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COMBATING TERRORISM

Accountability Over Medical Supplies Needs Further Improvement

Statement of Linda M. Calbom
Director, Financial Management and Assurance

GAO-01-666T

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the status of agencies' actions to establish effective internal control over the federal medical stockpiles that can be used to treat civilian and military victims in the event of a chemical or biological terrorist attack. The United States' ability to effectively respond to such an incident is dependent, among other things, on the plans, methods, and procedures that are in place to manage the pharmaceutical and medical supplies. We testified before this Subcommittee in March 2000[1] on the need to establish effective control over the stockpiles, which was the subject of our October 1999 report.[2] That work resulted in several initiatives by the responsible agencies to correct serious control weaknesses we identified. It also led your office to request that we follow up on the status of corrective actions taken by the Department of Health and Human Services' (HHS) Office of Emergency Preparedness (OEP) and Centers for Disease Control and Prevention (CDC), the Department of Veterans Affairs (VA), and the Marine Corps Chemical Biological Incident Response Force (CBIRF) to address our recommendations that they

1. conduct risk assessments;

2. arrange for periodic, independent inventories of the stockpiles;

3. implement a tracking system that retains complete documentation for all supplies ordered, received, and destroyed; and

4. rotate stock properly.

In completing our most recent work in these four areas, we found that OEP, CDC, VA, and CBIRF have made significant progress toward implementing our October 1999 recommendations. Management at each of the responsible agencies has given priority to and placed emphasis on strengthening internal control over the stockpiles. As a result, corrective actions have reduced inventory discrepancy rates and improved accountability. At the same time, we found that in all of the areas associated with our prior recommendations, additional steps could be

[1]*Combating Terrorism: Chemical and Biological Medical Supplies Are Poorly Managed* (GAO/T-HEHS/AIMD-00-59, Mar. 8, 2000).

[2]*Combating Terrorism: Chemical and Biological Medical Supplies Are Poorly Managed* (GAO/HEHS/AIMD-00-36, Oct. 29, 1999).

taken to ensure that pharmaceutical and medical supplies that can be used to treat victims of chemical and biological terrorist incidents are current, accounted for, and readily available for use. Accordingly, we made 13 new recommendations to the responsible agencies in order that they

- minimize the risks associated with partnering with private companies and other entities;
- improve accountability over pharmaceutical and medical supplies; and
- ensure the effectiveness of supplies on hand.

My statement will summarize the results of our recent follow-up review and highlight additional actions needed to further improve control over the stockpiles. A detailed discussion of our findings is contained in our report *Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement* (GAO-01-463), which is being released today. I will provide some background information to set the stage.

Background

The United States has established a national policy for combating chemical and biological terrorism and managing the consequences of terrorist attacks. In the event of a domestic chemical or biological terrorist incident, local and state governments would be the first to respond in assisting civilian victims. If the consequences of such an incident overwhelmed state and local capabilities, federal assistance could be given to support their efforts. Critical to that assistance are the chemical and biological medical supplies maintained by OEP, CDC, VA, and CBIRF.

The Federal Emergency Management Agency, through the Federal Response Plan, has designated HHS as the lead agency to coordinate medical assistance in the event of a federally declared natural or man-made disaster, including chemical or biological terrorist incidents. Within HHS, OEP is responsible for implementing and coordinating this medical assistance and has, among other efforts, established four National Medical Response Teams (NMRTs) in different regions of the country and staffed the teams with specially trained doctors, nurses, other health care providers, and emergency personnel whose mission it is to decontaminate and/or treat victims of a terrorist attack. Under a memorandum of agreement between VA and OEP, VA maintains a medical stockpile containing antidotes, antibiotics, and medical supplies at locations near each team for responding to chemical terrorist attacks. In addition, VA also maintains a smaller stockpile for OEP that contains only antidotes for

chemical incidents. This stockpile can be loaned to local governments or predeployed for special events, such as the Olympic Games.

Since November 1999, CDC has been building the National Pharmaceutical Stockpile (NPS). CDC partnered[3] with VA as the purchasing agent for the NPS materiel, providing CDC access to VA's purchasing experience and ability to purchase medical supplies at significant discounts. The NPS is comprised of two types of inventories. The first is a rapid-response inventory of pharmaceutical and medical supplies that can be positioned at any location in the nation within 12 hours of a federal decision to deploy them. The second is a larger stock of supplies that can be deployed within 24 to 36 hours of notification, and can be tailored to address a particular type of incident and augment the rapid-response inventory.[4] This second inventory is referred to as the vendor-managed inventory. The rapid-response inventory comprises approximately 20 percent of the NPS; the vendor-managed inventory comprises the remaining 80 percent of the stockpile. In the event of an incident, the CDC stock is shipped in bulk and is accompanied by CDC technical advisors who assist state and local officials in organizing the medication into individual doses and implement plans to distribute and dispense the medication.

CBIRF, created in April 1996 by the Commandant of the Marine Corps, is an incident response force and maintains a working stock of medical materiel to provide emergency medical care and stabilization of injured CBIRF personnel and a limited number of other casualties. CBIRF is also trained and equipped to detect and identify chemical agents as well as extract and decontaminate victims.

A graphic representation of the relationships of the agencies responsible for chemical and biological medical supplies that could be used to treat victims of a terrorist incident is shown in the attachment. I will now discuss the results of our follow-up work.

[3] Partnering, in the context of this testimony, is the association of two or more entities in a business relationship.

[4] These vendor-managed inventories are carried on the manufacturers' inventory records as either "government owned" or "government reserved" and may be rotated with the vendor's normal operating stock in order to ensure freshness.

Agencies Performed Risk Assessments but Did Not Recognize or Mitigate All Relevant Risks

In October 1999, we reported that neither OEP, VA, nor CBIRF had determined the risks that faced their stockpiles, assessed the likelihood of each risk's occurrence, and established plans to detect or mitigate the risks. Risk assessments are an important aspect of internal control that identify potential internal and external risks, rank them in terms of their possible effect on achieving mission objectives, and include actions to mitigate the risks. Since our 1999 review, each agency has prepared a risk assessment. CBIRF not only completed a risk assessment, including a physical security analysis, it also implemented controls to mitigate risks identified in its assessment. However, for CDC and OEP we found instances where the risk assessments were not sufficiently comprehensive or where actions identified to mitigate risks had not been fully implemented. For example, CDC and OEP are partnering with various federal and commercial entities for the storage, management, and transport of their pharmaceutical and medical supplies. As of the completion of our fieldwork in December 2000, neither agency had considered all of the risks posed by delegating key responsibilities to other entities, nor had they taken all the necessary steps to mitigate those risks.

Among CDC's partners is a wholesale distributor of pharmaceutical and medical supplies, which stores and/or manages most of CDC's rapid-response inventories at facilities around the country. While CDC issued standard operating procedures in the form of a handbook to the wholesale distributor in November 2000, as of the end of our fieldwork there was no signed agreement between CDC, VA, and the distributor to cover the distributor's responsibilities to CDC or to bind it to the procedures addressed in the handbook. In commenting on our draft report, CDC stated that it used existing contractual agreements between VA and its commercial partners. While these existing agreements are designed to address VA's hospital supply needs, they do not address key responsibilities, requirements, and control activities specific to the NPS Program. CDC further stated that some of its written contractual agreements with the NPS Program partners had been finalized, while others were undergoing legal evaluation. CDC has since finalized its agreement with the wholesale distributor and provided us with a copy, which we are now reviewing.

In addition, while CDC had finalized the lease agreements with two private warehouses for the storage of three of the rapid-response inventories, as of the end of our fieldwork it had not developed standard operating procedures for those entrusted with the inventory to cover such

responsibilities as granting access to the wholesale distributor for rotating supplies stored in the warehouses. Also, while CDC officials told us that they plan to use private air cargo and land transport companies to transport the stockpiles in the event of a terrorist incident, as of the completion of our fieldwork there were no standard operating procedures or signed agreements to cover these arrangements. Without adequate written procedures in place, CDC cannot be assured that mission-critical activities will be properly carried out by these other parties.

Similarly, OEP did not recognize all the risks associated with delegating responsibility for the storage and management of its stockpiles to VA. Although OEP and VA jointly drafted both national and local operating plans[5] in accordance with their memorandum of agreement, these plans had not been finalized or approved by OEP as of the end of our fieldwork. While the draft local operating plans had been provided to the VA locations storing the stockpiles, security personnel at two of the locations were unable to provide us with a copy of the draft plan or associated training materials. In addition, they could not demonstrate that the plan had been communicated to them or that they were prepared to put it into practice. In commenting on our draft report, OEP stated that the national and local operating plans had been approved and were being transmitted to VA. Subsequently, OEP provided us with evidence that the plans had been approved and sent to VA for immediate implementation.

For CDC and OEP, we also noted instances where risks had been appropriately identified, but plans for mitigating these risks were not fully implemented. For example, CDC's risk assessment identified physical security as a risk, and its handbook specified a number of actions to mitigate the risks, including the use of chain link fences at least 10-feet high with lock-secured gates around the NPS. However, the stockpiles were placed at four locations prior to erecting fences to segregate the CDC stock from that of the wholesale distributor or others sharing adjacent warehouse space. For up to 3 ½ months, supplies at these locations were not segregated by fencing, and management was unable to limit or control

[5]The OEP/VA national plan addresses the responsibilities, concept of operations, and procedures for the procurement, storage, management and deployment of OEP's stockpiles. The local plans address key responsibilities of VA personnel as they relate to each storage site (e.g., the amount of space and level of security to be provided and procedures to be followed for the controlled release of supplies when federal assistance is requested in response to a chemical or biological terrorist incident).

access to the supplies as prescribed in CDC's standard operating procedures.

In another example, one of the risks identified by OEP in its risk assessment was the sensitivity of the medical supplies to extreme temperatures, which could damage the drug or medical item. According to OEP's risk assessment, should this occur, the items affected were to be replaced. Since our October 1999 report, OEP had installed temperature monitoring devices at each location to record temperature minimums and maximums between site visits. We noted during our November 2000 visit to its central location that the temperature monitoring device at that facility registered 95 degrees Fahrenheit, and that manufacturers of some pharmaceuticals stored in this facility warrant their products only if the items are stored at temperatures not exceeding 86 degrees. In addition, we noted that the OEP storage cage used to store medical supplies, including controlled substances, was not equipped with an alarm system, which upon unauthorized entry would transmit a signal to VA security or the local police agency, as required by Drug Enforcement Agency (DEA) regulations.[6] During this site visit, OEP officials told us that they planned to relocate the stockpile to an environmentally controlled and DEA-compliant facility in April 2001. At that time, OEP would replace the affected supplies.

Inventory Accuracy Improved but Additional Actions Are Needed

In 1999 we reported large discrepancies between data recorded in CBIRF's and OEP's inventory systems and physical counts of their inventories. In our March 2001 report, we noted that while discrepancies still existed, the accuracy of both CBIRF and OEP inventory records had improved significantly. However, OEP lacked certain detailed written inventory procedures necessary to help ensure overall reliability of the inventory records. In addition, after our October 1999 report CDC began establishing the NPS and just recently began performing quarterly cyclical inventory counts, as well as quality assurance reviews. As of the end of our fieldwork, no unresolved discrepancies had been identified between the quantities of supplies recorded in its inventory system and physical counts taken by CDC.

Appropriately maintaining supplies depends on having a complete list of requirements and stocking supplies in accordance with the list. During our

[6]21 CFR 1301.72 (b)(4)(v), (2000).

1999 review, we noted that while OEP had prepared a requirements list, CBIRF had not. However, we found in our 2000 review that CBIRF had developed a requirements list, but it did not have on hand all items included in the list. In addition, we found that OEP had not updated its requirements list to reflect changes to the composition of its stockpile. Also, we found that while CDC had established requirements lists for its rapid-response and vendor-managed inventories, the requirements for the NPS were not completely filled by the end of our fieldwork. These issues need to be addressed to help ensure inventory readiness in the event of a chemical or biological incident.

Since our 1999 inventory count of CBIRF's medical supplies, the discrepancy rate has declined from 26 percent to approximately 10 percent. While this is a significant improvement, we found during counts performed in 2000 that the inventory system still had inaccurate or incomplete data. We found discrepancies in quantities, expiration dates, and lot numbers. It is important to note, however, that no discrepancies were found between the records for controlled substances and data from the physical inventory of controlled substances.

In response to our 1999 report, VA began performing quarterly inventory counts on behalf of OEP in April 2000. As a result, the inventory discrepancy rate declined from approximately 11 percent, as previously reported, to less than 1 percent in November 2000. Not included in VA's counts were certain expired controlled substances, which VA was holding for OEP, pending approval by the Food and Drug Administration (FDA) to extend the shelf life of these items. As of December 2000, 17,897 expired items were being held for this purpose. When we counted these expired items and compared the results to VA's inventory records, we found that approximately 5 percent of the expired items were not listed in the system. VA officials told us that they attribute the higher discrepancy rate for these expired items to less frequent inventory counts and a lack of periodic reconciliation of system data to on-hand stock.

While OEP's overall discrepancy rate had significantly improved, it had not provided, nor has VA established, written guidance stipulating acceptable discrepancy rates or the frequency of inventory counts. Sustained progress is dependent upon setting goals against which performance can be measured and conducting periodic inventories. Without these, OEP will not be able to measure improvement or determine the reliability of inventory records. In commenting on our report, OEP stated that it recently had established a tolerable discrepancy rate for mission-critical and

nonmission-critical supplies. It further stated that VA would perform annual inventory counts of OEP's medical supplies, beginning in 2001.

During our 1999 review, we also reported that OEP had a complete list of pharmaceutical and medical supplies and quantities required to meet its mission. Since then, OEP has made changes in its stockpile to increase the number of victims it could treat in a chemical incident. However, as of the end of our fieldwork, OEP had not updated and issued to VA an official inventory requirements list to reflect those changes. In commenting on our draft report, OEP stated that on February 27, 2001, it finalized the NMRT requirements list and asked VA to adjust the inventory at each location to comply with the list when it performs the June 2001 rotation of expiring stock.

Another issue noted in our October 1999 report was that CBIRF did not have an approved list of the items that should be kept in its inventory. In May 2000, CBIRF's Commanding Officer established an interim requirements list, pending receipt of the authorized medical allowance list (AMAL), programming of funds, and development of a fielding plan by the Marine Corps System Command. While we found that CBIRF did not have on hand all the items included in its interim requirements list, its officials told us that they did not plan to order additional stock and risk overstocking supplies based on the AMAL. At the end of our fieldwork, CBIRF officials told us that the Marine Corps System Command was developing/revising the AMAL, which it then planned to compare with on-hand materiel to identify shortfalls or excesses and develop and implement a fielding plan to adjust on-hand stock to the AMAL.

Since our October 1999 report, CDC has developed an inventory requirements list and is using the list as a basis for making inventory purchases to establish the NPS. We found that CDC had developed and followed internal guidelines for establishing the composition and stock levels of the pharmaceutical and medical supplies on the list. As of the end of our fieldwork, approximately 47 percent of the requirements for the rapid-response inventories had been acquired, and the first of approximately five contracts for the vendor-managed inventory had been finalized.

Current Tracking Systems Do Not Record Inventory Activity Over the Life Cycle of the Supplies

In 1999, we reported that the responsible agencies' inventory systems were not adequate, and recommended that they implement tracking systems that retain complete documentation for all supplies that have been ordered, received, and destroyed. The current inventory systems used by OEP, VA, CDC, and CBIRF still lack certain fundamental information, which impedes their ability to comprehensively track their pharmaceutical and medical supplies.

Each agency is in the process of replacing its current system with one that is expected to be able to track medical supplies from the time an order is placed until the item is consumed or otherwise disposed of. CDC's goal was to have its new system in place by April 2001. In commenting on our report, CDC stated that it awarded a contract for a new inventory management system on March 1, 2001. Because OEP's and CDC's system needs are similar, OEP told us that it planned to rely on the results of CDC's review of system capabilities and vendor proposals and use the same system as that selected by CDC. The Marine Corps has developed a new inventory management system, the ATLAS II +, that it expects to implement at CBIRF and be fully operational by June 2001.

Rotation Policies and Practices at CBIRF and CDC Need Improvement

In 1999, we reported that the responsible agencies' inventories included items that had expired but not been replaced and recommended that they properly rotate supplies. For example, we found that OEP had 2,000 amyl nitrite inhalants[7] on hand which had expired 8 months prior to our 1999 visit. In response to our 1999 report, we found that all responsible agencies have developed policies and procedures related to rotating stock in their inventories. However, in some cases, planned approaches were not completely implemented.

Proper rotation entails replacing pharmaceuticals and medical supplies that have expired or are close to their expiration dates with current stock. Agency policies require expired items to be segregated and destroyed, redistributed, or put into the shelf-life extension program. If expired items are not appropriately removed and replaced, there is an increased risk of ineffective items being deployed, an adequate supply of effective items being unavailable, or contemplated cost savings not being realized.

[7]An inhalation drug that is used as an antidote for cyanide poisoning. It is also a common recreational stimulant known as a popper.

During our October 2000 counts at CBIRF, we found 161 expired pharmaceutical and medical supplies, including 146 controlled substances, on hand. The senior member of the CBIRF controlled substances inventory board told us that CBIRF destroyed these expired controlled substances on December 20, 2000. However, as of January 2001, CBIRF had not replaced the expired items with current stock in sufficient quantities to meet the minimum stock levels determined by the Commanding Officer's interim requirements list. As previously mentioned, CBIRF does not plan to order additional stock until the Marine Corps System Command provides program funds and the fielding plan for the CBIRF specific AMAL.

Since our 1999 report, CDC developed a unique concept for medical materiel management that could result in significant cost savings that could be funneled back into the program. Under this plan, certain expiring stock of CDC, for which there was a sufficient market demand, could be returned for full or partial credit to the pharmaceutical wholesale company. The wholesale company could then resell these pharmaceuticals to its other customers, who could use the items before they reached their expiration dates. The wholesale company would then replace the expiring items with fresher stock. Thus, it would be unnecessary to hold the CDC stock until expiration, dispose of it, and replace the disposed items at full cost. According to CDC officials, the wholesale company requires that the items be returned not less than 6 months prior to the expiration date to allow it to redistribute the supplies to its other customers with a 6-month minimum shelf life remaining on the items. CDC adopted a 12-month "trigger" date to ensure that items would be flagged and rotated in time to meet the wholesale company's 6-month requirement.

However, at the end of our fieldwork, CDC had not yet finalized an agreement with the wholesaler to rotate the items. Approximately $4.3 million of CDC's initial purchase of supplies for its rapid-response inventories is scheduled to expire by December 2001. If an agreement is not finalized so that these supplies can be redistributed by June 2001, or within the 6-month timeframe required by the wholesaler, CDC could lose the opportunity for cost savings of up to $4.3 million. Without finalized agreements in place, the expiring medical materiel may have to be replaced at full cost and the expired items destroyed.

Conclusion

We are encouraged by the actions taken by the responsible agencies to improve accountability over the medical supplies designated to treat victims of chemical or biological terrorism. However, ensuring that

supplies are current, accounted for, and readily available for use is dependent in large part on successful collaboration with other entities. Until CDC and OEP formalize certain ad hoc arrangements with other entities covering the storage, management, stock rotation, and transport of supplies, they will face the risk that, should a chemical or biological incident occur, the appropriate supplies will not be available when needed. Also, unless the agencies' inventory requirements lists are up to date and reflective of their own identified needs, the agencies are limited in assuring that they have the supplies needed to fulfill their mission. We understand that since the completion of our review some additional steps have been taken by the agencies to address these issues.

Recommendations For Executive Action

We have included in our March 2001 report the following 13 actions that the Secretary of Health and Human Services and the Commandant of the Marine Corps should take to address the issues that I have discussed here today.

We recommended that the Secretary of Health and Human Services require the Director of the Centers for Disease Control and Prevention to

- execute written agreements as soon as possible with all CDC's partners covering the storage, management, stock rotation, and transport of medical supplies designated for treatment of biological or chemical terrorism victims;
- issue written guidance on security to private warehouses that store stockpiles, addressing such issues as granting access to the wholesale distributor for stock rotation; and
- to the extent practical, install proper fencing prior to placing inventories at storage locations.

In addition, we recommended that the Secretary of Health and Human Services require the Director of the Office of Emergency Preparedness to

- finalize, approve, and issue an inventory requirements list;
- improve physical security at its central location to comply with DEA regulations, or move the supplies as soon as possible to a location that meets these requirements;
- issue a written policy on the frequency of inventory counts and acceptable discrepancy rates;

- finalize and implement approved national and local operating plans addressing VA's responsibilities for the procurement, storage, management, and deployment of OEP's stockpiles;
- train VA personnel and conduct periodic quality control reviews to ensure that national and local operating plans are followed;
- immediately contact FDA or the pharmaceutical and medical supply manufacturers of items stored at its central location to determine the impact of exposure to extreme temperatures on these items;
- replace those items deemed no longer usable; and
- either add environmental controls to the current location or move the supplies as soon as possible to a climate-controlled space.

We recommended that the Commandant of the Marine Corps require the Marine Corps System Command to program funding and complete the fielding plan for the CBIRF-specific authorized medical allowance list and require the Commanding Officer of the Chemical Biological Incident Response Force to

- adjust its stock levels to conform with the authorized medical allowance list; and
- remove expired items from its stock and replace them with current pharmaceutical and medical supplies.

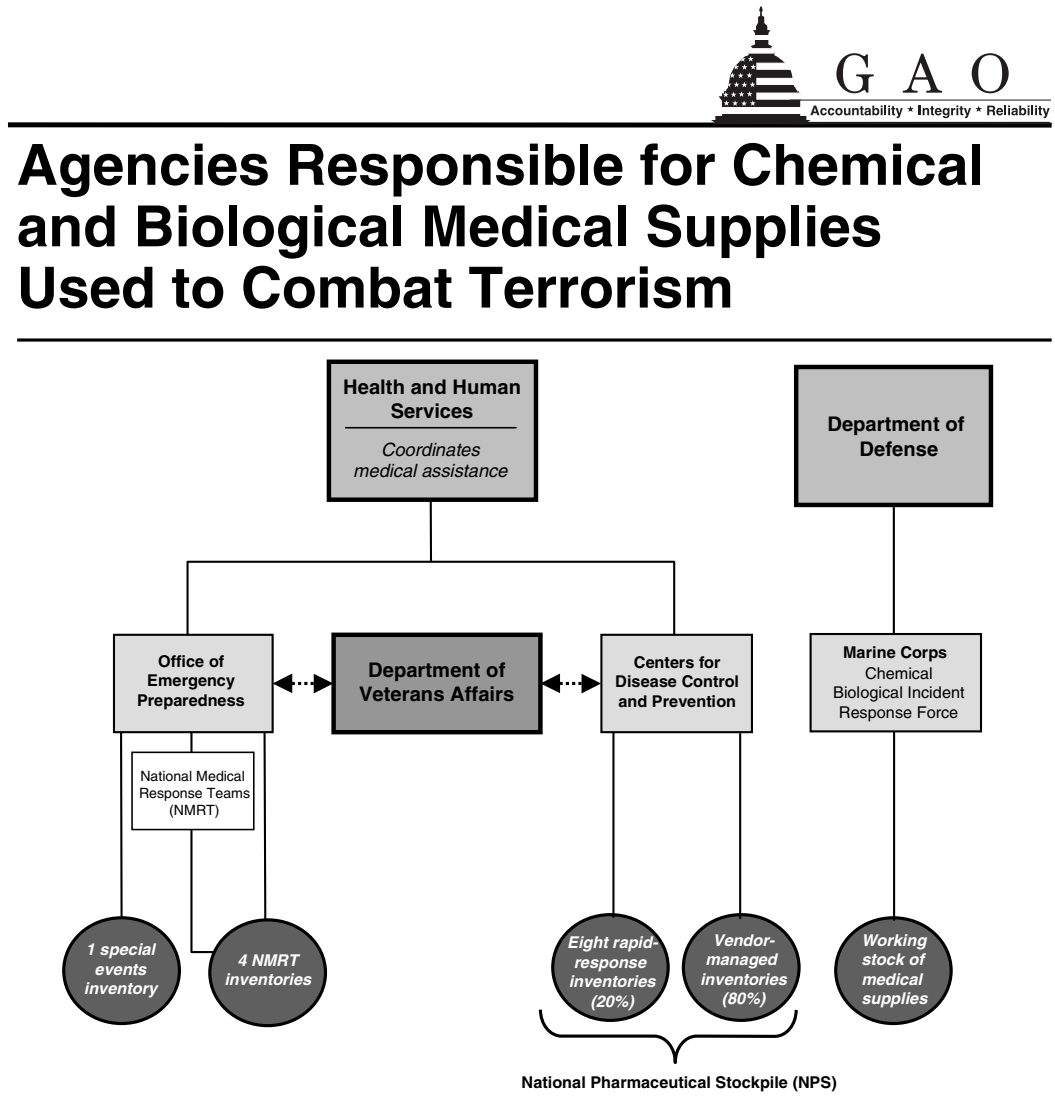
In commenting on our report, the responsible agencies generally agreed with our recommendations and agreed to take corrective actions.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

Contact and Acknowledgments

For further information regarding this testimony, please contact Linda M. Calbom, Director, Financial Management and Assurance, at (202) 512-9508. Individuals making key contributions to this testimony included Louise Beck, Cary Chappell, David Grindstaff, Bronwyn Hughes, Charles Norfleet, Alana Stanfield, McCoy Williams, and Maria Zacharias.

Attachment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Accountability * Integrity * Reliability
Agencies Responsible for Chemical and Biological Medical Supplies Used to Combat Terrorism
Health and Human Services
Coordinates medical assistance
Department of Defense
Office of Emergency Preparedness
Department of Veterans Affairs
Centers for Disease Control and Prevention
Marine Corps Chemical Biological Incident Response Force
National Medical Response Teams (NMRT)
1 special events inventory
4 NMRT inventories
Eight rapid-response inventories (20%)
Vendor-managed inventories (80%)
Working stock of medical supplies
National Pharmaceutical Stockpile (NPS)
Agencies and entities within those agencies directly responsible for the medical supplies
Business partner with delegated responsibility for the medical supplies
Agreements
Inventory of medical supplies used to combat terrorism
Source: GAO analysis based on the review of HHS's and CDC's NPSP Operating Plans and CBIRF documents.

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