



## Testimony

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

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# VETERANS' HEALTH CARE

## Oversight of Tissue Product Safety

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# GAO Highlights

Highlights of [GAO-14-463T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

## Why GAO Did This Study

In fiscal year 2013, approximately 59,000 tissue products were used to provide care to veterans at VAMCs; bone and skin grafts were the most common. While tissue products can repair the body and improve function and feeling, there is also the risk that communicable diseases can be transmitted from the donor to the recipients, potentially resulting in severe complications. FDA is responsible for regulating the manufacture of tissue products to help ensure the safety of such products marketed in the United States. For purchasing purposes, VHA considers tissue products to be a type of surgical implant and a prosthetic—items that support or replace a body part or function.

At recent hearings of this subcommittee, concerns were raised about VA's oversight of surgical implant purchases and its ability to identify veterans who received an implant that is being recalled by the manufacturer or FDA. This testimony addresses (1) whether VHA received tissue products that may have been contaminated and (2) VHA's safeguards to prevent the receipt and use of contaminated tissues, including VHA's ability to ensure the quality of its vendors and to respond to recalls of tissue products. GAO reviewed FDA and VHA data on recalls and adverse reactions related to tissue products and VHA purchasing data. GAO also interviewed VA, VA OIG, and FDA officials on tissue product safety requirements and oversight actions. GAO focused on the policies and procedures at the VA and VHA level.

View [GAO-14-463T](#). For more information, contact Marcia Crosse at (202) 512-7114 or [CrosseM@gao.gov](mailto:CrosseM@gao.gov).

April 2, 2014

## VETERANS' HEALTH CARE

### Oversight of Tissue Product Safety

## What GAO Found

Data from the Veteran's Health Administration (VHA), within the Department of Veterans Affairs (VA), do not show evidence of VHA receiving contaminated tissue products, although, it is difficult to link adverse events in recipients to such products. VA's National Center for Patient Safety (NCPS), which began operation in 1999, has not issued any patient safety alerts—mandates for action to address actual or potential threats to life or health—or advisories—guidance to address issues such as equipment design and product failure—related to tissue products potentially received by VA medical centers (VAMC) in the last 10 years. NCPS issues patient safety alerts and advisories for recalls that require specific clinical actions to ensure patient safety. Since NCPS began issuing and recording data on recalls in November 2008, NCPS has notified VAMCs of 13 recalls for tissue products from vendors from which VHA could have received affected products—none of these recalls have resulted in patient safety alerts or advisories. For 6 of the recalls, 27 VAMCs reported to NCPS that they had identified and removed the recalled products from their inventories. For the other 7 recalls, none of the VAMCs had the affected tissue products in their inventories. The 13 recalls were not issued for known tissue product contamination. Instead, most were initiated because of the possibility of contamination, such as compromise of product sterility and incomplete donor records. Further, VHA officials told us that their analysis of VHA data found no evidence of reported adverse events among VHA patients that were caused by contaminated tissue products. According to officials from the Food and Drug Administration (FDA), post-surgical infections often occur, even in the absence of tissue use, and it is often not possible to definitively attribute such infections to a tissue product.

VHA's identification of recalled tissue products may be limited, although recent actions by the agency may help. VA and VHA rely on FDA to ensure the quality of tissue vendors—who are generally required to register with FDA—but VA and VHA policies do not require that a vendor's FDA registration status be checked for most purchases. In addition, VHA's ability to track recalled tissue products in its inventories may be limited by poor inventory management practices. After receiving a recall notice, VAMCs are required to search their inventories for recalled products; however, GAO and VA Office of Inspector General (OIG) have previously reported concerns with the completeness and accuracy of VHA's inventory data and have made recommendations to improve VHA's ability to accurately identify all recalled products in VAMCs inventories. VA is in the process of responding to these recommendations. Further, while VAMCs are responsible for checking for and accurately identifying all implanted, applied, or injected tissue products subject to a recall, GAO found that VA and VHA conduct no oversight to ensure this is done and rely on VAMCs, which may have limited ability to conduct this check. For example, VHA officials stated that it is difficult to search for information on implanted tissue products, in part, because there is no automated search capability. VA is taking steps that may enhance its ability to identify tissue products after they have been used.

VA and FDA reviewed facts GAO developed in preparing this testimony. VA and FDA provided technical comments, which were incorporated as appropriate.

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

I am pleased to be here to discuss our work on the safety of tissue products used at the Veterans Health Administration (VHA), within the Department of Veterans Affairs (VA). Tissue products can be used to repair parts of the body, improve function and feeling, and restore appearance. In fiscal year 2013, approximately 59,000 tissue products were used to provide care to veterans at VA medical centers (VAMC).<sup>1</sup> Some of the more commonly used tissue products by VHA are bone and skin grafts.<sup>2</sup> Some tissue products, such as bone or tendon, may be permanently implanted into veterans in the operating room. Others, that are temporary in nature because they degrade over time or are absorbed into the body, may be applied or injected in outpatient clinics. These include skin grafts used in wound care and collagen injections.

While tissue products provide valuable methods to sustain and improve quality of life, there are also risks that they can transmit communicable disease from the donor to the recipient, potentially resulting in severe complications.<sup>3</sup> Transmissible pathogens can include viruses, bacteria, parasites, and fungi. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, is responsible for regulating the manufacture of tissue products to help ensure that these products are safe and to prevent disease transmission.

VHA, which oversees all VAMCs, considers tissue products to be a type of surgical implant for purchasing purposes.<sup>4</sup> VHA defines these as

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<sup>1</sup>For purposes of this testimony we refer to VAMCs to include the associated outpatient clinics.

<sup>2</sup>Other types of tissue products used by VHA include cartilage, collagen, connective tissues, heart valves, ocular tissues, and tendons. While tissue products can be derived from humans or animals, the majority of the tissue products used by VHA are derived from humans. Human tissue products that are derived from living or deceased donors are known as allografts. A patient's own tissue can also be used for a surgical reconstruction procedure—these are known as autografts. Our work did not include a review of VHA's use of autografts.

<sup>3</sup>Some tissues may be more prone to communicable disease than others, depending on the tissue type and processing methods used to prepare them for implantation, application, or injection.

<sup>4</sup>VHA codes tissue products as biological implants—a type of surgical implant—in its National Prosthetics Purchasing Database.

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prosthetics, which include all items that support or replace a body part or function. At recent hearings before this subcommittee, concerns were raised about VA's oversight of surgical implant purchases and the agency's ability to identify veterans who received an implant that is being recalled by the manufacturer or FDA. My remarks today will address the following two areas: (1) whether VHA received tissue products that may have been contaminated and (2) VHA's safeguards to prevent the receipt and use of contaminated tissue products, including VHA's ability to ensure the quality of its vendors and to respond to recalls of tissue products.

My remarks today are based on information we collected through reviewing agency documents and interviews with VA, VHA, and FDA officials. Specifically, to examine evidence related to possible receipt of contaminated tissue products, we reviewed VHA's analyses of purchasing data from its National Prosthetics Purchasing Database (NPPD) and NPPD data on tissue products used for treatment of veterans. We also reviewed VHA's and FDA's analyses of data on recalls and reported adverse events related to tissue products, including outcomes of these events. To determine the actions VHA takes to prevent the use of contaminated tissue products, we interviewed VA and VHA officials and reviewed documentation on VA's processes and requirements related to tissue product safety. For example, we reviewed certain aspects of VHA's oversight of and purchasing from tissue product vendors, such as whether VHA requires its vendors to have an active registration with FDA. We also reviewed VHA's tracking of, and response to, manufacturer recalls of tissue products. In addition, we interviewed officials from the VA's Office of Inspector General (OIG) regarding its related work on this topic. Our work focused on the policies and procedures at the VA and VHA level. Our work did not focus on VAMCs, though VAMCs may have their own policies and procedures, such as those related to purchasing and responding to recalls.

To assess the reliability of the data used to prepare this statement, we gathered information from VHA and FDA on their data collection methods, including controls used to help ensure the data recorded is accurate and complete. We recently reported that NPPD data has some inconsistencies and errors that are attributable to data entry errors and

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omissions.<sup>5</sup> In our work for this statement, we also found data errors in NPPD data on VHA's tissue product vendors, such as missing or incorrect values. These errors could affect the accuracy of VHA's reports of its tissue product purchases made through contracts with vendors and purchases made on the open market.<sup>6</sup> However, NPPD data represent the best information available and are the data VHA relies on to determine the vendors it uses and to manage its purchasing. As a result, we found that these data were sufficiently reliable for our use in preparing this statement.

We conducted this performance audit from January 2014 to April 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We shared the information we used to prepare this statement with VA and FDA. After reviewing this information, VA and FDA provided us with technical comments, which we incorporated as appropriate.

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## Background

VHA operates one of the largest health care delivery systems in the United States, providing care to more than 6 million veterans annually. Its health care system includes 151 VAMCs nationwide that offer a variety of outpatient and inpatient services, ranging from routine examinations to complex surgical procedures. VHA also provides outpatient care at more than 800 community-based outpatient clinics.

Like other health care providers, VHA relies on FDA to regulate the manufacture of tissue products to help ensure the safety of such products marketed in the United States. Depending upon whether the tissue

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<sup>5</sup>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), 31.

<sup>6</sup>VA negotiates national, regional, and local competitive contracts with vendors for all types of items—including tissue products. Items that are not purchased from these contracts are referred to as open-market purchases.

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product is derived from a human tissue or an animal tissue, different FDA regulations apply.

- Human tissue products: FDA generally regulates human tissue products under a regulation specific to human cells, tissues, and cellular and tissue-based products.<sup>7</sup> Establishments that manufacture human tissue products must register annually with FDA and submit a list of each type of human tissue product manufactured.<sup>8</sup> FDA regulations include requirements for human tissue establishments to screen and test potential tissue donors for relevant communicable disease agents and diseases, report certain adverse events involving a communicable disease, and follow current good tissue practice requirements.<sup>9</sup> Some human tissue establishments may also manufacture products regulated as drugs, devices, or biological products that would be subject to additional regulatory requirements including premarket review, and the adverse event reporting requirements specific to those products.<sup>10</sup> FDA conducts inspections of foreign and domestic human tissue establishments to ensure they are in compliance with applicable regulations.<sup>11</sup>

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<sup>7</sup>21 C.F.R. pt. 1271. In this statement we refer to these regulations as FDA's "human tissue regulations." Under FDA regulations, the manufacture of human tissue includes the recovery, processing, storage, labeling, packaging, or distribution of human tissue, and the screening or testing of the tissue donor. 21 C.F.R. § 1271.3(e).

<sup>8</sup>21 C.F.R. § 1271.21(a), (b). Establishments subject to these requirements include a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. 21 C.F.R. § 1271.3(b).

<sup>9</sup>Current good tissue practices are intended to ensure that tissue products do not contain communicable disease agents, are not contaminated, and do not become contaminated. They include requirements related to tissue storage and distribution, labeling, record keeping, and tracking tissue products from the donor to the consignee. 21 C.F.R. § 1271.150.

<sup>10</sup>21 C.F.R. § 1271.1(b)(2).

<sup>11</sup>FDA conducts inspections of human tissue establishments based on available resources and uses certain risk-based priorities when determining which establishments to inspect. In fiscal years 2012 and 2013, FDA inspected 592 and 671 establishments regulated under its human tissue regulations, respectively. FDA officials stated that, due to data constraints, the agency could not determine if all establishments regulated under its human tissue regulations had an inspection. Human tissue establishments that are also regulated under FDA's drug, device, or biologics regulations are subject to inspection requirements under those provisions. 21 C.F.R. § 1271.390.

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- Animal tissue products: FDA generally regulates tissue products derived from animals under its medical device regulations.<sup>12</sup> Similar to human tissue establishments, device establishments must register annually with FDA and submit a list of each product manufactured, report certain adverse events that may have been caused or affected by use of one of its devices, and follow current good manufacturing practice requirements.<sup>13</sup> FDA inspects certain foreign and domestic device establishments to ensure they meet required manufacturing standards.<sup>14</sup> Similar to human tissue products regulated as devices, animal products regulated as devices also must meet certain premarket review requirements.<sup>15</sup>

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<sup>12</sup>21 C.F.R. pts. 800-898. Some tissue products derived from animals may be regulated as drugs or biological products. 21 C.F.R. pts. 200-499, 600-680.

<sup>13</sup>A device establishment is a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3(c).

<sup>14</sup>FDA is required to inspect domestic establishments that manufacture devices that meet certain risk classifications every two years. 21 U.S.C. § 360(h). FDA is not required to inspect foreign establishments on a specific schedule.

<sup>15</sup>In general, unless exempt by regulation, new devices are subject to premarket review either through the premarket notification process, to determine whether a new device is substantially equivalent to another legally marketed device, or the more stringent premarket approval process, which requires the manufacturer to supply evidence providing reasonable assurance that the device is safe and effective. 21 U.S.C. §§ 360(k), 360e. On January 23, 2014, FDA issued draft guidance related specifically to medical devices containing materials derived from animal sources. FDA stated that although the use of animal derived-material in medical devices is well established, animal materials may carry a risk of transmitting communicable disease when improperly collected, stored, or manufactured. The draft guidance describes the information that should be documented at the manufacturing facility and included in any premarket submissions to FDA.

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## VHA Data Do Not Show Evidence of Contaminated Tissue Products, Although Attributing Adverse Events to Tissue Product Contamination Is Difficult

While there have been thousands of tissue products used at VAMCs, VHA data do not show evidence of VHA receiving contaminated tissue products. However, it is difficult to attribute adverse events to tissue product contamination. VA's National Center for Patient Safety (NCPS) issues patient safety alerts, patient safety advisories, and recalls to notify VAMCs of possible receipt of unsafe or defective medical products, including tissue products. NCPS, which began operation in 1999, has not issued any patient safety alerts—mandates for action to address actual or potential threats to life or health—or advisories—guidance to address issues such as equipment design and product failure—related to tissue products in the last 10 years, according to NCPS officials.<sup>16</sup> NCPS issues patient safety alerts or advisories for recalls that require specific clinical actions to ensure patient safety. Since NCPS began issuing and recording data on recalls in November 2008, it has notified VAMCs of 13 recalls through September 2013 for tissue products from vendors from which VHA could have received the affected products—none of these recalls have resulted in patient safety alerts or advisories.<sup>17</sup> Each of these recalls could represent the recall of just one product, multiple products, or all products processed within a specific date range from a particular vendor. After NCPS issues recalls, it receives reports from VAMCs on whether recalled products were identified in their inventories—VAMCs do not report to NCPS if any products were used. Of the 13 recalls, 6 resulted in 27 VAMCs reporting back to NCPS that they had identified and removed the recalled products from their inventories. For the other 7 recalls, no VAMCs indicated that they had the affected products in their inventories. None of the 13 recalls were issued for known tissue product contamination. Instead, most were initiated because of the possibility of contamination for reasons such as compromise of product sterility, tissue recovered from donors with risk factors for communicable diseases,

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<sup>16</sup>Patient safety alerts or advisories are classified as such based on the severity and frequency of the incident.

<sup>17</sup>NCPS identified recalls related to tissue products through September 30, 2013. The products included in these 13 recalls were obtained from 11 different vendors. NCPS issues recall notifications through VHA's Alerts & Recalls intranet database to ensure that every applicable facility receives them and assigns facilities to review and take any designated actions, such as removing the product(s) from inventories. NCPS does not issue notices for all recalls. According to officials, reasons not to issue a recall notice include FDA reports that the recall is complete or terminated, the vendor reports that VHA did not receive the affected product(s), the product at the time of reporting is expired, or the product was not a remove-from-use (pull off the shelf) recall notification.

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incomplete donor records, or manufacturers suspected to have deviated from FDA's current good manufacturing practices.<sup>18</sup>

Further, VHA officials told us that their analysis of VHA data found no evidence of reported adverse events among VHA patients that were caused by contaminated tissue products. Specifically, NCPS officials stated that they searched the NCPS Patient Safety Information System database, commonly known as "SPOT," which did not yield any evidence of proven adverse events being caused by tissue product contamination. SPOT contains root cause analysis reviews (investigations conducted by VAMCs to evaluate the system or process causes of reported adverse events) and patient safety incident reports (patient safety-related adverse events reported to NCPS).<sup>19</sup> Collectively, NCPS officials stated that their search of SPOT encompassed nearly 1 million records over more than 11 years.

Nonetheless, it is also important to note that it is difficult to determine whether adverse events are caused by contaminated tissue products. FDA officials told us that it is often not possible to definitively attribute post-surgical infections to a tissue product, despite thorough investigations of reported adverse events. FDA noted that there may be multiple possible causes of an adverse event, given the several potential sources of infection (e.g., the patient, the clinical setting, or the medical product itself). FDA also pointed out that infections following surgical procedures often occur, even in the absence of tissue use. Adverse events specifically caused by contaminated tissue appear to be rare nationwide. Of the approximately 850 reported adverse events potentially related to human tissue products received by FDA between January 1,

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<sup>18</sup>One of the 13 recalls was initiated for reasons other than potential contamination.

<sup>19</sup>All root cause analyses are required to be reported to NCPS. According to NCPS, each VAMC can submit patient safety incident reports to NCPS using a web-based form that is standardized across VAMCs. However, officials cautioned that they rely on personnel in the field to recognize an event as a patient safety-related adverse event and enter it into the system. Since it is a voluntary reporting system, NCPS officials said they would not feel comfortable stating that every adverse event that has happened in all VAMCs is represented in the database. In addition, the level of detail in each report is often not enough to say why an event happened. Besides submitting patient safety incident reports to NCPS, each VAMC maintains its own incident reporting system, which is used by VAMC staff to report information on adverse events. Our review did not include those adverse events maintained in the individual VAMC's reporting systems.

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2006, and June 30, 2013, FDA informed us of 2 cases where infection could reasonably be attributed to the tissue product.<sup>20</sup>

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## VA Does Not Ensure Vendors are Registered with FDA; VHA's Identification of Recalled Tissue Products May Be Limited, Although Recent Actions May Help

VA relies on FDA's oversight of tissue vendors, but VA and VHA policies do not require that staff check tissue vendors' FDA registration status for most purchases. VHA's ability to track recalled tissue products may be limited by poor inventory management practices. We and VA OIG previously have reported similar concerns with VHA's inventory management practices and have made recommendations to improve VHA's ability to accurately identify all recalled products in VAMCs' inventories. Although VAMCs are responsible for checking for all implanted, applied, or injected tissue products subject to a recall, VA and VHA have no oversight to ensure this is done. VAMCs' ability to conduct this check may be limited, but VA has taken steps that may enhance its ability to identify tissue products after they have been used.

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## VA Relies on FDA Oversight of Tissue Vendors but Does Not Ensure Its Vendors Are Registered with FDA

The VA and VHA policies we reviewed suggest that VA and VHA do not require staff to check tissue vendors' FDA registration status for most types of purchases, despite VHA's reliance on FDA's oversight of tissue establishments to ensure the quality of the tissue products the agency receives. In addition, VA does not conduct additional oversight of its own.<sup>21</sup> Registration is important to ensure that tissue establishments are subject to proper federal oversight. This oversight includes, for example, FDA inspections to determine compliance with regulatory requirements pertaining to tissue product safety, such as testing and screening donors for communicable diseases. It is important to note that, according to officials, VA's vendors could include some distributors who are not required to register with FDA because they never take physical possession of tissue products. VHA has no policies requiring purchasing

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<sup>20</sup>The data included those products regulated solely under FDA's human tissue regulations with the exception of cell therapy products or reproductive tissue products, which are tissue products not generally used by VHA. These data did not include tissue products that are also regulated under FDA's drug, device, or biologics regulations and are, therefore, subject to those regulations' adverse event reporting requirements.

<sup>21</sup>We reviewed VA and VHA-wide policies; our review did not include any policies that may exist at the VAMC-level. For example, VAMCs may have established their own VAMC-specific purchasing policies.

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staff to check whether these distributors are supplying tissue products from registered tissue establishments. When discussing their purchasing requirements, VA and VHA officials told us that:

- The majority—51 percent—of tissue product purchases were open-market purchases below the Federal Acquisition Regulations (FAR) micro-purchase threshold of \$3,000 in fiscal year 2013; pursuant to VHA’s purchasing processes, these purchases are made by local VAMC purchasing staff.<sup>22</sup> VHA officials told us that the agency has no policies requiring VAMC purchasing staff to check whether tissue vendors are registered with the FDA when making these purchases.
- VHA likewise does not require VAMC purchasing staff and contracting officers to check FDA registration status of the tissue product vendor for open-market purchases over \$3,000. Such purchases are rare—just 6 percent of VHA’s fiscal year 2013 tissue product purchases were open-market purchases over \$3,000.
- Finally, VHA can also purchase tissue products through national, regional, or local contracts, including national-committed use contracts and Federal Supply Schedule (FSS) contracts.<sup>23</sup> Of VHA’s fiscal year 2013 tissue product purchases, 40 percent were FSS purchases below \$3,000 and 2 percent were FSS purchases greater than \$3,000.<sup>24</sup> VA officials stated that before issuing an FSS contract they check vendors’ FDA registration status for medical devices and

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<sup>22</sup>The Federal Acquisition Regulations (FAR) are government wide regulations that establish uniform policies and procedures used by all executive branch federal agencies for their acquisitions. Purchases above \$3,000 are completed through a contracting process that involves the VAMC purchasing staff and Networking Contract Office staff.

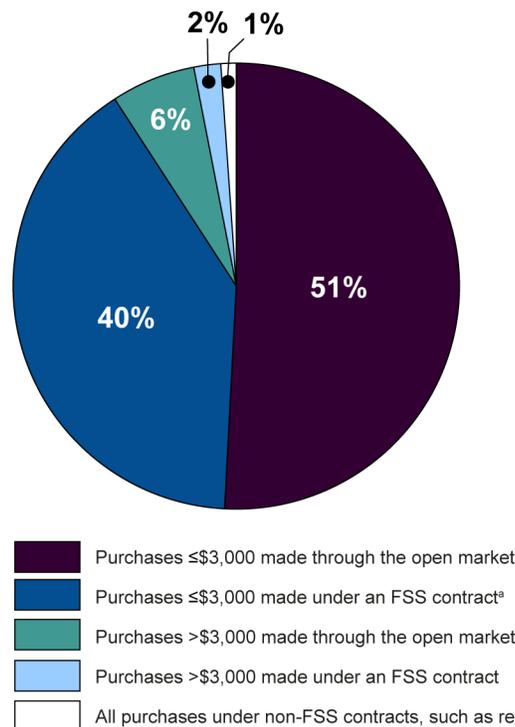
<sup>23</sup>These national level contracts are negotiated by VA’s National Acquisitions Center. However, VHA currently has no national committed-use contracts for biologic implants, although other surgical implants could be purchased through these contracts. National committed-use contracts typically establish a fixed price for several models of a certain type of surgical implant, which VHA must use throughout its healthcare system. Federal Supply Schedule (FSS) contracts are indefinite delivery and indefinite quantity contracts awarded to vendors for various types of surgical implants and include some biologic implants, such as skin grafts.

<sup>24</sup>According to VA officials, there are 9 vendors with FSS contracts that could supply tissue products to VA. In January 2014, we recommended that VA develop a plan for evaluating the benefits of developing more national contracts—such as FFS contracts—with vendors of surgical implants, which could include vendors of tissue products. VA concurred with this recommendation and told us that it plans to develop a national contract procurement package for tissue products by the end of fiscal year 2014. See [GAO-14-146](#), 26-27, 35.

drugs, which may include some tissue products. However, there is no policy requiring staff to check a vendor's FDA registration status for other tissue products, such as those regulated under FDA's human tissue regulations. Purchases under other contracts, such as regional or local contracts are rare—less than 1 percent of purchases in fiscal year 2013—and VHA has no requirements to check a vendor's FDA registration status for these purchases.

However, VHA officials stated that these data may undercount the number of purchases made under a contract, because NPPD does not require staff to enter contract information when recording purchases in the database. For VHA's tissue product purchases by purchase type see figure 1.

**Figure 1: Veterans Health Administration (VHA) Tissue Product Purchases in Fiscal Year 2013**



Source: GAO analysis of data provided by VHA from its National Prosthetics Purchasing Database (NPPD) for fiscal year 2013.

Note: According to VHA, these data may undercount the number of purchases made under a contract, because NPPD does not require staff to enter contract information when recording purchases in the database. This was the best data available from VHA at the time we did our work.

<sup>a</sup>Federal Supply Schedule (FSS) contracts are national level contracts negotiated by the Department of Veterans Affairs National Acquisitions Center.

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<sup>b</sup>This includes all purchases under non-FSS contracts—both those above and below \$3000.

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## VHA's Ability to Track Recalled Tissue Products May Be Limited by Poor Inventory Management Practices

In the event of a recall, NCPS informs VAMCs, which check their inventories for the recalled items; however, in the past we and VA OIG have reported concerns with VA's inventory management practices.<sup>25</sup> According to VHA policy, VAMCs must have a program for responding to recalls that includes identifying numbers and locations of tissue products at the VAMCs. To ensure products are removed, VAMCs are required to report the results of these inventory searches to NCPS—which manages recalls for VHA and documents recalled products found in VAMC inventories in VHA's recall database.

However, VAMC inventory searches may be limited by poor inventory management practices. For example, in May 2011, we reported that VA may lack complete information about expendable medical supplies and reusable medical equipment in its inventories.<sup>26</sup> In the event of a manufacturer recall or patient safety alert for such items, VAMCs may be unable to use their inventory management systems to systematically determine whether the affected items are in their facilities. Instead, they may need to resort to a physical search, which could miss items, creating the risk that recalled products could be used in patient care. This is consistent with findings of our previous work related to VAMCs' poor inventory management practices. In our 2011 report, we recommended that VAMCs be required to enter information about all expendable medical supplies and reusable medical equipment into an appropriate inventory management system.<sup>27</sup> To address deficiencies we identified, VHA issued new requirements in 2011 for the management of medical supplies and equipment in VAMCs inventories. However, in 2013 we

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<sup>25</sup>NCPS learns of recalls from designated officials at the regional and local level; other federal agencies, including FDA and the Department of Defense; and tissue vendors. According to VHA Directive 2008-080, vendors are required to notify VHA of any recalls or important product safety issues. VHA is required to report to NCPS any problems identified by its subordinate chain that may necessitate a recall, such as voluntary recall notices received from tissue vendors and observed clinical problems with tissue products. VHA is also required to contact NCPS should it become aware of a recall or other product safety information from vendors.

<sup>26</sup>GAO, *VA Health Care: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety*, [GAO-11-391](#) (Washington, D.C.: May 3, 2011).

<sup>27</sup>[GAO-11-391](#), 19.

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again reported that none of the VAMCs we reviewed had fully complied with all of VHA's new requirements for managing inventories, and that VAMC inventories were still incomplete. We additionally recommended that VAMCs ensure that medical supplies and equipment are tracked in the appropriate inventory management system and VA concurred with our recommendation and described specific actions that it plans to take to improve VAMCs' compliance with VHA's new requirements for managing inventories, such as providing training to VAMC staff.<sup>28</sup> If these recommendations are effectively implemented, it will help improve VA's overall inventory management practices.

Similarly, in March 2012, VA OIG reported concerns that VHA's prosthetics inventory data—which includes tissue products—are incomplete and inaccurate.<sup>29</sup> VA OIG officials reported that VAMCs should use an automated inventory system—the Prosthetics Inventory Package—to manage certain prosthetic inventories including tissue products.<sup>30</sup> However, VA OIG told us that the few tissue products found at the VAMCs they inspected were tracked in inventory spreadsheets or logs, rather than through the Prosthetics Inventory Package. These informal tracking systems are maintained by clinical staff in the operating room and are therefore not standardized or shared across VAMCs. They are prone to error due to manual entry, thus making accurate identification of all recalled products and oversight of VAMCs' actions more challenging. In addition, when conducting the work for this statement, VA officials told us that NCPS would not notify VAMCs of recalls in certain situations; for example, if FDA reports that the recalled product is expired at the time of reporting and thus should no longer be in VHA's inventory. However, VA OIG also found that expired products often remain on VAMC's inventory shelves, which suggests that they may retain expired products that have been recalled. VA OIG recommended that VAMCs be required to conduct comprehensive physical inventories

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<sup>28</sup>GAO, *Veterans Health Care: VHA Has Taken Steps to Address Deficiencies in Its Logistics Program, but Significant Concerns Remain*, [GAO-13-336](#) (Washington, D.C.: Apr. 17, 2013), 7-8, 25.

<sup>29</sup>The VA OIG report reviewed VHA's prosthetic inventory management practices. Department of Veterans Affairs, Office of the Inspector General, Office of Audits and Evaluations, *Veterans Health Administration: Audit of Prosthetics Supply Inventory Management*, 11-00312-127 (Washington, D.C.: Mar. 30, 2012).

<sup>30</sup>VA OIG 11-00312-127, 14.

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of stocked prosthetics supplies and adjust the Prosthetics Inventory Package to match inventory quantities. It also recommended that the Prosthetics Inventory Package be replaced with a comprehensive modern inventory system and a mechanism be established to identify surgical device implants stored in VAMC inventories. VA concurred with these recommendations. According to VA OIG, VA completed its physical inventory in June 2012 and plans to have a comprehensive inventory system in place in March 2015. VHA's development of a mechanism to identify surgical device implants in inventories is in process.<sup>31</sup>

Although NCPS tracks and responds to recalls, NCPS does not track warning letters, which notify vendors of violations found during inspections, including conditions that could lead to tissue contamination.<sup>32</sup> VA officials stated that they do not track warning letters because they are intended to give vendors an opportunity to take voluntary corrective action before FDA initiates an enforcement action and do not necessarily provide information on specific tissue products. For example, in 2012, FDA issued a warning letter to a vendor used by VHA that outlined problematic inspection results including conditions that could result in accidental exposure of tissue products to communicable diseases. NCPS officials explained that they did not receive this FDA warning letter, and would not expect to, as there is no recall action indicated in these letters.

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### Identification of Recalled Tissue Products Already Implanted, Applied, or Injected May Be Limited, but VA Is Taking Steps That May Improve Its Ability to Identify Such Products

VAMCs are responsible for checking for and accurately identifying all tissue products subject to a recall that have been implanted, applied, or injected. However, VA and VHA conduct no oversight to ensure this is done. While we did not review policies and procedures that may exist at individual VAMCs, our work suggests that VAMCs' ability to check for implanted, applied, or injected tissue products may be limited. NCPS officials told us that, unlike tissue products stored in VAMCs' inventories, NCPS is not responsible for managing and documenting recalls of tissue products that have been used and does not require VAMCs to report back the results of their search for these tissue products. Rather, according to officials, each VAMC is responsible for ensuring it tracks the recalled products to individual patients. However, there is no oversight at the VA

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<sup>31</sup>VA OIG, 11-00312-127, 21-22.

<sup>32</sup>FDA issues warning letters for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected.

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or VHA level to make certain that VAMCs are indeed conducting this check. In addition, VHA officials stated that it is difficult to search for this information. For example, although VAMC operating room staff have been required to include the serial and model numbers of the tissue products used in the surgical patient records since 2011, VHA officials told us that there is no way to automatically search these data. Consequently, according to VHA officials, VAMCs generally rely on tissue product vendors to provide information on the medical facilities that have received recalled tissue products and staff must check individual patients' records to verify the vendor's information. Further, the quality of the data on tissue products recorded in the surgical patient records—which is entered manually by clinical staff—has not been assessed. It also does not include information on tissue products used in outpatient settings, such as skin grafts—one of VA's more commonly used tissue products. VHA's National Prosthetics Purchasing Database—NPPD—contains the serial and model number of prosthetics used for individual patients, including tissue product implants; however, VHA officials told us that NPPD is not used to track patients with implants in the case of a recall, but is generally used for purchasing and accounting purposes. Additionally, we recently reported that NPPD data was often found to be incomplete or incorrect.<sup>33</sup>

VA is taking steps that may enhance its ability to identify implanted, applied, or injected tissue products at VAMCs. VHA began developing a system, the Veterans Implant Tracking and Alert System (VITAS), in 2008. VITAS provides a means to track and retrieve identifying information—including the serial and lot number—of surgical implants placed in patients, including tissue products. VITAS's development was temporarily suspended due to data-reliability challenges stemming from inaccurate or missing entries in NPPD and interoperability challenges between VITAS and other VHA systems. However, VA officials told us that they plan to fund further development of VITAS in fiscal year 2014. In addition, VHA officials told us that they have established a working group to determine the feasibility of utilizing scanning and tracking technology to automatically upload tissue product implant information into electronic

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<sup>33</sup>We reported in January 2014 that the lot number and serial number of items used in patients is not always entered into NPPD by purchasing and procurement staff, as required. In addition, this information must be entered manually, which has the potential to cause inaccuracies in information that is entered into NPPD. [GAO-14-146](#), 33.

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patient medical records.<sup>34</sup> Scanning a universal code on a tissue product can reduce errors in tracking implants; for example, those that occur when transcribing this information into patient records by hand. In addition, FDA issued a final rule on September 24, 2013, to establish a system to identify devices through distribution and use. The rule requires the label of medical devices to include a unique device identifier (UDI) in plain text and in a form that uses automatic identification and data capture technology, such as a bar code scanner. This rule applies to tissue products regulated under FDA's medical device regulations, and could help with the identification of these products both before and after they have been used.<sup>35</sup>

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

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## GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact me at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this statement include Geri Redican-Bigott, Assistant Director; Emily Binek; Deirdre Brown; Sandra George; and Cathleen Hamann.

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<sup>34</sup>Officials also cited another recent change noting that as of January 24, 2014, this tissue implant data from the medical records can be captured in VHA's Corporate Data Warehouse, which would allow these data to be extracted and searched at a national level. However, access to the data is permission-based, and while VHA officials said the data could be searched at a national level, there are currently no VHA policies in place for VHA or VAMC staff to search the database during a recall.

<sup>35</sup>This rule does not apply to products subject only to FDA's human tissue regulations. These requirements will be phased in over a 7-year period; however, the labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI within 2 years. 78 Fed. Reg. 58786 (Sept. 24, 2013).

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