (VHA) has made significant changes in the last 3 years to the way it procures surgical implants and prosthetics appliances for the benefit of Veterans. These changes are intended to improve procurement performance and accountability while ensuring effective health care delivery for our Veterans. Beginning in Fiscal Year (FY) 2012 and concluding at the end of FY 2013, VHA transitioned the purchase of surgical implants and prosthetics appliances valued at greater than $3,000 to warranted contracting officers in the VHA procurement organization. This change strengthened our procurement performance for the acquisitions above the micro purchase level. Over 1,100 warrants have been pulled back from non-contracting officer prosthetics staff. VHA's procurement organization has hired and provided specialized training to contracting staff to ensure prosthetics procurements are properly executed, both systematically and in accordance with Federal and VA policies and regulations.

Throughout this transition period, VHA's procurement team's main focus was ensuring that orders were completed timely and in concert with clinicians' prescriptions. With the transition now complete, VHA continues to closely monitor ordering timeliness and accuracy while auditing procurement quality and increasing its use of negotiated contracts for sourcing surgical implants and prosthetic appliances. As a result of this transition, our acquisitions above micro-purchase limits are now recorded in our electronic contract management system and the Federal Procurement Data System.

These audits for compliance and procurement quality have led to changes in VHA procedures and ordering templates use in our electronic contract management system. Further improvements to our ordering processes will occur in the near term. Quality assurance reviews will begin in this fiscal quarter to provide continuous management oversight into ordering processes. These quality reviews will focus on the sourcing practices and will be used to improve our utilization of existing national contracts and our ability to place biologics and implants on national contracts. These efforts to establish national contracts will be directly informed by our clinical leadership to ensure we are emphasizing quality and value.

VHA is currently updating and finalizing its policy for prosthetics procurement. Once published, this new directive will provide more comprehensive and clear guidance to VA medical center staff on how to appropriately order prosthetic appliances to include surgical implants and biologics. VA is still reviewing the recently released Government Accountability Office (GAO) report titled, "VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement." Prior to receiving the GAO report, VA had initiated a number of reforms to its acquisitions process. Any further opportunities

identified by GAO to enhance our prosthetics acquisition procedures will be considered in our ongoing efforts.

The presence of vendors in the operating room is a common practice in health care. There are broadly accepted professional ethics standards pertaining to the presence of vendors in operating rooms from the American College of Surgeons and the American Medical Association. Physicians use their professional judgment to determine when the presence of vendors in clinical settings will improve the safety and effectiveness of patient care. VHA Handbook 1004.01, entitled Informed Consent for Clinical Treatments and Procedures, requires that physicians obtain the patient's signature on VA Form 10–431 before undertaking specific procedures such as surgery. The policy also requires that physicians discuss the contents of this form with patients. The form states that under certain circumstances the presence of a vendor representative is important to the success of the procedure, that prior to the procedure the representative will sign an agreement to strictly adhere to VA's privacy rules, that the representative may provide technical advice but will not physically participate in the procedure, and that the representative will be closely monitored by the VA treatment team. 38 CFR 1.220. also provides additional guidance related to vendors in clinical settings.

In VA, the consent form that is used for all treatments and procedures (VA Form 10–0431a) that patients (or their surrogate) must sign prior to undergoing operative procedures, contains the following language:

"VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure. In certain circumstances, the presence of a vendor representative (company representative) is important to the success of the procedure. Prior to the procedure, the representative will sign an agreement to strictly adhere to VA's privacy rules. The representative may provide technical advice but will not physically participate in the procedure. The representative will be closely monitored by the VA treatment team."

Conclusion

Mr. Chairman, we appreciate your support and encouragement in identifying and addressing issues regarding the procurement of surgical implants at VA medical centers. My colleague and I are prepared to respond to any questions you may have.

QUESTIONS FOR THE RECORD

QUESTIONS FROM SUBCOMMITTEE CHAIRMAN MIKE COFFMAN

Question: 1 Please provide a detailed statement with citations to all guidance, including but not limited to directives, handbooks, and/or regulations, regarding VA and/or VHA policies on access by surgical implant vendor representatives to clinical settings where implantation occurs? Please also describe any changes that are planned in this regard.

Question: 2 Please provide a detailed statement with citations to all guidance, including but not limited to directives, handbooks,

and/or regulations, regarding VA and/or VHA policies related to credentials and other qualifications necessary for surgical implant vendor representative participation in implant procedures. Please also describe any changes that are planned.

Question: 3 Please describe in detail the oversight and enforcement processes that are in place or are planned regarding the agreed conditions of informed consent notices signed by patient/veterans, including those with respect to vendor presence.

Question: 4 In Mr. Matkovsky's written testimony, he refers to 38 CFR § 1.220, as guidance for vendors in clinical settings but on its face, this regulation applies to pharmaceuticals. Does VA and/or VHA interpret the regulation to include surgical implants? If so, please explain. If not, then please indicate whether VA and/or VHA plan to promulgate a similar regulation for surgical implants.

Question: 5 Please describe in detail the steps VA and/or VHA plan to take to include biological implants on Federal Supply Schedule contracts and/or national committed use contracts.

Question: 6 Please describe in detail the circumstances under which VA unilaterally deleted biologics from VA's Federal Supply Schedule contracts and then did an immediate about face to put them back on schedule.

Question: 7 In a memorandum dated May 23, 2012, Mr. Matkovsky indicated that biological implants should be purchased on the Federal Supply Schedule. Please indicate whether this directive has been followed and provide the specific number of such purchases.

Question: 8 The GAO report states that VHA has a number of policy documents and trainings under development that are designed to improve compliance with the new purchasing process for surgical implants over $3,000. Please give us an overview of what these documents and trainings will entail and when you expect them to be in place. Also, please describe what steps VHA is taking to monitor the timeliness of orders and to make the process more efficient.

Question: 9 Given that VA and/or VHA is making open market purchases and not properly documenting them, how does VA ensure that it is not violating the Competition in Contracting Act? How will VA ensure compliance and hold employees accountable for adherence to federal acquisition regulations related to future open market purchases?

Question: 10 GAO found that VA and/or VHA have oversight mechanisms in place regarding procurement of surgical implant purchases but that corrective action to prevent recurrence of poorly documented open market purchases is not pursued. What plans does VA and/or VHA have for improvement in this regard?

Question: 11 Please describe the status of the Veterans Implant Tracking and Alert System (VITAS) and VA and/or VHA plans and timetables to implement the system. Also, please describe how VA and/or VHA expect to overcome the data reliability problems that in 2012 prevented VITAS from succeeding?

Question: 12 Please describe the controls that VA and/or VHA have in place or plan to implement to prevent implantation of expired or contaminated surgical implants and enable the identification of patients with such implants for recall purposes.

QUESTIONS AND RESPONSES FOR THE RECORD

QUESTIONS FROM SUBCOMMITTEE CHAIRMAN MIKE COFFMAN AND RESPONSES FROM VA

Question: 1 Please provide a detailed statement with citations to all guidance, including but not limited to directives, handbooks and/or regulations, regarding VA and/or VHA policies on access by surgical implant vendor representatives to clinical settings where implantation occurs? Please also describe any changes that are planned in this regard.

VA Response: VHA Handbook 1004.01, Informed Consent for Clinical Treatment and Procedures (available at http://www.ethics.va.gov/ETHICS/docs/policy/VHA—Handbook—1004–01—Informed—Consent—Policy—20090814.pdf), requires the use of the informed consent process and the use of the iMedConsentTM software program (or VA Form 10–431a, Consent for Clinical Treatment or Procedures when iMedConsentTM cannot be used) for procedures performed in and out of the operating room (OR) by any provider. Notably, VA's informed consent form specifically informs the patient that vendor representatives may provide technical advice but will not physically participate in the procedures. However, the informed consent process does not address vendors who are present in non-procedure areas. National level policy regarding vendors is in development.

VA has issued informal guidance to VA health care facilities in the form of two Privacy Fact Sheets titled, "Vendor Representatives in Surgical Setting" (dated December 2003) and "Disclosing the Minimum Amount of Protected Health Information (PHI) to Vendors Assisting with Implantable Devices or Observing Surgery" (dated September 2007). Both Fact Sheets address access to PHI by surgical implant vendor representatives in clinical settings. These Privacy Fact Sheets are meant to provide VA health care facility Privacy Officers with information on the legal requirements under the Privacy Act and Health Insurance Portability and Accountability Act (HIPAA) for disclosing or sharing PHI with surgical implant vendor representatives.

Question 2: Please provide a detailed statement with citations to all guidance, including but not limited to directives, handbooks, and/or regulations, regarding VA and/or VHA policies related to credentials and other qualifications necessary for surgical implant vendor representative participation in implant procedures. Please also describe any changes that are planned.

VA Response: There are no national level VA or VHA policies related to credentials and other qualifications necessary for surgical implant vendor representative participation in implant procedures. Consistent with professional ethics standards and guidelines promulgated by professional medical societies, the policy currently in development will clarify that vendor representatives in VA are not allowed to engage in the practice of surgery or medical decision making or to be involved in direct patient contact during procedures; and that the role of vendor representatives is only to provide technical advice and/or to be involved in the remote calibration or adjustment of medical devices to the surgeons and manufacturers' specifications. The policy will further clarify requirements that ven-

dors must meet before they are allowed to be present in clinical settings.

It is anticipated that the policy should be completed in early 2015. In the interim, VA's iMedConsentTM form states that vendor representatives may provide technical advice, but they will not physically participate in the procedures.

Question 3: Please describe in detail the oversight and enforcement processes that are in place or are planned regarding the agreed conditions of informed consent notices signed by patient/veterans, including those with respect to vendor presence.

VA Response: VHA Handbook 1004.01 constitutes VHA national policy on informed consent. It mandates the use of the iMedConsentTM software program or VA Form 10–431a to document the informed consent process. This policy applies to procedures performed both inside and outside of the OR by a provider. The oversight responsibility is assigned to the facility.

Question 4: In Mr. Matkovsky's written testimony, he refers to 38 CFR § 1.220, as guidance for vendors in clinical settings but on its face, this regulation applies to pharmaceuticals. Does VA and/or VHA interpret the regulation to include surgical implants? If so, please explain. If not, then please indicate whether VA and/or VHA plan to promulgate a similar regulation for surgical implants.

VA Response: 38 Code of Federal Regulations (CFR) § 1.220 provides guidance regarding pharmaceutical representatives. VA has not interpreted the regulation to apply to vendor representatives for surgical implants. As for changes that are planned with regard to policy concerning surgical implant vendor access, please refer to VA's response to question #1 and #2 above.

Question 5: Please describe in detail the steps VA and/or VHA plan to take to include biological implants on Federal Supply Schedule contracts and/or national committed use contracts.

VA Response: In the fall of 2012, the Office of Acquisition, Logistics, and Construction's National Acquisition Center (NAC) attempted to increase the number of biologic sources under Federal Supply Schedule (FSS) Group 65 Part II Section A (FSS 65IIA) Medical Equipment and Supplies. During this process, a review of the FSS Agency Specific clause AS1904, Regulatory Requirement Provisions (August 2000), which includes CFR Part 800–1200 revealed that human cells, tissues and cellular, and tissue-based products (i.e., allografts) which as classified under 21 CFR 1271 were believed to be a controlled-substance in lieu of a medical device. As such, it was then determined allografts should be removed from all FSS contracts awarded under 65IIA. During the week of May 31, 2013, VA Contracting Officers notified all affected FSS 65IIA contractors, via a bilaterally-generated modification, that all allografts line items would be effectively removed from their respective contracts by June 15, 2013. All FSS contractors were given until June 6, 2013, to sign, date, and return the bilateral modification. FSS contractors who did not comply by June 6, 2013, received a unilaterally-executed modification removing allograft products with an effective date of June 15, 2013.

After additional fact finding and consultation with VHA and the Office of General Counsel, VA determined that the NAC misinter-

preted the language of AS1904 as it pertained to allografts. As a result, effective June 21, 2013, the Deputy Assistant Secretary for Acquisition and Logistics directed the NAC to rescind its decision to remove allografts from VA's FSS and restore all products previously offered by the schedule holders.

Question 6: Please describe in detail the steps VA and/or VHA plan to take to include biological implants on Federal Supply Schedule contracts and then did an immediate about face to put them back on schedule.

VA Response: VHA performed the following steps to include biological implants on national committed use contracts:

1) Convened a VHA-led panel of experts on February 27, 2014, to support establishing appropriate national committed use contracts for biological implants by; and

2) Developed and submitted complete requirements documentation to the VA Strategic Acquisition Center (SAC) by the end of fiscal year (FY) 2014 to support their follow through for award of national committed use biological implant contracts.

Question 7: In a memorandum dated May 23, 2012, Mr. Matkovsky indicated that biological implants should be purchased on the Federal Supply Schedule. Please indicate whether this directive has been followed and provide the specific number of purchases.

VA Response: The memorandum communicated requirements to both procurement and non-procurement staff to adhere to sourcing and waiver processes. The memorandum was not, however, a directive. Following the release of the memorandum, VHA undertook the full transition of procurements above the micro-purchase threshold (of $3,000) as indicated below:

Waivers

The data below identify the number of waivers from FSS orders processed through local contracts:

FY 2012: 10 Waivers approved

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Through the first quarter of FY 2014, there are eight waivers approved or under review. Waiver requests are typically for multiple items on a local contract. VHA is identifying improvements to further improve the level of adherence to waiver processes. As VHA has transitioned procurements above the micro-purchase threshold from prosthetics staff to procurement staff, it will be more feasible to improve adherence with internal VA policies.

Purchases From FSS Biologics Vendors

It is difficult to track specific biologics vendors due to limitations in VA FSS tracking systems. The data below identify general trends for purchases from FSS vendors.

FY 2013: Total: $23.2 Million

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Transition of Warrants: Beginning in FY 2012 and concluding at the end of FY 2014, VHA removed procurement authority above the micro-purchase from over 1,000 for facility prosthetics staff. These duties were transitioned to approximately 200 warranted Contracting Officers.

Question 8: The GAO report states that VHA has a number of policy documents and trainings under development that are designed to improve compliance with the new purchasing process for surgical implants over $3,000. Please give us an overview of what these documents and trainings will entail and when you expect them to be in place. Also, please describe what steps VHA is taking to monitor the timeliness of orders and to make the process more efficient.

VA Response: The VHA Procurement Policy Office has drafted VHA Directive 1081, Procurement Process for Individual Prosthetic Appliances, which establishes procedures for procuring prosthetic appliances and sensory aids including surgical implants over the $3,000 micro-purchase threshold. This directive is undergoing VA's coordination, concurrence, and approval process and has obtained almost all required concurrences. The directive defines and standardizes the processes and policies that VHA Acquisition workforce will follow when procuring the specified items. The directive also defines the circumstances under which Veteran Affairs Acquisition Regulation (VAAR) and Federal Acquisition Regulation (FAR) may be cited and other than full and open competition procedures utilized. Once approved and published, the directive will define the roles and responsibilities of the acquisition team members and streamline the procurement process to make it more efficient.

1. *Issuing Consignment Agreements:* A standard operating procedure (SOP) is being developed that provides guidance to the acquisition workforce for procuring implantable devices on a consignment basis so that the medical centers will have instant availability to the different type or model.

2. *Monitoring Timeliness of Orders:* VHA has developed a dashboard that tracks the timeliness of prosthetic orders by the Network Contracting Office. The tool tracks four events in the procurement process so when delays happen, the cause can be readily identified. These events include the following:

- Consult to electronic Contract Management System (eCMS) Planning Module—This captures the date of the patient consult and the date a Network Contracting Office receives a procurement request.
- eCMS Planning Module to Graphical User Interface Purchase Order (GUI PO)—This captures the date of receipt of a procurement request by the Network Contracting Office and the date funds are committed to support the contract award.
- GUI PO to eCMS Award—This tracks the date that funds are committed and the date the purchase order is awarded by the Contracting Officer.
- Consult to eCMS Award—This tracks the overall time frame from the patient consult to the date the purchase orders are awarded by the Contracting Officer.

The Network Contracting Office dashboard shows the average amount of days for each of the above events. The dashboard is robust and allows us to drill down by the types of products purchased to identify what may be causing overall timeframes to be less than optimal. Network Contracting Offices and Network Prosthetics Departments each own part of the process, and there are conference calls each week to discuss performance and timeliness. Good per-

formers will share best practices, and performance outliers are required to describe the actions they are taking to reduce timelines. VHA is successfully using this dashboard to not only monitor timeliness but also work with Network Prosthetics Representatives and Network Contracting Officers to improve performance.

Question 9: Given that VA and/or VHA is making open market purchases and not properly documenting them, how does VA ensure that it is not violating the Competition in Contracting Act? How will VA ensure compliance and hold employees accountable for adherence to federal acquisition regulations related to future open market purchases?

VA Response: VA takes several steps to ensure it is not violating the Competition in Contracting Act. VHA clinicians determine which surgical implants will best meet the clinical needs of individual patients. This is not a decision made by Contracting Officers. Many times, the manufacturer and size of a particular implant is not known until the surgery is being performed, and the surgeon observes the internal physical characteristics of the patient. Title 38 United States Code § 8123, Procurement of Prosthetic Appliances, states, "The Secretary may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the Secretary may determine to be proper, without regard to any other provision of law." VHA has provided justification templates to our acquisition workforce and has an audit program to ensure contract files have proper documentation. When a specific product is not identified in the physician's consult, competition is used by Procurement/Contracting Officers. Effective October 1, 2013, VHA transitioned purchasing authority for items greater than $3,000 to Contracting Officers. This threshold is significant because it denotes the micro-purchase limit. For these transactions, VHA performs quality assurance reviews to assess compliance of our procurement staff.

Question 10: GAO found that VA and/or VHA have oversight mechanisms in place regarding procurement of surgical implant purchases but that corrective action to prevent recurrence of poorly documented open market purchases is not pursued. What plans do VA and/or VHA have for improvement in this regard?

VA Response: VHA has provided justification and approval templates to our acquisition workforce and has an audit program to ensure contract files have proper documentation. The transition of the procurement workload for open-market surgical implant purchases from VA medical center prosthetics departments to Network Contracting Offices was completed on October 1, 2013. Although it is still early in the transition, expectations are the existing guidance and oversight program will produce improvements in the documentation of open-market surgical implant purchases. The oversight program includes a corrective action plan/improvement plan requirement.

Question 11: Please describe the status of the Veterans Implant Tracking and Alert System (VITAS) and VA and/or VHA plans and timetables to implement the system. Also, please describe how VA and/or VHA expect to overcome the data reliability problems that in 2012 prevented VITAS from succeeding.

VA Response: VITAS is designed to track implants (e.g., coronary stents, dental, aortic valves, etc.) to include both non-biologic and biologic implants. Biologics that are not "implanted" such as wound care products will not be tracked by this software solution. VITAS, as designed, will draw on a number of registries for source implant device data including, but not limited to, the VistA Dental Package, Cardiovascular Assessment, Reporting and Tracking (CART) System, and VistA Surgery Package. VITAS software, as developed, was undergoing Initial Operating Capability (IOC) testing when the developer contract concluded prior to VITAS release and implementation. If funded for completion, two challenges identified in IOC will require resolution. The first challenge identifies the National Prosthetics Patient Database (NPPD) as an unreliable resource for implant tracking purpose. The proposed solution is to replace the NPPD with the VistA Surgery Package as source data for surgical implants placed in the operating room. The second challenge relates to locating the patient for notification in the event of a product recall. VITAS, as designed, queried the VA Primary Care Management Module (PCMM) to provide a primary care physician as the sole point of contact for recall notification. This was identified in IOC testing as a potential risk to timeliness of notification since PCMM is currently not a comprehensive data source for Veterans receiving care and treatment in VA. The solution is for VITAS to provide notification to additional providers (e.g., surgeon, cardiologist, and dentist) and VHA administrators (e.g., facility Chief of Staff) for patient notification in the event of a product recall consistent with current VHA policy.

Question 12: Please describe the controls that VA and/or VHA have in place or plan to implement to prevent implantation of expired or contaminated surgical implants and enable the identification of patients with such implants for recall purposes.

VA Response: VHA Directive 1039, Ensuring Correct Surgery and Invasive Procedures, mandates that "time-outs" must be facilitated by a checklist and occur immediately prior to the start of a procedure including verification that the correct implant is available, if applicable. An additional step is required immediately prior to implantation of the medical device. The privileged provider performing the procedure must confirm the correct implant with a team member, including a "read-back" of the relevant information. Documentation of the correct medical implant must be placed in the patient's electronic health record.

If a potentially contaminated surgical implant is recalled by the manufacturer or the Food and Drug Administration, VA's National Center for Patient Safety (NCPS) Product Recall Office posts a recall notice with a timeline for removal actions to affected VA facilities through the VHA Alerts and Recalls intranet database.

Facility Recall Coordinator (FRC) in each facility receive the recall notices from the Product Recall Office and work daily to remove defective medical products and food through assignments made to the Facility Designated Area Specialists within each medical center. Through this process, established by VHA Directive 2008.080, Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, VA facilities remove po-

tentially harmful products from inventory in a timely and effective manner.

NCPS' Product Recall Office receives feedback confirmation from each FRC that the facility did or did not have the affected product in stock at the time of the recall and removed any recalled product from inventory. This prevents potentially contaminated surgical implants from being used. The Product Recall Office monitors compliance to the recall process for each facility.

January 24, 2014
The Honorable Eric K. Shinseki
Secretary, U.S. Department of Veterans Affairs
810 Vermont Avenue, NW, Washington, DC 20420,
Dear Mr. Secretary:

Please provide written responses to the attached questions for record for the Oversight and Investigations Subcommittee hearing entitled "Vendors in the OR—VA's Failed Oversight of Surgical Implants" that took place on January 15, 2014.

In responding to these questions for the record, please answer each question in order using single space formatting. Please also restate each question in its entirety before each answer. Your submission is expected by the close of business on February 25, 2014, and should be sent to Ms. Bernadine Dotson at *Bcrnadine.dotson@mail.house.gov*.

If you have any questions, please call Mr. Eric Hannel, Majority Staff Director of the Oversight & Investigations Subcommittee, at 202–225–3527.

Sincerely,

Mike Coffman, Chairman
Subcommittee on Oversight & Investigations

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