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COMBATING TERRORISM: MANAGEMENT OF MEDICAL SUPPLIES

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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CONTENTS

	Page
Hearing held on May 1, 2001	1
Statement of:	
Calbom, Linda M., Director, Financial Management and Assurance, General Accounting Office, accompanied by Alana B. Stanfield, Assistant Director, Financial Management and Assurance; and Louise Beck	3
Mather, Susan, Chief, Public Health and Environmental Hazards Office, Department of Veterans Affairs, accompanied by John Ogden, Chief Consultant, Pharmacy Benefits Management Strategic Health Group; and Kristi L. Koenig, Chief Consultant, Emergency Management Strategic Healthcare Group; Robert F. Knouss, Director, Office of Emergency Preparedness, Public Health Service, Department of Health and Human Services, accompanied by Mark Gnitzke, Chief Pharmacist; and Terry Wagner, Finance Officer; James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention, accompanied by Steven D. Bice, Director, National Pharmaceutical Stockpile Program, National Center for Environmental Health; and Colonel Carlos R. Hollifield, Commanding Officer, Chemical Biological Incident Response Force [CBIRF], U.S. Marine Corps, Department of Defense, accompanied by Commander Corley Puckett, Second Marine Expeditionary Force Sergeant's Office	29
Letters, statements, etc., submitted for the record by:	
Calbom, Linda M., Director, Financial Management and Assurance, General Accounting Office, prepared statement of	6
Hollifield, Colonel Carlos R., Commanding Officer, Chemical Biological Incident Response Force [CBIRF], U.S. Marine Corps, Department of Defense, prepared statement of	62
Hughes, James M., Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention, prepared statement of	47
Knouss, Robert F., Director, Office of Emergency Preparedness, Public Health Service, Department of Health and Human Services, prepared statement of	40
Kucinich, Hon. Dennis J., a Representative in Congress from the State of Ohio, prepared statement of	26
Mather, Susan, Chief, Public Health and Environmental Hazards Office, Department of Veterans Affairs, prepared statement of	32
Shays, Hon. Christopher, a Representative in Congress from the State of Connecticut, prepared statement of	23

COMBATING TERRORISM: MANAGEMENT OF MEDICAL SUPPLIES

TUESDAY, MAY 1, 2001

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2247, Rayburn House Office Building, Hon. Adam Putnam (acting chairman of the subcommittee) presiding.

Present: Representatives Putnam, Kucinich, Platts, Shays, and Tierney.

Staff present: Lawrence J. Halloran, staff director and counsel; Kristine McElroy, professional staff member; Alex Moore, fellow; Jason M. Chung, clerk; Michael Yang, minority counsel; and Teresa Coufal, minority staff assistant.

Mr. PUTNAM. The Subcommittee on National Security, Veterans Affairs and International Relations hearing entitled, "Combatting Terrorism: Management of Medical Supplies" is called to order.

Welcome, Congressman Platts. Thank you for being here. I know that your constituents have a major issue going on upstairs.

I'll begin with the opening statement, standing in for Chairman Shays.

In the event of mass casualties inflicted through the use of chemical, biological, or radiological weapons, State and local public health officials will need help. They will look for timely access to Federal stockpiles of the antidotes, antibiotics, and vaccines necessary to save lives. Will those critical medicines get there in time? Last year we could not be certain. Weak internal controls, lax security, and sloppy inventory management practices increased the risks of stockpiling the wrong medicines, expired medicines, or not enough of the medicines needed to meet the consequences of a terrorist attack.

Today the General Accounting Office releases a report requested by this subcommittee on steps taken to address those weaknesses. According to GAO, the Department of Health and Human Services' Office of Emergency Preparedness and the Centers for Disease Control and Prevention have made substantial improvements in both purchasing and stockpile management practices. As a partner with OEP and CDC, the Department of Veterans Affairs has simplified stockpile storage.

The Marine Corps' Chemical Biological Incident Response Force has formalized its medical equipment list and upgraded inventory

controls. The GAO remains concerned. The extent and pace of improvements continue to pose risks to the adequacy and quality of the stockpiles. Agreements with critical supply and transportation contractors are still incomplete or are vague. Security standards are not yet uniform. Temperature monitoring at some storage facilities may be inadequate to protect sensitive supplies from damage. Operational plans and training are not well developed.

The threat of domestic terrorism demands we amass and pre-position costly perishable medical supplies we hope never to use, but when called upon to stem the toll of a terrorist attack the stockpiles must arrive at the right place at the right time containing the types and amounts of medicines needed to save lives.

Testimony today from the GAO and from those responsible for maintaining Federal medical stockpiles and reserves will describe tangible progress toward that goal. We welcome their testimony and look forward to a discussion of how they plan to meet the substantial challenges of preparing for medical contingencies on an unprecedented, almost unthinkable scale.

We begin with our first panel, Ms. Linda Calbom, Director, Financial Management and Assurance, General Accounting Office, who is accompanied by Ms. Alana Stanfield, Assistant Director of Financial Management and Assurance, also with GAO.

We welcome you ladies here, and if you would, please rise and raise your right hand to be sworn in.

Mr. PLATTS. Mr. Chairman, just before you get into the panel, if I can just make a brief statement.

Mr. PUTNAM. Absolutely. I apologize. Congressman Platts.

Mr. PLATTS. Thank you, Mr. Chairman. I appreciate Chairman Shays and yourself holding this important hearing, and will apologize to not hear the testimony in person. There is a subcommittee hearing regarding the downing of the missionary plane in Peru 11 days ago, and that association of missionary individuals is based in my District, so I will be returning to that, but I do appreciate the written testimony by our first panel, as well as the other panelists, and will be giving close scrutiny to that. I apologize I won't be able to stay. Hopefully I'll get back, but time will tell.

Thank you, Mr. Chairman.

Mr. PUTNAM. Thank you, and we certainly understand.

Ms. CALBOM. Mr. Chairman, we'd also like to have Ms. Louise Beck be sworn in in case we need to have her confer at the table, if that's all right.

Mr. PUTNAM. Fine with me.

Ms. CALBOM. OK.

Mr. PUTNAM. Thank you.

[Witnesses sworn.]

Mr. PUTNAM. Thank you. A note for the record that the witnesses have responded in the affirmative. Who would like to begin? Ms. Calbom.

Ms. CALBOM. Yes. I'll read the oral statement, and Ms. Stanfield is here to assist me in answering questions.

Mr. PUTNAM. You are recognized. Thank you.

STATEMENT OF LINDA M. CALBOM, DIRECTOR, FINANCIAL MANAGEMENT AND ASSURANCE, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY ALANA B. STANFIELD, ASSISTANT DIRECTOR, FINANCIAL MANAGEMENT AND ASSURANCE; AND LOUISE BECK

Ms. CALBOM. Mr. Chairman, I am pleased to be here today to discuss the status of agencies' actions taken to establish effective internal control over the Federal medical stockpiles that can be used to treat victims of a chemical or biological terrorist attack.

We originally testified before this subcommittee in March of last year on the need to establish effective control over the stockpiles, which was also the subject of a report that we issued in October 1999. That work resulted in several initiatives by the Office of Emergency Preparedness, the Centers for Disease Control and Prevention, and the Department of Veterans Affairs, as well as the Marine Corps' Chemical Biological Incident Response Force that I'll refer to as CBIRF.

The responsibility areas for each of these agencies are actually shown on this chart, which I know is also hard to see, but it is also an attachment to my written testimony, which is in your folder. It's the last page of the testimony.

Today I will focus on responding to the committee's request that we followup on the status of corrective actions taken by the responsible agencies to address the recommendations in our prior report. A detailed discussion of our findings is included in our report that is being issued here today. I would like to just spend a few minutes talking about the issues that we came up with in that followup review.

The first area of followup had to do with risk assessments. In the October 1999 report we reported that neither OEP, VA, nor CBIRF had determined the risk that faced their stockpiles, assessed the likelihood of each risk's occurrence, and established plans to detect and mitigate the risk.

Since our last review, each agency has prepared a risk assessment. In fact, CBIRF not only completed a risk assessment, it also implemented controls to mitigate the risks identified in that assessment.

However, for CDC and OEP we found instances where the risk assessments were not sufficiently comprehensive or where actions identified to mitigate the risks had not been fully implemented. For example, neither agency had addressed all of the risks posed by delegating key storage, management, and transport responsibilities to other entities.

The next area we looked at was inventory accuracy. Our prior reviews showed large discrepancies between the data recorded in CBIFR's and OEP's inventory systems and the actual physical counts of their inventories. In our most recent review, we noted that, while some discrepancies did still exist, the accuracy of both CBIRF and OEP inventory records had improved significantly. However, we found that OEP lacks certain detailed written inventory procedures necessary to help ensure the overall reliability of their inventory records.

In addition, while we found that CBIRF had developed an inventory requirements list, which they didn't have at the time of our

last review, it did not have on hand all the items included in the list.

We also found that OEP had not updated its requirements list to reflect changes to the composition of its stockpile.

And, finally, we found that, while CDC had established requirements list for its national pharmaceutical stockpile, the requirements were not completely filled by the end of our field work.

The next area we followed up on was inventory tracking systems. We previously reported that the responsible agencies' inventory systems did not adequately track inventory items, and we recommended that they implement tracking systems that retain complete documentation for all supplies they have 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; however, each agency is currently 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 time it is consumed or otherwise disposed of.

The last area we looked at was rotation. We previously reported that the agencies' inventories included items that had expired but not been replaced, and therefore we recommended that they properly rotate these supplies. In response to our report, we found that all of the agencies have developed policies and procedures related to rotating stock in their inventories; however, in some cases planned approaches were not completely implemented. For example, during our October 2000, counts at CBIRF we found 161 medical supply items had expired but not been replaced.

In addition, at the time of our review CDC had not finalized agreements with a private sector partner to implement a cost-saving strategy to rotate soon-to-expire pharmaceuticals into the commercial marketplace and replace them with fresh stock.

Just to sum up, in completing our most recent work, we did find that all of the agencies have made significant progress toward implementing our October 1999, recommendations. Management in each of the 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 should be taken to ensure that the medical and pharmaceutical supplies are current, accounted for, and readily available for use.

Our current report includes several additional recommendations to address these issues. We do understand that since the completion of our review some actions have been taken by the agencies in response to our recent findings.

That concludes my statement, Mr. Chairman. We'd be happy to answer any questions at this time.

Mr. PUTNAM. Thank you very much.

[NOTE.—The GAO report entitled, "Combating Terrorism, Accountability Over Medical Supplies Needs Further Improvement," GAO–01–463, may be found in subcommittee files.]

[The prepared statement of Ms. Calbom follows:]

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on National Security, Veterans Affairs and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
2:00 p.m.
Tuesday,
May 1, 2001

COMBATING TERRORISM

Accountability Over Medical Supplies Needs Further Improvement

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

AO-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.

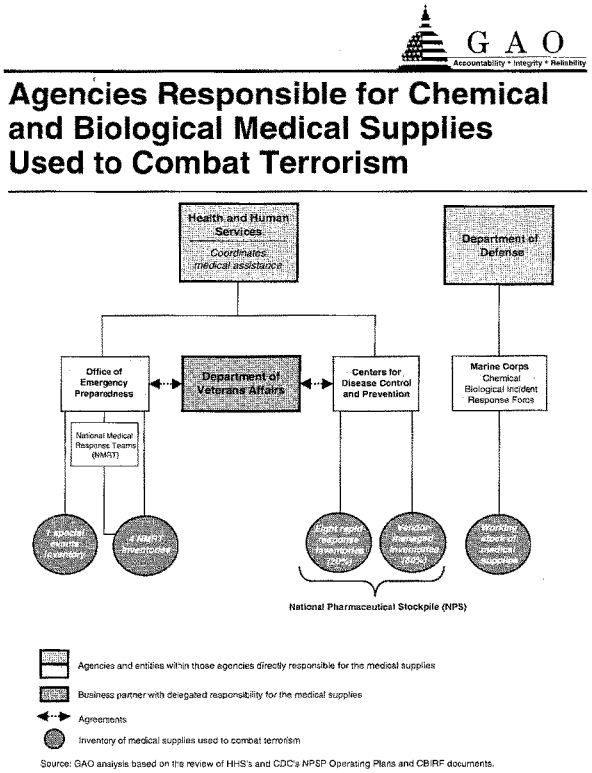
In commenting on our report, the responsible agencies generally agreed with our recommendations and agreed to take corrective actions.

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


GAO
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)
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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Mr. PUTNAM. To what extent have the agencies responded to the 13 new recommendations?

Ms. CALBOM. They've done actually quite a bit already. In the course of our review I think, you know, they were aware of our findings as we came across them. They have put into place some of the agreements with third parties that we talk about in our report. For instance, I know OEP has completed its agreements with VA. I believe that CDC has completed a lot of its agreements with its wholesale distributor. There are still a couple areas where we have concerns. For instance, CDC has not completed all of its agreements, or at least last that we knew of, with some of its carriers to ensure proper transport of these supplies, which we think is very important.

I'll ask Ms. Stanfield if she'd like to add on to some of the areas that perhaps improvements have been made.

Ms. STANFIELD. Actually, a couple areas where the recommendations are still open—as you know, in our report we talk about one of the locations, the central location at OEP, where the goods were stored at temperatures at 95 degrees or above, and also at that same location there were security issues. There was not an alarm on the cage.

And, as we understand it, they do plan to move that cache to a new location some time. They had originally planned to move it in April, but they will be moving that in the May/June timeframe instead. So that's one area that is open.

We are particularly, on the positive side, pleased with the improvements in the inventory discrepancy rates, and those have improved.

At CBIRF the one open recommendation, which I'm sure they will discuss, too, is the fact that there is a new authorized medical allowance list, and we have recommended that they stock up to that list, and they have not yet done so, but they will probably provide you some updates on that.

Mr. PUTNAM. Is there a single inventory management system that CBIRF and the other agencies are using so that there is some uniformity to the categorization and cataloging of the pharmaceuticals?

Ms. CALBOM. Well, Mr. Chairman, all three of the agencies are working on getting the inventory systems in place. CDC is taking the lead as far as the HHS side of things, and I believe their system is due to be in place in May or June, which I'm sure they'll update us on. That same system will be used by OEP, and then CBIRF has its own system that it is putting in place, and I believe we were just told that may be delayed until September.

Mr. PUTNAM. So everybody is on the same page then except CBIRF?

Ms. CALBOM. Yes. And, of course, CBIRF is a little bit different, you know. Their inventory is really more of a self-contained inventory. Their mission is a bit different. They really aren't in the business of having in place a stockpile to treat the masses, as OEP and CDC are. CBIRF's stockpile is really more or less to treat their own troops or civilians that happen to be in the area where they are carrying out their mission.

Mr. PUTNAM. Would you elaborate a little bit on the difficulty that they've had in making arrangements with transport and mobilization contractors? You know, contemplating the scenario where we would need to have those arrangements in place, who is the ideal subcontractor to deliver that kind of a supply, enter that kind of a hot zone? What avenues have been explored? What current arrangements are in place as it relates to that?

Ms. CALBOM. I guess, as far as who is the ideal person, I don't know that we can answer that. That's not something that we've really done an assessment of. But Alana may want to expand on what kind of arrangements are currently in place.

Ms. STANFIELD. Currently they do have arrangements with two transport companies. They are interim arrangements. Those, as of the end of our field work, though, had not been finalized, but they do have arrangements with two transport companies that are very well known.

Mr. PUTNAM. And, finally, the mobile stockpile that is available for special events such as the Olympics, what other instances or gatherings are appropriate uses for the mobilization of that stockpile? And is that limited to the United States or is that international events abroad, as well?

Ms. STANFIELD. Another example of an event would be like the inauguration. I believe it is just for domestic events, but you might want to check with them just to make sure.

Mr. PUTNAM. OK.

Ms. STANFIELD. But I'm pretty sure it is just for domestic.

Mr. PUTNAM. We welcome Chairman Shays.

Mr. SHAYS. Thank you, Mr. Chairman. I'm very apologetic to have missed the testimony of the first panel.

I have no questions. I just want to say that I lost a good friend of mine, Barbara Bate, and her husband was a State legislator, and we got elected in 1974, and I just learned about it today, so I wanted to make sure I went to see him back in Connecticut, but I will be ready for the next panel.

I thank you very much.

[The prepared statement of Hon. Christopher Shays follows:]

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Statement of Rep. Christopher Shays
May 1, 2001

In the event of mass casualties inflicted through the use of chemical, biological or radiological weapons, state and local public health officials will need help. They will look for timely access to federal stockpiles of the antidotes, antibiotics and vaccines necessary to save lives.

Will those critical medicines get there in time?

Last year, we could not be certain. Weak internal controls, lax security and sloppy inventory management practices increased the risks of stockpiling the wrong medicines, expired medicines or not enough of the medicines needed to meet the consequences of a terrorist attack.

Today, the General Accounting Office (GAO) releases a report requested by this Subcommittee on steps taken to address those weaknesses.

According to GAO, the Department of Health and Human Services' Office of Emergency Preparedness (OEP) and the Centers for Disease Control and Prevention (CDC) have made substantial improvements in both purchasing and stockpile management practices. As a partner with OEP and CDC, the Department of Veterans Affairs has simplified stockpile storage. The Marine Corp's Chemical Biological Incident Response Force has formalized its medical equipment list and upgraded inventory controls.

But GAO remains concerned the extent and pace of improvements continue to pose risks to the adequacy and quality of the stockpiles. Agreements with critical supply and transportation contractors are still incomplete or vague. Security standards are not yet uniform. Temperature monitoring at some storage facilities may be inadequate to protect sensitive supplies from damage. Operational plans and training are not well developed.

The threat of domestic terrorism demands we amass and preposition costly, perishable medical supplies we hope never to use. But when called upon to stem the toll of a terrorist attack, the stockpiles must arrive at the right place, at the right time, containing the types and amounts of medicines needed to save lives.

Testimony today from the GAO, and from those responsible for maintaining federal medical stockpiles and reserves, will describe tangible progress toward that goal. We welcome their testimony, and look forward to a discussion of how they plan to meet the substantial challenges of preparing for medical contingencies on an unprecedented, almost unthinkable, scale.

Mr. PUTNAM. Thank you, Mr. Chairman.

And that concludes the questions for the first panel. We appreciate your hard work and diligence on this issue, and we look forward to hearing from panel two.

Ms. CALBOM. Thank you.

Mr. PUTNAM. Thank you.

While we're setting up for the second panel, I ask unanimous consent that all members of the subcommittee be permitted to place any opening statement into the record and that the record remain open for 3 days for that purpose.

Without objection, so ordered.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Opening Statement
Representative Dennis J. Kucinich

Ranking Member
Subcommittee on National Security,
Veterans Affairs, and International Relations

May 1, 2001

GOOD ~~MORNING~~ AFTERNOON. LET ME WELCOME OUR WITNESSES FROM THE GENERAL ACCOUNTING OFFICE, AS WELL AS THE DISTINGUISHED OFFICIALS FROM THE VARIOUS AGENCIES WHO WILL TESTIFY IN THE NEXT PANEL. I AM GLAD YOU ALL COULD BE WITH US TODAY.

I WAS NOT RANKING MEMBER WHEN THIS SUBCOMMITTEE HELD ITS PREVIOUS HEARING ON THIS ISSUE IN MARCH OF 1999. I HAVE REVIEWED G.A.O.'S RECOMMENDATIONS FROM THAT HEARING, HOWEVER, AND I AM HEARTENED BY THE PROGRESS MADE TOWARD IMPLEMENTING THEM.

I RECOGNIZE THAT G.A.O. HAS SOME CONTINUING ISSUES, AND I COMMEND THEM ON THEIR THOROUGH AND DETAILED OVERSIGHT OF THIS PROGRAM. IN FACT, I CONGRATULATE BOTH G.A.O. AND THE AGENCIES FOR WORKING TOGETHER AFFIRMATIVELY TO IMPROVE THE PROGRAM.

I ALSO WANT TO THANK THE CHAIRMAN AND HIS STAFF FOR THEIR CONTINUED VIGILANCE AND THEIR EFFORTS TO FULFILL THE

MISSION OF THIS COMMITTEE, WHICH IS TO PREVENT WASTE, FRAUD, AND ABUSE, AND TO ENSURE THAT THE AMERICAN TAXPAYERS GET THE MOST PROTECTION FOR THEIR MONEY.

SINCE I WAS NOT RANKING MEMBER LAST CONGRESS, I DID NOT CONTRIBUTE TO FRAMING THE ISSUES THAT WE CONTINUE TO REVIEW TODAY. IF I MAY, HOWEVER, I WOULD LIKE TO ADD ONE OBSERVATION THAT PERHAPS COULD BE INCORPORATED INTO A FUTURE HEARING OR G.A.O. STUDY.

IN THIS SUBCOMMITTEE'S PAST FEW HEARINGS ON TERRORISM ISSUES, WE HAVE HEARD VARIOUS PROPOSALS TO RESTRUCTURE FEDERAL AGENCIES, TO REVISE FEDERAL SPENDING, AND TO REVISIT ACCOUNTABILITY STANDARDS ~~SPENDING PRIORITIES~~. THE COMMON LINK AMONG THESE PROPOSALS IS A REQUIREMENT TO CONDUCT A COMPREHENSIVE THREAT AND RISK ASSESSMENT. ALTHOUGH IT MAY BE OUTSIDE THE SCOPE OF TODAY'S HEARING, I WOULD BE INTERESTED TO KNOW HOW SPENDING LEVELS FOR THESE MEDICAL STOCKPILE PROGRAMS WERE DETERMINED.

HOW DO WE KNOW THAT SPENDING $51 MILLION PER YEAR ON VACCINES, ANTIBIOTICS, AND OTHER MEDICAL SUPPLIES IS THE MOST EFFECTIVE USE OF FEDERAL DOLLARS? PERHAPS WE SHOULD BE SPENDING MORE? HOW DO WE KNOW THAT THE TYPES, QUANTITIES, AND PLACEMENT OF STOCKPILED PHARMACEUTICALS ARE PROPORTIONAL TO THE VARIOUS THREATS POSED?

THESE ARE JUST A FEW OF THE BROADER QUESTIONS I THINK MIGHT BE ADDRESSED AT A LATER DATE. FOR NOW, I LOOK FORWARD TO G.A.O.'S UPDATE AND REPORTS BY THE AGENCIES CONDUCTING THIS PROGRAM.

THANK YOU, MR. CHAIRMAN.

Mr. PUTNAM. I ask further unanimous consent that all witnesses be permitted to include their written statements in the record.

Without objection, so ordered.

Pursuant to House rules and committee rules I note for the record that the subcommittee requested and all witnesses appearing at this hearing in a non-governmental capacity have provided a resume and a disclosure of Federal grants and contractor receipt.

With that, we welcome the second panel: Dr. Susan Mather, Dr. Robert Knouss, Dr. James Hughes, Mr. Steven Bice, and Colonel Carlos Hollifield.

If you would, please stand, raise your right hands, and any other persons accompanying the witnesses who may be called upon to answer a question, please stand and raise your right hand.

[Witnesses sworn.]

Mr. PUTNAM. Note for the record that the witnesses responded in the affirmative.

Mr. SHAYS. I'd just like to note, Mr. Chairman, I was going through withdraw. When you stood up, I felt I should have stood up, as well. [Laughter.]

Mr. PUTNAM. With that, Dr. Susan Mather, if you would please begin with your testimony. Welcome to the committee.

STATEMENT OF SUSAN MATHER, CHIEF, PUBLIC HEALTH AND ENVIRONMENTAL HAZARDS OFFICE, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY JOHN OGDEN, CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT STRATEGIC HEALTH GROUP; AND KRISTI L. KOENIG, CHIEF CONSULTANT, EMERGENCY MANAGEMENT STRATEGIC HEALTHCARE GROUP; ROBERT F. KNOUSS, DIRECTOR, OFFICE OF EMERGENCY PREPAREDNESS, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY MARK GNITZKE, CHIEF PHARMACIST; AND TERRY WAGNER, FINANCE OFFICER; JAMES M. HUGHES, DIRECTOR, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ACCOMPANIED BY STEVEN D. BICE, DIRECTOR, NATIONAL PHARMACEUTICAL STOCKPILE PROGRAM, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH; AND COLONEL CARLOS R. HOLLIFIELD, COMMANDING OFFICER, CHEMICAL BIOLOGICAL INCIDENT RESPONSE FORCE [CBIRF], U.S. MARINE CORPS, DEPARTMENT OF DEFENSE, ACCOMPANIED BY COMMANDER CORLEY PUCKETT, SECOND MARINE EXPEDITIONARY FORCE SERGEANT'S OFFICE

Dr. MATHER. Thank you, Mr. Chairman and members of the subcommittee. I am pleased to have this opportunity to address the significant progress that VA has made in response to GAO's October 1999, report concerning management of chemical and biological medical supplies.

I am accompanied by Dr. Kristi Koenig, chief consultant of the Emergency Management Strategic Healthcare Group [MSHG], and Mr. John Ogden, chief consultant of the Pharmacy Benefits Management strategic Health Group.

VA is a partner with HHS' Office of Emergency Preparedness in assuring the availability of medical supplies that may be needed by

the national medical response teams to treat victims where weapons of mass destruction have been used.

OEP officials determine the contents of the inventories; provide funding for the procurement, maintenance, and deployment of the medical supplies; and determine the location of the stockpiles at sites across the United States.

The partnership between OEP and VA began late in 1995 and evolved to a formal interagency agreement in April 1997. MSHG has overall VA responsibility for emergency management activities while VA's emergency pharmacy service is directly responsible for managing the pharmaceutical and medical supply stockpiles and works in coordination with MSHG.

I am pleased to describe VA's actions to address each of the four recommendations from the 1999 GAO report.

First, GAO recommended that all the agencies, including VA, establish sufficient systems of internal control over management of their chemical and biological stockpiles so that the stockpiles could be provided, as planned.

To implement this recommendation, OEP contracted with Logistics Management Institute to evaluate the program, conduct a risk assessment, and advise us on areas for improvement. MLI reviewed the program from April to August 2000, and reported their findings to EOP in December 2000.

Concurrently, the Emergency Pharmacy Service implemented numerous improvements to simplify the inventory process, refine the inventory data base, improve cache security, color code all inventory categories, monitor storage temperatures, and improve inventory results. LMI noted many of these improvements in their reports and recommended adding an inventory management system with bar codes. OEP has selected a computer package that will be implemented during the summer of 2001.

Second, GAO recommended that the agencies arrange for periodic independent inventories of the stockpiles. The results of each inventory showed improvement over the previous, including a less than 1 percent discrepancy rate from the November inventory. Inventories will be continuing in 2001.

Third, GAO recommended that VA implement a tracking system that retains complete documentation for all supplies that have been ordered, received, or destroyed. In January 2000, VA began using an enhanced inventory management system. The resulting data base was verified during the April 2000, inventories. LMI reviewed this inventory management system and recommended that it be replaced by a commercial system that would provide additional enhancements. OEP decided we would use the same inventory management system CDC selected for use with the national pharmaceutical stockpile, and training will begin this month.

Fourth, GAO recommended that supplies be rotated properly, and this is now being done. The current inventory management system allows for the necessary planning for ordering, receiving, shipping, and rotating stock at each location on a timely basis. No outdated drugs or supplies were found in the caches at the August and November 2000, inventories. The new inventory management system should enhance this capability.

Mr. Chairman, I would like to close with a description of additional actions taken since the testimony provided you in March 2000.

First, GAO conducted a followup review of this program from August to November 2000. The draft report of this visit indicates that GAO was pleased with the progress VA has made.

Second, VA moved the one cache that was stored outside VA control into a VA warehouse location. Both LMI and GAO have favorably reviewed this site.

Third, VA placed refrigerator units with a self-contained battery pack at all sites that will maintain refrigeration of stockpile when deployed or when there is a power failure.

Fourth, VA replaced all products at the central—will replace all products at the central cache that may be heat sensitive as soon as the cache is moved to the new storage location. The new storage location has been selected. Plans have been approved for the necessary construction, and the contractor has been chosen. The move is currently targeted for June 2001.

Fifth, an update to the 2000 MOA between OEP and VA further defining expectations and responsibilities has been developed and is in the clearance process with MVA.

Sixth, VA initiated an internal risk assessment group, including members with financial security, emergency management, and risk assessment expertise. The group is charged with conducting a new risk assessment and reporting findings to VA officials and ultimately OEP later this year.

Seventh, to improve security at each cache, installation of locking devices at the access point is underway. These devices will record date, time, and the individual gaining access.

Eight and finally, all the caches were successfully deployed and then returned to storage.

Mr. Chairman, the management of the emergency supplies has greatly improved since the first GAO review. We appreciate the benefits of GAO's work on the Congress' behalf. Should incidents involving the use of weapons of mass destruction occur, we are prepared to meet our responsibilities as part of the Nation's readiness capability.

Dr. Koenig, Mr. Ogden, and I would be happy to respond to questions.

Mr. PUTNAM. Thank you very much. We appreciate your testimony.

[The prepared statement of Dr. Mather follows:]

STATEMENT OF
SUSAN H. MATHER, M. D., M.P.H.
CHIEF OFFICER, PUBLIC HEALTH AND ENVIRONMENTAL HAZARDS
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS
COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES

MAY 1, 2001

Mr. Chairman and Members of the Subcommittee:

I am pleased to have this opportunity to address the significant progress that VA has made pursuant to GAO's October 1999 report concerning management of chemical and biological medical supplies. I am accompanied by Dr. Kristi L. Koenig, Chief Consultant, Emergency Management Strategic Healthcare Group, and Mr. John Ogden, Chief Consultant, Pharmacy Benefits Management Strategic Healthcare Group.

BACKGROUND

As you recall from the hearing in March of last year, one of VA's missions is to ensure health care for eligible veterans, military personnel, and the public during Department of Defense (DoD) contingencies and natural, manmade, and technological emergencies. VA has assigned lead responsibility for this mission to the Emergency Management Strategic Healthcare Group (EMSHG), which is headquartered at the Martinsburg, WV, VA Medical Center. The primary responsibilities and authorities governing VA's program implementation are outlined below.

- VA/DoD Contingency Hospital System, Public Law 97-174, May 1982, requires VA to serve as the primary contingency back-up to DoD medical services.

- National Disaster Medical System (NDMS) was established in 1984 by agreement between DoD, Department of Health and Human Services (HHS), VA, and Federal Emergency Management Agency (FEMA). It operates to provide capability for treating large numbers of patients who are injured in a major peacetime disaster within the continental United States, or to treat casualties resulting from a conventional military conflict overseas.
- Federal Response Plan, required by Public Law 93-288, the Robert T. Stafford Act as amended, April 1992, established the architecture for a systematic, coordinated, and effective Federal response to a disaster or emergency situation.
- Executive Order 12656, Assignment of Emergency Preparedness Responsibilities, November 1988, charged VA to plan for emergency health care services for veterans, active duty personnel, and, as resources permit, to civilians in communities affected by national security emergencies.
- Presidential Decision Directive – 62, Combating Terrorism, May 1998, tasked U.S. Public Health Service (USPHS), working with VA, with ensuring that adequate stockpiles of antidotes and other necessary pharmaceuticals are maintained nationwide and to train medical personnel in NDMS hospitals.

Under the provisions of the Federal Response Plan (FRP), VA is involved in the planning for, and response to, catastrophic disasters that require federal assistance. Over the past ten years, VA has deployed over 1,000 health care personnel, and provided medical supplies, equipment (including mobile health clinics), and facilities.

Under Presidential Decision Directive 62 (PDD 62), VA has an agreement with USPHS to maintain caches of pharmaceuticals at strategic locations throughout the United States that may be needed for treatment of victims of an event involving weapons of mass destruction (WMD). If an event occurs, these caches would be deployed to the site of the incident to augment the capability of the National Medical Response Teams (NMRTs) that are maintained and directed by the USPHS. In addition, these pharmaceuticals would provide supplemental capability to local medical caregivers and facilities to treat WMD victims.

VA also has an agreement with the Centers for Disease Control and Prevention (CDC) to assist with procurement and maintenance of the supplies under the National Pharmaceutical Stockpile Program (NPSP). This agreement is being revised now to reflect VA's diminished role in maintenance of the stockpile. In both instances VA receives funds from the agencies involved to procure and maintain these stockpiles for the respective agencies.

GAO REPORT - MANAGEMENT OF MEDICAL SUPPLIES

I am pleased to have this opportunity to update the Committee concerning VA's activity as a partner with the Department of Health and Human Services' Office of Emergency Preparedness (OEP) in the procurement, inventory, storage, maintenance and delivery of medical supplies that may be needed by NMRTs to treat victims where weapons of mass destruction may have been used. The development and maintenance of these stockpiles are integral parts of the Nation's ability to provide needed health care following an emergency. OEP officials determine the contents of inventories; provide funding for the procurement, maintenance and deployment of the medical supplies; and determine the locations of the stockpiles at sites across the United States.

The partnership between OEP and VA began in late 1995 and evolved to a formal interagency agreement in April 1997. EMSHG has overall VA responsibility for emergency management activities. VA's Emergency Pharmacy Service (EPS) is directly responsible for managing the pharmaceutical/medical supplies stockpiles and works in coordination with EMSHG. GAO reviewed this program during the summer of 1999 and reported their findings in October 1999. In calendar year (CY) 2000, GAO conducted a follow-up review; their final report is pending. With the above background, what follows is a description of VA's actions to address each of the four recommendations from the 1999 GAO report.

First, GAO recommended that OEP, CDC, the Marine Corps Chemical and Biological Incident Response Force, and VA establish sufficient systems of internal control over their chemical and biological stockpile management to reasonably assure

that personnel conduct risk assessments and organize program activities to identify and mitigate risks so that, when needed, the stockpiles will be provided as planned. To implement this recommendation, OEP contracted with Logistics Management Institute (LMI) to evaluate the program, conduct a risk assessment, and advise us on areas for improvement. LMI reviewed the program from April to August 2000, visited each storage site, and reported their findings to OEP in December 2000. Concurrently, EPS implemented numerous improvements to simplify the inventory process (bagged or banded and labeled like products, adjusted quantities to full manufacturer containers); refine the inventory database (standardize nomenclature, label products to clarify nomenclature, record all lot numbers and expiration dates); improve cache security (extend cages to ceiling, spot weld bolts, seal pallets with security tape); color code all inventory categories; monitor storage temperatures; and improve inventory results. LMI noted many of these improvements in their report. LMI recommended adding an inventory management system with bar codes. OEP has selected a computer package that will be implemented during the summer of 2001.

Second, GAO recommended that the agencies arrange for periodic, independent inventories of the stockpiles. Four complete inventories were conducted during CY 2000 using personnel from EMSHG, EPS and the Office of Acquisition and Material Management. OEP staff participated in the inventories as well. The results of each inventory showed improvement over the previous, concluding in a less than 1% discrepancy rate in the November inventory. The majority of findings were attributed to data discrepancies, particularly expiration date or lot number differences. There were no controlled substance discrepancies, and all outdated products were replaced with fresh stock. All inventory participants were invited to provide suggestions for improvement. At the completion of the November 2000 inventory, all suggestions were reviewed by OEP and EPS to determine lessons learned. Using this information, OEP specified the inventory process and frequency for 2001.

Third, GAO recommended that VA implement a tracking system that retains complete documentation for all supplies that have been ordered, received or destroyed. In January 2000, VA began using an enhanced inventory management system. The resulting database was verified during the April 2000 inventories. LMI reviewed this

inventory management system and recommended that it be replaced by a commercial system that would provide additional enhancements. OEP decided we would use the same inventory management system CDC selected for use with the (NPSP). Training on this system is scheduled to begin in May 2001.

Fourth, GAO recommended that supplies be rotated properly. I am pleased to report that supplies are being rotated properly. The current inventory management system provides reports indicating future expiration dates. These reports allow for necessary planning for ordering, receiving, shipping and rotating stock at each location on a timely basis. No outdated drugs or supplies were found in the caches at the August and November 2000 inventories. The new inventory management system should enhance this capability.

Mr. Chairman, I would like to close with a description of additional actions taken since the testimony provided you in March 2000. First, GAO conducted a follow-up review of this program from August to November 2000. The draft report of this visit indicates that GAO was pleased with the progress that VA has made. Second, VA moved the cache that was stored outside VA control into a VA warehouse location. Both LMI and GAO have favorably reviewed this site. Third, VA placed Vaxicool refrigerator units into service at all sites. These units have a self-contained battery pack that will maintain refrigeration when deployed, or if there is a power failure. Fourth, VA, with HHS funding, will replace all products at the Central cache that may be heat sensitive as soon as the cache is moved to the new storage location. The new storage location has been selected. OEP recently approved the plans for the necessary construction and the contractor has been selected. The move is currently targeted for June 2001. Fifth, an update to the 2000 MOA between OEP and VA has been developed and is in the clearance process within VA. The MOA further defines responsibilities and expectations by OEP and VA. Sixth, VA has initiated an internal Risk Assessment Group, including members with financial, security, emergency management, and risk assessment expertise. The group is charged with conducting a new risk assessment and reporting findings to Pharmacy Benefits Management Strategic Healthcare Group (PBMSHG), EMSHG and ultimately, OEP later this year. Seventh, to improve security of each cache, installation of locking devices at the access

point is underway. These devices will record date, time, and the individual gaining access. Eighth, all of the caches were successfully deployed and then returned to storage.

Mr. Chairman, the efforts of OEP and EPS staff to develop, maintain, and deploy emergency supplies have been greatly improved since the first GAO review. We look forward to receiving the findings of our internal risk assessment to make the program more successful in the future. We appreciate the benefits of GAO's work on the Congress's behalf. Should incidents involving the use of weapons of mass destruction occur, we are prepared to meet our responsibilities as a part of the Nation's readiness capability.

Dr. Koenig, Mr. Ogden and I will be happy to respond to questions from the Committee.

Mr. PUTNAM. Dr. Robert Knouss, Director, Office of Emergency Preparedness, Department of Health and Human Services, welcome to the committee. You are recognized.

Dr. KNOUSS. Thank you very much, Mr. Chairman. It is a pleasure to be able to be back here again testifying about these programs.

I'm also accompanied today by my chief pharmacist, Mark Gnitzke, and my finance officer, Terry Wagner.

I appeared here last year before the committee to discuss the original GAO report about our specialized pharmaceutical caches, and I'm pleased to be back here again to be able to discuss with you the improvements that have been made since those initial hearings.

These pharmaceutical stockpiles were designed to be deployed with our NMRTs, or national medical response teams, in responding to a weapon of mass destruction event and providing medical care to its victims.

Three of the teams—one on the West Coast, one in the central part of the country, and one on the East Coast—can be deployed anywhere in the country. The middle Atlantic team is committed to responding to incidents in Washington, DC, including the U.S. Capitol, and I would just like to mention that it is pre-positioned here when we have the State of the Union event or the inauguration or other major events here at the capital.

The stockpiles associated with each of these four teams contains specialized pharmaceuticals to treat up to 5,000 victims of a chemical exposure to nerve agents such as sarin and VX, to vesicants such as mustard gas, and to pulmonary agents such as phosgene. In addition, each stockpile has medicines to provide the initial care at the scene for these victims, stabilizing them medically until they arrive at a health care facility.

In the original report on the status of the stockpiles, GAO raised concerns about the manner in which the caches were managed and the oversight provided by OEP.

We have appreciated GAO's comments, suggestions, and insights, and have been working diligently with the VA to correct problems, improve internal controls, and tighten our management practices.

We have made a great deal of progress in these areas. We've ensured appropriate storage and physical security of the stockpiles; strengthened internal controls, including 100 percent inventories of all the caches, as well as independent reviews; established regular communications with the VA; conducted risk assessments; ensured regular and recurring management oversight; approved operational plans for each location; and ensured that an improved, updated inventory requirement list is maintained.

However, we still have a number of things to do. GAO recently completed its final report on the stockpiles, and we appreciate that they noted the significant progress that we've made to bring these caches into compliance with all the regulations and appropriate internal control procedures.

In its recently released report, GAO commented on some of the progress that still needed to be made and made some additional recommendations to OEP. At this time I'd like to address these recommendations and discuss what we still are doing to complete the

activities, to ensure the stockpiles meet all requirements, and to be able to deploy them in a timely and effective response.

Within the next month or two, we'll be moving our central cache to a new location in order to ensure that appropriate physical security and safeguards are in place, as well as to ensure that temperature controls are maintained. This action will mitigate problems that have occurred at the current location, with some of the cache being exposed to higher-than-acceptable temperatures.

We do not believe that the observed temperature fluctuation degraded the effectiveness of the pharmaceuticals; however, we will be replacing all of the affected drugs when the cache is moved.

While the GAO report notes that the items that were exposed to the higher temperature may not be effective in the event of a terrorist incident, we'd note that we have three other caches that can be moved, if necessary.

GAO noted that OEP lacked detailed, written inventory procedures necessary to help ensure overall reliability of inventory records. They also said that OEP had not updated its requirements list for significant increases to its stockpile. Both of these issues have subsequently been addressed and detailed inventory procedures and operating plans have been approved for each cache location, and detail requirement lists have been updated and transmitted to the VA.

GAO also stated that there were no published discrepancy rates, and that in the absence of this information there were no data with which to measure the inventory results. Error rates have been discussed with the VA. We have a zero tolerance error rate for controlled substance and an error rate of 3 to 5 percent for low-cost items.

Finally, GAO expressed concern about the lack of training for VA personnel involved in stockpile management, and later this month we will be bringing VA personnel, in addition to other public service teams, to the Noble Training Center in Anniston, AL, to conduct training in conjunction with CDC. We will be providing Oracle software training to VA staff for managing cache inventories, and we recently provided HAZMAT training for their staff at the NDMS conference that was held in Dallas.

Mr. Chairman, OEP has been working diligently to ensure that all internal control procedures are met, that the stockpiles are current and adequately safeguarded, and that we can deploy them quickly. It is my sincere hope that these stockpiles will never have to be used, but we will continue to assure our readiness to respond, if necessary.

That, sir, concludes my prepared remarks, and I obviously would be pleased to answer any questions you may have.

Mr. PUTNAM. Thank you very much, sir.

[The prepared statement of Dr. Knouss follows:]

STATEMENT OF

ROBERT F. KNOUSS, M.D.
DIRECTOR, OFFICE OF EMERGENCY PREPAREDNESS
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

COMMITTEE ON GOVERNMENT REFORM

U. S. HOUSE OF REPRESENTATIVES

MAY 1, 2001

Mr. Chairman and Members of the Committee,

Once again, it is my pleasure to appear before this Committee to discuss program activities of the Office of Emergency Preparedness (OEP). I am Dr. Robert Knouss, the Director of OEP.

Last year, I appeared here to discuss the General Accounting Office (GAO) report that had been recently released about the four specialized pharmaceutical caches used by our National Medical Response Teams (NMRTs).

These pharmaceutical stockpiles were designed to be deployed with our NMRTs in responding to a weapon of mass destruction (WMD) event and providing medical care to its victims. Three of the teams (West Coast, Central and East Coast) can be deployed anywhere in the country. The Mid-Atlantic team is committed to responding to incidents in the Washington, D.C. metropolitan area, including the U.S. Capitol. The stockpiles associated with each of these four teams contain specialized pharmaceuticals to treat up to 5,000 victims of a chemical exposure to nerve agents such as sarin and VX; to vesicants, such as mustard gas; and to pulmonary agents such as phosgene. In addition, each stockpile has medicines to provide the initial care at the scene for these victims, stabilizing them medically until they arrive at a health care facility.

In the original report on the status of the stockpiles, GAO raised concerns about the manner in which the caches were managed and the oversight provided by OEP. We have appreciated GAO's comments, suggestions and insights, and have been working diligently with the Department of Veterans Affairs (VA) to correct problems, improve internal controls and tighten OEP management practices.

We have made a great deal of progress in these areas. We have ensured appropriate storage and physical security of the stockpiles; strengthened internal controls, including 100 percent inventories of all of the caches, as well as independent reviews; established regular communications with the VA; conducted risk assessments; ensured regular and recurring management oversight by OEP; approved operational plans for each location; and ensured that an approved, updated inventory requirement list is maintained.

However, we still have a number of things to do. GAO recently completed its final report on the stockpiles. We appreciate that they noted the significant progress that we have made to bring these caches into compliance with all regulations and appropriate internal control procedures.

In its recently released report, GAO commented on some progress that still needed to be made, and made some recommendations to OEP. At this time, I would like to address these recommendations and discuss what we are still doing to complete the activities, to ensure that the stockpiles meet all requirements and to be able to

deploy them in a timely and effective response.

Within the next month or two, we will be moving our Central cache to a new location, in order to ensure that appropriate physical security and safeguards are in place, as well as to ensure that temperature controls are maintained. This action will mitigate problems that have occurred at the current location with some of the cache being exposed to higher than acceptable temperatures. We do not believe that the observed temperature fluctuation degraded the effectiveness of the pharmaceuticals. However, we will be replacing all of the affected drugs when the cache is moved. While the GAO report notes that the items that were exposed to the higher temperature may not be effective in the event of a terrorist incident, we would note that we have three other caches that can be moved if necessary.

GAO noted that OEP lacked detailed written inventory procedures necessary to help ensure overall reliability of inventory records. They also said that OEP had not updated its requirements list for significant increases to its stockpile. Both of these issues have subsequently been addressed. Detailed inventory procedures and operating plans have been approved for each cache location and detailed requirements lists have been updated and transmitted to the VA. I would add that this was, in large part, a procedural matter in that plans had been approved but lacked solely the final signature.

GAO also stated that there were no published discrepancy rates, and that in the absence of this information, there were no data with which to measure the inventory results. Error rates have been discussed with the VA. We established a zero tolerance error rate for controlled substances and an error rate of three to five percent for low cost items.

Finally, GAO expressed concern about the lack of training for VA personnel involved in stockpile management. Later this month, we will be bringing VA personnel, in addition to other Public Health Service teams, to the Noble Training Center in Anniston, AL, to conduct training, in conjunction with CDC, on deploying and distributing the National Pharmaceutical Stockpile. We will be providing Oracle software training to VA staff for managing cache inventories. And we recently provided HAZMAT training for VA staff at the National Disaster Medical System conference that was held last month in Dallas.

Mr. Chairman, OEP has been working diligently to ensure that all internal control procedures are met, that the stockpiles are current and adequately safeguarded, and that we can deploy them quickly. It is my sincere hope that these stockpiles will never have to be used, but we will continue to assure our readiness to respond, if necessary.

That concludes my prepared remarks. I would be pleased to answer any questions you may have.

Mr. PUTNAM. We now look forward to hearing from Dr. James Hughes, the Director of the National Center for Infectious Diseases, Centers for Disease Control and Prevention, Department of Health and Human Services.

Never a dull moment in your line of work, is there?

Dr. HUGHES. That's true, sir.

Mr. PUTNAM. Welcome to the committee.

Dr. HUGHES. Thank you very much, Mr. Chairman. Good afternoon.

I am accompanied by Mr. Steven Bice, Director of CDC's National Pharmaceutical Stockpile Program in our National Center for Environmental Health.

CDC appreciates the opportunity to discuss the national pharmaceutical stockpile, one component of our overall public health response to the threat of bioterrorism.

CDC provides leadership to detect, diagnose, respond to, and prevent illnesses, including those resulting from bioterrorism. In 1998 we issued "Preventing Emerging Infectious Diseases: A Strategy for the 21st Century," our plan to prevent emerging diseases. This plan emphasizes the need to be prepared for the unexpected, whether it be a naturally occurring influenza pandemic or the deliberate release of anthrax spores by a terrorist.

CDC is continuing to build on these efforts. One example is the public health strategy that we are developing with our partners to define priorities to prepare the country to respond to bioterrorism. We have moved aggressively in multiple areas, including preparedness planning, laboratory diagnostics, strengthened surveillance and epidemiologic investigative capacity, and enhanced communications.

Another integral component of public health preparedness has been developing a national pharmaceutical stockpile or NPS which can be mobilized in response to an episode caused by a biological or chemical agent.

The goal of CDC's NPS is to ensure the availability of lifesaving pharmaceuticals and medical supplies for delivery to the site of a biological or chemical terrorism event.

The NPS has two basic components: eight pre-assembled sets of supplies called "12-hour push packages" that can be delivered to the scene of a terrorism event within 12 hours of activation; and vendor-managed inventory, which consists of additional pharmaceuticals and supplies that can be tailored to a specific threat agent and will arrive at the scene within 24 to 36 hours after activation.

CDC provides guidance and oversight of all aspects of the NPS. We have chosen the Department of Veterans Affairs National Acquisition Center as our acquisition partner. An electronic inventory management system has been purchased and will allow for efficient and accurate inventory tracking, ordering, receipt, and scheduled rotation of stock. We have instituted a rigorous quality assurance program to ensure the integrity of the NPS.

I will now comment briefly on the GAO report released today, specifically on its recommendations pertaining to CDC.

We very much appreciate GAO's ongoing contributions to assure that the NPS functions to protect the American people. First, GAO recommends executing written agreements with all NPS program

partners covering storage, management, stock rotation, and transportation. We have final written agreements with our principal commercial partners for storage and rotation, and interim agreements with our transportation partners.

Our partners in storage sites were selected based on their known good business practices, security measures, and procedural methods for handling large pharmaceutical and supply inventories. These strengths enable the NPS to ensure the integrity of the inventory and to maintain readiness.

GAO's second recommendation to CDC is to issue written security guidance to private storage warehouses. Each NPS storage partner has procedures in place to admit only authorized individuals to the facilities. We are updating the standard operating procedures to include controlled access to NPS inventory and guidelines for stock rotation. The first quantity of stock has been successfully rotated.

Finally, GAO recommends installing proper fencing to physically secure the NPS inventory. Although fencing does provide an additional level of security, it was also intended to separate NPS assets from other materials within a larger warehouse.

The facilities chosen to store the push packages are bonded, licensed by the Food and Drug Administration, or approved by the Drug Enforcement Administration and operate under strict security controls to ensure the environmental and physical safety of pharmaceuticals. Fencing has been installed at all locations for which it was intended.

In summary, the NPS involves direct coordination and management by CDC staff, ongoing monitoring, quality assurance, and evaluation, and collaboration with partners.

Through our NPS program, we will continue to ensure the rapid availability of life-saving pharmaceuticals and medical supplies to the Nation in the event of a biological or chemical terrorism incident.

Mr. Chairman, this concludes my testimony. Mr. Bice and I will be happy to answer any questions you or members of the subcommittee may have.

Mr. PUTNAM. Thank you very much, Dr. Hughes.

[The prepared statement of Dr. Hughes follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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TESTIMONY OF

JAMES M. HUGHES, M.D.

DIRECTOR

NATIONAL CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL AND PREVENTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS,
AND INTERNATIONAL RELATIONS

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

May 1, 2001

Good afternoon, Mr. Chairman, and Members of the Subcommittee. I am Dr. James M. Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied by Steven D. Bice, Director of the National Pharmaceutical Stockpile program, in CDC's National Center for Environmental Health. I appreciate the opportunity to update you on the activities of CDC's National Pharmaceutical Stockpile program, one component of CDC's overall public health response to the threat of bioterrorism. Significant progress in the development of the stockpile has been made since a hearing on this subject approximately one year ago.

As the Nation's disease prevention and control agency, it is CDC's responsibility on behalf of the Department of Health and Human Services (DHHS) to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent illnesses, including those that occur as a result of bioterrorism or any other deliberate attempt to harm our citizens. This task is an integral part of CDC's overall mission to monitor the health of the U.S. population. This mission unfolds every day in various forms, such as disease outbreak response, concern for worker safety, and critical work in global health. CDC, working with other partners inside and outside of DHHS, also has significant experience in responding to explosions and chemical related events and emergencies.

In 1998, CDC issued *Preventing Emerging Infectious Diseases: A Strategy for the 21st Century*, which describes CDC's plan for combating today's emerging diseases and preventing those of tomorrow. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research to develop diagnostic tests, drugs, vaccines, and surveillance tools; infrastructure and training; and disease prevention and control. This plan emphasizes the need to be prepared for the unexpected -- whether it be a

naturally occurring influenza pandemic or the deliberate release of anthrax by a terrorist. Copies of this CDC plan have been provided previously to the Subcommittee.

CDC is continuing to build on these efforts. An example of this is a public health strategy that CDC is developing with its partners to define the specific activities that will need to be conducted over the next several years to ensure that the country is prepared to respond to any threat or actual act of bioterrorism.

Unlike an explosion or a tornado, in a biological event, it is unlikely that a single localized place or cluster of people will be identified for traditional first responder activity. The initial responders to such a biological attack will include hospital staff, members of the outpatient medical community, and a wide range of response personnel in the public health system, in conjunction with county and city health officers.

Increased vigilance and preparedness for unexplained illnesses and injuries are an essential part of the public health effort to protect the American people against bioterrorism. Toward this end, CDC, working in collaboration with State and local health departments, many other public health partners, and other Federal agencies, has begun the effort to upgrade public health capabilities locally and nationally to respond to biological and chemical terrorism. With these partners, CDC has moved aggressively in multiple areas, including model preparedness planning, developing national biological and chemical agent laboratory diagnostic capacity, promoting laboratory security to prevent the misuse of dangerous biological or chemical agents, strengthening surveillance and epidemiologic investigation capacity, and enhancing communications systems, particularly at the local level. Another integral component of public health preparedness has been the development of a National Pharmaceutical Stockpile (NPS), which can be mobilized in response to an episode caused by a biological or chemical agent.

Today I will be discussing CDC's ongoing development and implementation of the pharmaceutical stockpile, but it should be stressed that for its optimal utilization nationally, it should be developed in concert with the other five areas of the public health infrastructure just mentioned.

The role of the CDC's NPS program is to maintain a national repository of life-saving pharmaceuticals and medical materiel that can be delivered to the site of a biological or chemical terrorism event in order to reduce morbidity and mortality in a civilian population. The NPS is not considered to be a first response tool, but rather a backup and means of support to state and local first responders and public health officials. Key elements of the NPS program include procurement, logistics/transportation, readiness/response, training, operational research/evaluation, and quality assurance/monitoring. The CDC has developed this program in collaboration with federal and private sector partners and with input from the states.

Components of the Stockpile

The NPS program consists of a two-tier response. The first tier consists of 12-hour push packages, which are pre-assembled arrays of pharmaceuticals and medical supplies that can be delivered to the scene of a terrorism event within 12 hours of the federal decision to deploy the assets. The push packages will allow for the treatment or prophylaxis of disease caused by a variety of threat agents. There are now eight identical push packages which will be stored at strategic locations across the United States.

In the past year, special air cargo containers were designed and purchased by the NPS program. Load plans were developed for each air cargo container, and most of the push packages have been loaded into these air cargo containers. Load plans have also been developed for all common types of civilian and military aircraft.

Secure, environmentally controlled warehouse space meeting all applicable Food and Drug Administration (FDA) and Drug Enforcement Administration regulations has been identified, with contracts negotiated. These storage sites are now in use, have been secured, and have limited access. The parent companies for these storage sites also partner with the NPS program to assist in stock rotation and replacement. Inventory is flagged prior to expiration so it can be resold and replaced with fresh stock. At present, nearly all of the eight push packages have been moved to their permanent locations, and the first round of expiring inventory has been successfully rotated.

The second tier is the Vendor-Managed Inventory (VMI), which will arrive at the scene 24 to 36 hours after activation. The VMI packages consist of additional pharmaceuticals and medical supplies and will be sent if more supplies are needed. They can be tailored to a specific threat agent which should be identified within that time frame using the resources of the Laboratory Response Network for Bioterrorism, a collaborative effort of CDC, the Association of Public Health Laboratories, and other federal and state public health partners. CDC has put in place two of the VMI contracts and is in final negotiations with pharmaceutical companies to provide the remainder of these services to the NPS program.

Contents of the Stockpile

CDC is continuing its ongoing deliberative process to guide purchasing decisions for the NPS program. In 1999, CDC convened two working groups of experts including representatives from the intelligence community, DHHS, academic experts, and state and local health authorities to provide extensive input to the initial formulary. This panel will be reconvened this summer. A medical review panel has been established, and is consulted on all formulary decisions and equipment selections. CDC also continues to work with the intelligence community and various national security agencies to stay abreast of any potential emerging bioterroism threat agents.

Antibiotics have been purchased for the treatment and prophylaxis of anthrax, plague, and tularemia. The 12-hour push packages are in place for plague, tularemia, and chemical agents based on the predicted affected population for these agents as outlined in the DHHS Operating Plan for Anti-Bioterrorism Initiative, Fiscal Year 1999. Additional pharmaceuticals, supplies, and equipment are being purchased to meet the readiness capability levels required for other agents.

CDC has begun the additional research, regulatory, and production steps required to meet the needs for smallpox and botulism preparedness. CDC has entered into a contract with Acambis (formerly OraVax) to produce new generation smallpox vaccine to supplement the existing stockpile of vaccine. Studies are also underway, in collaboration with the National Institutes of Health, to determine if the existing vaccine will retain its effectiveness if it is diluted, which would allow for more vaccinations from the existing quantity of vaccine. For botulism, CDC is working with the Department of Defense on development of a botulinum antitoxin.

Deployment Process for the Stockpile

The decision to deploy will be based on the best epidemiological, laboratory, and public health information regarding the threat. A potential scenario for a bioterrorist event would be that CDC, at the request of a state health department, would begin investigating an unusual pattern of illness or injury and conclude that the outbreak might be the result of bioterrorism. When a biological or chemical terrorist incident is suspected, CDC will begin or intensify surveillance activities, laboratory confirmation procedures, notification of appropriate Federal agencies, and provision of pertinent technical support. If the stockpile is needed, 12-hour push packages will be deployed initially, followed by specific vendor managed inventory packages as warranted. A Technical Advisory Response Unit (TARU) will be deployed wherever stockpile material is sent. The TARU consists of pharmacists, public health experts, and emergency responders. These

advisors are prepared to help states and cities with transfer of the push packages to the designated official and with other issues surrounding the NPS. They will also be in constant contact with the NPS operations center.

CDC has negotiated contracts with commercial cargo carriers to provide for the rapid transport of the stockpile. These carriers will provide transportation at a moment's notice, via ground or air, to any U.S. location.

Stockpile Management

The CDC provides guidance, oversight, and evaluation of all aspects of the NPS. All staff members bring professional backgrounds and technical expertise to a variety of issues related to the management of the NPS.

CDC has chosen the Department of Veterans Affairs National Acquisition Center (VA NAC) as its acquisition partner for the NPS, and this partnership has proved to be beneficial and has resulted in cost savings through negotiation of favorable prices and contracts. VA NAC has dedicated a staff person as the single point of contact committed to NPS matters. VA NAC and CDC have worked closely to acquire all the pharmaceuticals and medical supplies that comprise the stockpile. VA NAC was instrumental in negotiating contracts for storage locations and transport of the stockpile. VA NAC is also aiding in negotiation of VMI contracts.

An electronic inventory management system has recently been purchased and will allow for efficient and accurate inventory tracking, ordering and receipt of all products, status of transactions, and scheduled rotation of stock to maintain current expiration dating. CDC expects this system to be fully implemented by this summer, and it will be available to all requiring

access to this information. The new electronic system replaces the current labor-intensive system.

The CDC has instituted a rigorous quality assurance and quality control program in order to ensure the integrity of the NPS. Site visits are made quarterly to each storage location. In addition to scheduled visits, unannounced visits are also made to each location. CDC staff use a standardized protocol to cover all aspects of NPS program responsibility, including storage, security, and deployment procedures. Partners are held accountable to correct any deficiencies noted at the time of inspection. To date, no deficiencies have been discovered.

Participation in exercises at local, state, and national levels has also occurred in the past year. The NPS program has had representation at numerous tabletop exercises and has participated in large-scale national exercises such as Launch Relief 2000 and TOPOFF. These exercises were conducted to test the responsiveness of the federal systems to a terrorist event. Further participation is scheduled throughout the coming year.

CDC's NPS program continues to work with other key federal partners involved with issues surrounding management and deployment of the stockpile. These agencies include the Federal Bureau of Investigation (FBI), FDA, and the Federal Emergency Management Agency (FEMA). CDC's staff efforts have increased in order to provide technical assistance to the states and cities receiving the NPS.

An intense effort is underway to fully inform state and local responders about the specifics of the stockpile. All FEMA regions have been briefed on the NPS. In addition, two face-to-face training sessions were held at CDC with invitees from both public health planning and emergency management units from all 50 states. Further sessions will be conducted in the

future. CDC also has recently begun helping states plan for dispensing medications in the stockpile.

Comments on GAO Report

I would like to comment on the U.S. General Accounting Office report released today, *Combating Terrorism: Accountability Over Medical Supplies Needs Further Improvement.* CDC reviewed a draft of the report, which recognized the substantial effort that CDC and other DHHS agencies have made to improve the management of their pharmaceutical stockpiles since GAO's October 1999 report on the subject. CDC appreciates the ongoing contributions of GAO to assure the NPS functions to the maximal benefit of the American people.

In its draft report, GAO recommended executing written agreements (including standard operating procedures and finalized contractual agreements) with all NPS program partners covering storage, management, stock rotation, and transportation. CDC agrees with the need to have final written agreements. Currently, CDC has final written agreements/contracts with principal commercial partners for storage and rotation, as well as interim SOPs and contractual agreements with transportation partners. It is also of note that the NPS program used existing contractual agreements that were in place between the VA and commercial partners before purchasing or placing assets at storage locations.

CDC selected its program partners and storage location sites based on their known good business practices, security measures, and procedural methods associated with handling large pharmaceutical and medical materiel inventories. These strengths enable the NPS program to ensure the integrity of the inventory and the ability of the program to maintain readiness. While some final contractual agreements are in place, others are undergoing legal evaluation. CDC will

finalize all outstanding SOPs; once completed, the SOPs and written contractual agreements will serve to codify procedures already in place.

In its second recommendation to CDC, GAO recommended that CDC issue written guidance on security (i.e., access to storage sites for rotation purposes) to two private warehouse storage facilities. GAO expressed concern that, without adequate SOPs or a final written contractual agreement in place to guide access and security control activities, there is increased risk of unauthorized access to NPS inventory, and that inventory may not be rotated in a consistent and timely manner.

CDC agrees that written guidance is necessary. In regard to access and rotation, each NPS program storage partner has procedures in place to ensure admittance of only authorized individuals to their facilities. CDC is in the process of updating the existing SOP to ensure it includes information regarding controlled access to NPS inventory (particularly at private warehouses) and key responsibilities and guidelines for stock rotation. The first quantity of stock has been successfully rotated prior to expiration.

CDC's NPS program uses a stringent regimen of regularly scheduled quality assurance/quality control inventory checks and unannounced visits in order to assure that NPS inventory is accounted for and secure.

In its third recommendation to CDC, GAO recommended installation of proper fencing as a theft deterrent at selected storage sites prior to placement of inventory. The draft report identified inventory as having been at risk for pilferage and theft for several months due to lack of fencing.

Fencing was installed to serve as a demarcation of NPS assets within a larger warehouse, and it has provided an additional level of security at nominal expense. CDC believes there has been no risk of theft of materiel during the initial months of 12-hour push package placement, as the commercial facilities chosen to store the push packages are bonded, FDA-licensed, or DEA-approved warehouses that operate under strict security controls. All aspects of the existing operations are designed to ensure the environmental safety and physical integrity of pharmaceuticals and eliminate all risks of loss/theft.

The regularly scheduled quality assurance/quality control monitoring of NPS inventory, unannounced visits to each location, and other redundancies built into the program further contribute to elimination of the risk of loss/theft.

GAO recognized the extensive effort that went into the development of the NPS "rotation in place" concept, which allows the program to prevent unnecessary waste due to expiring materiel. However, we would like to clarify the timetable associated with this concept. The wholesale distributor requires six months of shelf life left on a product in order to sell it to another customer and replenish the NPS stock with fresh product. However, the NPS program begins "flagging" the inventory one year before it expires to ensure adequate resale time for the wholesale distributor. The majority of the inventory totaling $4.3 million identified in the GAO draft report as being "at risk" has already been rotated. CDC has until June 2001 to complete rotation of that stock.

The GAO draft report also noted that CDC had followed its internal guidelines for establishing the composition and stock levels of medical supplies. Additionally, no expired items were found in NPS inventory, nor were there any unresolved discrepancies between NPS inventory and management system data.

CDC was tasked with creating the NPS in fiscal year 1999, and much has been achieved since then. The NPS program involves direct coordination and management by CDC staff; ongoing monitoring, quality assurance, and evaluation; and the formation of partnerships with ongoing collaboration and communication.

Through its NPS program, CDC will continue to ensure the availability and rapid deployment of life saving pharmaceuticals and medical materiel to the nation in the event of a biological or chemical terrorism incident. Current priorities for the remainder of 2001 include finalizing contractual arrangements for storage and transportation of 12-hour push packages and VMI, continuing procurement of medical materiel to meet target levels for all threat agents, and finalizing standard operating procedures and memoranda of understanding for storage, management and transport of the 12-hour push packages and VMI.

Thank you, Mr. Chairman and members of the Subcommittee, for the opportunity to testify before you today about CDC's National Pharmaceutical Stockpile Program. I will be happy to answer any questions you may have.

Mr. PUTNAM. The committee also welcomes Colonel Carlos Hollifield, Commanding Officer, Chemical Biological Incident Response Force, U.S. Marine Corps. Welcome. You are recognized.

Colonel HOLLIFIELD. Thank you. Good afternoon, Mr. Chairman.

With me today is Commander Corley Puckett from the Second Marine Expeditionary Force Sergeant's Office, which is my higher headquarters. I'm honored to again have the privilege to appear before this subcommittee and want to be thankful for the opportunity to update you on the actions that we've taken to improve internal control over the medical supply working stocks that we hold in the Marine Corps' Chemical Biological Incident Response Force.

You invited me here today simply to talk about the management of our medical supplies, and I'm pleased to tell you that the status of our medical supply count has vastly improved since I last appeared before this subcommittee. We pursued multiple courses of action, and significant progress has been made, resulting in a stronger internal control environment.

I'd like to highlight the key actions that we've taken, specifically as they pertain to the two recommendations in the recent GAO followon report.

When GAO visited my unit in 1999, we had a fundamental problem—that the unit had no authorized medical allowance list of those items it was authorized to hold and maintain. Specifically, we refer to this as an authorized medical allowance list [AMAL]. None had ever been developed or approved for a chemical or biological unit such as the CBIRF. This resulted in the absence of a basic foundation upon which to establish fundamental internal control procedures and to gauge the effectiveness of inventory management practices.

We've worked diligently to fix this problem. As an interim measure, we developed an internal allowance list of the medical supplies that were necessary to meet our unit's mission. Concurrently, we requested that a CBIRF-specific authorized medical allowance list be developed and approved, and today I'm proud to report that problem is nearing resolution as the Navy Medical Logistics Command published a chemical biological authorized medical allowance list for my unit in October 2000.

The Marine Corps Systems Command, in its capacity as the program manager for medical material within the Marine Corps, has finalized the configuration of those AMAL contents, and we will work with the Marine Corps Systems Command to acquire the necessary supplies to bring my working stock into compliance with the recently approved AMAL standards.

The filling of the standardized AMAL will provide a solid basis for accountability, as well as inventory control of medical supplies, and will permit me to be able to fully comply with GAO's first recommendation made as a result of their October 2000, visit.

Inventory discrepancies were further reduced in my organization from 26 percent in 1999 to 10 percent during the recent October visit. In this 14-month period, this represents a 16 percent reduction in inventory variance rates. My supply personnel since October have researched all inventory discrepancies noted by the GAO during their October count, and all accounting records were adjusted in January 2001.

The upcoming implementation of a new supply management data base will enhance asset visibility and improve our ability to minimize inventory discrepancies. The Marine Corps is currently filling an upgrade to the asset tracking for logistics and supply system [ATLASS], an automated supply management data base. This upgrade, known as ATLASS-II+ will improve CBIRF's ability to do inventory management, as well as enable us to overcome existing data base shortfalls which the GAO has highlighted.

I'm pleased to report that implementation of ATLASS-II+ is currently underway, having commenced yesterday, and will be completed late this summer. This will permit all CBIRF medical supplies and my working stock to be entered into the ATLASS-II+ data base not later than the commencement of the new fiscal year on October 1st.

GAO noted that during their October 2000, counts they identified 161 expired items on hand. This number of expired items represents less than 1 percent of the working stock of medical supplies that my unit maintains. All expired items had been clearly identified, were labeled as being expired, and were segregated from active medical supplies prior to GAO's inventory in October in order to preclude their reissuance. These expired items were pending disposal at the time of GAO's visit.

As you may be aware, CBIRF executed a significant undertaking during the period between the two GAO visits. From May through August 2000, the entire unit relocated from Camp Lejeune, NC, to Indian Head, MD. Accordingly, procedures for the exposure of expired medications at our new location had not been finalized when the GAO visited in October 2000. The expired items noted by the GAO were reviewed to ensure that none were subject to shelf life extensions, and all disposal actions were completed in December 2000.

To better manage disposal actions in the future, we are currently evaluating the feasibility of disposing the expired medications through the use of a pharmaceutical return program. This program may offer me the ability to dispose of expired medications in a more timely and cost-effective manner.

Implementation of the ATLASS-II+ upgrade, use of the pharmaceutical return program, and acquisition of those necessary items to bring my working stock up to the levels of the AMAL approval standards will all strengthen internal management within my medical supply block that I hold.

These actions will also ensure that we fully comply with both the recommendations and the GAO's recent followon report.

In addition to these key areas, we have taken many other measures to help VA's strong internal control environment. I have provided details on these in my statement for the record.

All recommendations made by the General Accounting Office as a result of their visits to my unit have been fully acted upon, and I believe the resulting measures have yielded positive results; however, I would be extremely remiss if I did not point out that the progress that we have achieved to date is a direct result of the dedication and professionalism of the young enlisted marines and sailors that I'm blessed to lead.

My supply warehousemen and Navy corpsmen worked many long and demanding hours in an effort to improve our medical supply operations. The tasks that they were completed were accomplished in the face of tremendous obstacles—obstacles presented by the unit's relocation—transfer of families, the packing and shipping of all equipment and supplies, loss of experienced personnel as a result of the move, and the need to train newly joined personnel, delays in construction and subsequent impact upon the occupancy of new facilities, and the requirement to maintain a viable operational response capability throughout the entire unit movement.

They did this not simply because I told them to; they did this because they take pride in the uniforms they wear and because they realize the gravity of the threat that confronts us. They know that when our Nation is least prepared they've got to be most prepared.

So I would like to express my sincere appreciation for this committee's leadership in addressing the threat posed by weapons of mass destruction. I want to tell you I'm equally grateful for the support of the Marines and sailors that comprise your CBIRF team.

Once again I thank you and I am prepared to answer any questions you may have.

Mr. PUTNAM. Thank you very much, Colonel. We appreciate the hard work that your Marines and sailors put in, as well.

[The prepared statement of Colonel Hollifield follows:]

NOT FOR PUBLICATION UNTIL
RELEASED BY THE HOUSE
COMMITTEE ON GOVERNMENT REFORM

STATEMENT OF

COLONEL CARLOS R. HOLLIFIELD

COMMANDING OFFICER,

CHEMICAL BIOLOGICAL INCIDENT RESPONSE FORCE

UNITED STATES MARINE CORPS

BEFORE THE

HOUSE COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS

AFFAIRS, AND INTERNATIONAL RELATIONS

ON

1 MAY 2001

CONCERNING

COMBATING TERRORISM: MANAGEMENT OF MEDICAL STOCKPILES

NOT FOR PUBLICATION UNTIL
RELEASED BY THE HOUSE
COMMITTEE ON GOVERNMENT REFORM

I would like to thank you for the opportunity to appear before this subcommittee today to update you on actions that have been taken to improve internal control of medical supply working stocks maintained by the Marine Corps' Chemical Biological Incident Response Force (CBIRF). Your interest in this area and the assessments that have been provided by the General Accounting Office (GAO) have aided me in ensuring that the medical supplies held by my unit are ready when our nation calls.

You invited me here to talk about management of CBIRF's medical supplies. I am pleased to tell you that the state of our medical supply account has vastly improved in the past year. My staff and I fully embraced the previous recommendations made by the GAO following their initial visit to CBIRF in July 1999. We have pursued multiple avenues of corrective action and significant progress has been made resulting in a stronger internal control environment.

Before I comment on the specific issues and recommendations of the GAO review conducted in October 2000, I would like to take a moment to highlight some of the actions that have occurred since last March, when I last testified before you. At that time, I noted that one difficulty we had in establishing sound accountability stemmed from the fact that we did not, at that time, have a foundation upon which to base accountability and inventory procedures for our medical working stock. The requirement for medical supplies were not clearly articulated due to the fact that, unlike other military units, no Authorized Medical Allowance List (AMAL) had been developed or approved for chemical biological units such as CBIRF. As an interim measure, my medical staff and I developed an internal allowance list. While this list did not represent validated requirements, it nonetheless provided a baseline upon which to establish inventory control procedures pending the approval of an AMAL.

Since then we have worked diligently on this problem. I am pleased to report that the Navy Medical Logistics Command published a chemical-biological specific AMAL in October 2000. Subsequently, we modified our internal allowance list to comply with the requirements for medical supplies published in the new AMAL. We have recently completed a comparison of on-hand quantities of medical supplies with AMAL requirements and provided the Marine Corps Systems Command with a listing of the items that will be required to bring unit working stock into compliance with AMAL requirements. At present, Marine Corps Systems Command, in its role as the Program Manager for medical material within the Marine Corps, is in the process of finalizing AMAL line item configurations and has requested establishment of a Table of Authorized Material Control Numbers (TAMCNs). These are the final administrative steps that will facilitate the fielding of those medical supplies necessary to meet our mission requirements while establishing a solid basis for positive accountability and inventory control in the future. CBIRF will work with Marine Corps Systems Command to identify funding required to bring CBIRF's working stock of medical supplies to approved AMAL standards.

The GAO noted during their October 2000 visit that we did not possess every item on my internally developed allowance list. Adjustments between on-hand quantities and the internal allowance list were not made prior to GAO's visit in October 2000 for several reasons. First, I wanted to avoid the appearance that my internal allowance list was simply modified to better match on-hand quantities prior to GAO's review. More importantly, approval of a standardized AMAL for my unit was pending at the time of GAO's October 2000 visit. Accordingly, adjustments to on-hand stocks of medical supplies were held in abeyance to avoid potential overstocking of medical supplies that may no longer have been authorized upon approval of the

AMAL. This action did not have any adverse impact upon the ability of the unit to fulfill its mission requirements.

The fielding of the recently approved chemical biological AMAL will provide a solid basis for accountability and inventory control of medical supplies. It will also permit us to fully comply with the first recommendation made by GAO in the report of their October 2000 visit, which is to adjust our stock levels to conform with the approved CBIRF specific medical allowance list.

Approval and fielding of the AMAL is a significant step in enhancing internal control over my working stock of medical supplies. However, we also implemented numerous other measures during the period between GAO's July 1999 and October 2000 visits to CBIRF. Since last March, I have taken the following measures to enhance the overall efficiency of my medical supply account:

Realigned oversight of medical supply operations from my Senior Medical Officer to my Supply Officer to reduce the risk of error by segregating duties; conducted several risk assessments; obtained a formal review to enhance the overall physical security of medical supply storage areas; required crime prevention and loss awareness training for all warehouse personnel; developed an electronic spreadsheet for inventory control of medical supplies; published Standard Operating Procedures for Management of Medical Supplies; developed desktop procedures for each position involved in the handling of medical supply transactions; conducted periodic inventories (to include unannounced, random spot checks) of medical supplies; brought an additional Supply Officer from the Marine Corps Reserve on active duty to assist in standardizing supply operations; requested an increase in personnel staffing; and solicited

external reviews by independent teams of subject matter experts comprised of medical, supply, and logistics personnel from my higher headquarters.

As a result of this focused attention on medical supply operations, inventory discrepancies were reduced by 16% in the 14 months between the two GAO reviews. We continue to look for ways to further reduce inventory discrepancies. The fielding of the AMAL will help in this regard, but more importantly the implementation of a new supply management database will enhance our ability to minimize inventory discrepancies. When GAO reviewed our operations in July 1999, they noted that the database in use at the time was inadequate to ensure that medical supplies were properly accounted for, maintained, rotated, and disposed of in a timely manner. Accordingly, following GAO's initial visit we suspended use of that database system and developed an internal electronic inventory control spreadsheet that provides an interim improvement to asset tracking and visibility. While this interim measure has improved accountability, it still falls short of adequately capturing important fields of data for real-time asset visibility such as shelf-life expiration, disposal actions, and supply replenishment status.

The Marine Corps is fielding an upgrade to the Asset Tracking for Logistics and Supply System (ATLASS), an automated supply management database. This database upgrade, ATLASS II +, will improve CBIRF's inventory management capability and enable us to overcome existing database shortfalls. Implementation planning has already begun and installation of ATLASS II + within CBIRF is programmed to be completed late this summer with subsequent operator training for supply personnel to follow. This timeline will permit all CBIRF medical supplies to be entered into the ATLASS II + database in sufficient time to begin fully operating on this database not later than the beginning of the new fiscal year commencing October 1, 2001.

The GAO noted in their follow-on report that during their October 2000 visit to CBIRF they identified 161 expired items of medical supplies on hand. However, it is important to note that these items represented less than 1 percent of the total working stock of medical supplies held by CBIRF. All expired items had been clearly identified and were clearly labeled as "expired" by unit supply personnel prior to GAO's October 2000 inventory count. Additionally, all expired items had been segregated from serviceable, active stock to preclude issue. The expired items were pending disposal at the time of GAO's visit.

As you may be aware, CBIRF executed a significant undertaking in the period between GAO's initial and follow-on visit to my unit. From May through August 2000, the entire unit relocated from Camp Lejeune, North Carolina to a new base of operations at Indian Head, Maryland. Accordingly, it was necessary to pack, ship, and subsequently inventory all unit property, to include medical supplies. As a result of this relocation effort and unforeseen construction delays, normal warehousing operations were not resumed until mid-September 2000. Until that time most supplies were not readily accessible due to being either in transit or in temporary storage pending occupancy of the new facilities. Hence, procedures for the disposal of expired items of supply at our new location had not been finalized when GAO visited the unit in October 2000. The expired items noted by GAO were reviewed to ensure none were subject to shelf-life extensions under the Department of Defense/Food and Drug Administration Shelf-Life Extension Program and disposal actions were completed in December 2000.

To better manage disposal actions, we are currently evaluating the feasibility of disposing of expired medical supplies through the Pharmaceutical Return Program. This program, recently implemented by the Medical Logistics Company at Camp Lejeune, may offer CBIRF the ability to dispose of expired medical items in a more timely and cost-effective manner.

Implementation of ATLASS II +, use of the Pharmaceutical Return Program, and acquisition of the necessary medical supplies by Marine Corps Systems Command to bring my medical supply inventory into compliance with the approved AMAL will all strengthen internal management of CBIRF medical supplies. These actions will also ensure we fully comply with the second recommendation made by GAO in the report of their October 2000 visit, which is to remove expired items from our stock and replace them with current pharmaceuticals and medical supplies.

All recommendations made by the GAO as a result of their visits to my unit have been acted on, and I believe resulting measures have yielded positive results. However, I would be remiss if I did not point out that the majority of the progress achieved to date is the direct result of the dedication and professionalism of the young enlisted Marines and Sailors that I am blessed to lead. My Marine supply warehousemen and Navy Corpsmen worked many long and demanding hours in an effort to improve medical supply operations. The tasks they completed were accomplished in the face of obstacles presented by CBIRF's relocation – transfer of families, the packing and shipping of equipment and supplies, loss of experienced individuals and the resultant need to train new personnel, delays in construction and its subsequent impact on the occupancy of new facilities, and the requirement to maintain a viable operational response capability throughout all phases of the relocation. They did this not simply because I directed them to do so, but because they take pride in their job and the uniforms they wear. They realize the gravity of the threat confronting us. And they know that when our nation is least prepared, they must be most prepared to execute their response mission.

Once again, I would like to express my sincere appreciation for this opportunity to appear before you and I am grateful for your support of the young men and women of the Marine Corps' CBIRF.

Mr. PUTNAM. I'd like to recognize or acknowledge that the gentleman from Massachusetts, Mr. Tierney, has joined our subcommittee, and I would ask our chairman, Mr. Shays, to lead off with the questions.

Mr. Shays, you are recognized.

Mr. SHAYS. Thank you, Mr. Chairman.

Mr. Chairman, first I want to again thank the GAO for their testimony and also our witnesses on this panel, and, with no disrespect to the other panelists, just particularly thank you, Colonel Hollifield, for your cooperation with the committee. We felt cooperation with all, but the site visit was appreciated by our staff.

Also, to say like a true Marine you are here—evidently, your wife's father, Robert Cobb, passed away and you will be going back down there to make arrangements, and it is just very thoughtful of you to be here. Thank you.

Colonel HOLLIFIELD. Thank you, sir.

Mr. SHAYS. This chart is an accurate chart of the flow of responsibility? There's no disagreement with this chart on the part of all four of you?

Colonel HOLLIFIELD. No disagreement, Mr. Chairman, but a point of clarification. I think we established this the last time that I appeared. You know, we—you acknowledged at our last hearing, sir, that our unit is somewhat different from the other agencies that sit at the table with us. We are not a part of the—formal part of the pharmaceutical stockpile program, but we do have a responsibility.

Mr. SHAYS. I see the line of authority coming straight down from the Department of Defense, and that's accurate?

Colonel HOLLIFIELD. Yes, sir.

Mr. SHAYS. And basically I get the sense that HHS is using the Department of Veterans Affairs to contract. Dr. Knouss and also Dr. Hughes, is that an accurate description? Are you—is the Department of Veterans Affairs basically the contractor by—the partner? Tell me the relationship between HHS coordinates and medical services, medical assistance, and what your role is, Dr. Mather.

Dr. MATHER. We consider ourselves to be a partner with HHS, and there are essentially two functions, the one being the stockpiles that Dr. Knouss described, and in that case we actually house the stockpiles and manage them on the site so that they are ready when the national medical response teams are activated and can pick up the stockpile.

Mr. SHAYS. Do you have oversight responsibility to the Office of Emergency Preparedness and the Centers for Disease Control and Prevention?

Dr. MATHER. No.

Mr. SHAYS. So you basically contract with them in——

Dr. MATHER. We are a contractor with the Office of Emergency Preparedness, and then VA also functions in a—for acquisition of the stock or the pharmaceutical supplies that CDC has on hand.

Mr. SHAYS. What I'd like to wrestle with a bit, I heard the concept of the scene, and I've never thought of it as a scene. My sense is that it rapidly becomes many scenes.

If you will, if I could just get a sense of, first, the antidote for a chemical versus a biological agent. Is the antidote as effective?

Is it—just describe to me how we should view chemical versus biological. I throw it open to the floor, whoever.

Dr. HUGHES. Well, perhaps I can begin with it.

Mr. PUTNAM. Sure.

Dr. HUGHES. I'm sure the others will want to add.

For a biological agent, we have to deal with what is known as an "incubation period." That's the time from exposure to the time of onset of illness, which can range, depending on agent, from several hours——

Mr. SHAYS. Right.

Dr. HUGHES [continuing]. To several days, and in some cases several weeks. It is that difference that is very important in terms of a biological event requiring for recognition good disease surveillance, because people will be widely dispersed from their site of exposure.

Mr. SHAYS. But this is one reason why we contact hospitals in urban areas every day to see if they have a particular outbreak of a problem—it's one of the reasons. They may have an outbreak of a natural cause, or it may be terrorist induced.

Dr. HUGHES. That's right. In the absence of an overt claim by a terrorist, a bioterrorism event will present as any complicated infectious disease outbreak that requires alert health care workers and a vigilant public health system to recognize problems.

Mr. SHAYS. And it grows geometrically.

Dr. HUGHES. Yes, it can. It certainly can.

Mr. SHAYS. Whereas chemical, it will be a little more instant and spread, but not necessarily in the same way.

Dr. HUGHES. Well, for many chemicals there will be a much shorter interval from exposure to onset of illness.

Mr. SHAYS. And not contagious.

Dr. HUGHES. Well, not directly contagious the way some infections are, but a victim may be contaminated with the chemical, so it is possible for a victim of a chemical exposure to expose people who are caring for that individual.

Mr. SHAYS. OK. So it can spread.

Dr. HUGHES. On a limited basis.

Mr. SHAYS. Right. And then it goes many places. So describe to me how the system would work. It is, you know—and the location of these stockpiles is not something we advertise, but let's just say the stockpile is in a particular place and it needs to go 200 miles to Columbus. Describe for me what happens. How does this system work?

Dr. HUGHES. Well, we, in an event like the where an episode was recognized and characterized and a decision was made that it was appropriate to mobilize the stockpile, a push-pack, one of these push-packs that I mentioned would be mobilized either by air or by land, depending on its proximity to its ultimate destination, and can be moved within 12 hours to such a site, and in many cases——

Mr. SHAYS. And who is responsible for making sure that gets there?

Dr. HUGHES. Well, that would be the CDC response for our stockpile for those push-packs. It would be our responsibility.

Mr. SHAYS. Colonel, tell me how you fit into that process.

Colonel HOLLIFIELD. Sir, I don't really fit into that push-pack process at all. We maintain a limited amount of medical supplies, primarily to provide care for our own first responders. My unit's role is to provide assistance to the lead Federal agency when tasked to do so.

Mr. SHAYS. OK. Walk me through this a bit. I mean, we had an exercise in Connecticut——

Colonel HOLLIFIELD. Yes.

Mr. SHAYS [continuing]. And that was fascinating, but just walk me through. We have an outbreak. The first responders didn't survive. Sometimes the firemen tell us the police are the canary in the field. So let's say a few policemen have died. We're trying to determine what the cause is. Is that your job, Dr. Hughes, or are you just responding to whatever you're asked for?

Dr. HUGHES. No. The stockpile is only one component of the CDC and the public health.

Mr. SHAYS. Right.

Dr. HUGHES. There's detection, diagnosis, assessment of risk factors, definition of the——

Mr. SHAYS. You just have to get it there, whatever you're asked for? You have to get the supplies there to the site?

Dr. HUGHES. Well, the mobilization of the stockpile is one component——

Mr. SHAYS. Right.

Dr. HUGHES [continuing]. Of what we would be doing, but we would be responsible for ensuring that the stakeholder is moved using our transportation partners to the site or sites where it is needed.

Dr. KNOUSS. May I step in, please?

Mr. SHAYS. Yes, please.

Dr. KNOUSS. Just with a context, because I think that there is an entire context of a Federal response plan in the event that we have one of these emergencies. The difficulty with a biological event that looks like it is just a regular—let's say like West Nile did in New York where it is a naturally occurring disease that is being transmitted and spread from Europe. There was no indication as to whether or not that was a human-caused or a naturally occurring disease. But in the event of a terrorist attack, that would be a—that might be appearing originally as a naturally occurring disease and then all of a sudden becomes apparent that it is a terrorist attack.

But when we know that there is a chemical event or a terrorist attack with a biological agent, there is a Federal response plan that really mobilizes the whole of the Federal Government.

Mr. SHAYS. And you would be responding whether it is a terrorist attack, or not? You would be responding either way?

Dr. KNOUSS. We would be responding either way.

Mr. SHAYS. Yes.

Dr. KNOUSS. If it's a mass—actually, we have enormous numbers of resources to be able to respond to mass casualty situations in the United States, and this is just one other way of getting to a mass casualty situation.

Mr. SHAYS. I just—I guess what I maybe need to do is just—because my time is running out here—I just want to appreciate obvi-

ously how we maintain these—this medicine and these antidotes is one issue, but how we get it to the field—and I'm just trying to understand that basic point.

And I just heard the word "scene" more than I was comfortable, instead of "scenes." So it is in Columbus, and, guess what, it is in Dayton and it is in Chicago and, my god, it's down in Miami all of a sudden. I just want to know who in this group responds and how you respond when that happens, and then, thank you, Mr. Chairman, I'll come back for a second round.

Dr. KNOUSS. That's a very complicated question, but basically we all respond and there are prescribed procedures that we use to respond.

Mr. SHAYS. It's not classified, is it?

Dr. KNOUSS. No. It's the Federal response plan that we use. It's for emergencies.

Mr. SHAYS. OK. So just walk me through it.

Dr. KNOUSS. And the bioterrorism—or the terrorism annex to that plan.

If there is an event that occurs and the FBI is notified or law enforcement notifies, the initial response is going to be a local response.

Mr. SHAYS. OK.

Dr. KNOUSS. That's one of the reasons why we are trying to improve local resources around the country. Both CDC, both the local and State level, and we, in terms of the health systems at the metropolitan level, and we are now active in over 100 major metropolitan—about 100 major metropolitan areas.

So if it happens in one of those areas, plans are being developed now for the initial local response, including the stockpiling of antidotes and some antibiotics.

Mr. SHAYS. And we don't have stockpile like at Pearl Harbor where we put all our ships?

Dr. KNOUSS. No, sir.

Mr. SHAYS. They're all around the country.

Dr. KNOUSS. They're all around the country. And we're doing two things for chemicals. We're buying some stockpile to put in our major metropolitan areas because of the rapidity of the responses needed, so that our first responders have immediately at their disposal enough stockpile to take care of anywhere from 1,000 to 6,000 people, and for some of our larger cities even more than that.

Mr. SHAYS. And chemical has a longer shelf life?

Dr. KNOUSS. No. It all depends on——

Mr. SHAYS. So we're constantly having to update.

Dr. KNOUSS. That's correct.

Mr. SHAYS. If you don't mind, Mr. Chairman, since there are only two of us——

Mr. PUTNAM. There's nobody else to go.

Mr. SHAYS. Let me just appreciate—I'm pleased the others jumped in, but I just want to have—maybe this is so redundant for you that you don't want to keep talking about it. I get tired of talking about campaign finance reform. You can get tired of talking about this.

Dr. KNOUSS. Well, hopefully this is not in the same category.

Mr. SHAYS. Tell me how—we've got Columbus, we've got Dayton, we've got Chicago, we've got Miami, and you're on the phone. You may be—tell me—and then, Colonel, I just need to know how you interface since you're not part of the system. I don't want to leave a void here. You can jump in.

Colonel HOLLIFIELD. Let me tell you how I fit into the system, sir, how my unit responds.

First of all, we are outlined in the emergency Federal response plan. Specifically, we are tasked to support emergency support function eight, and we don't do that in a vacuum. We only do that when a lead Federal agency has come in and asked DOD specifically for support. And that may be my unit or it may be some other entity within the Department of Defense.

Typically, if we are tasked and employed to provide support, we may be working in close conjunction with one of these other agencies, such as providing support for the Public Health Service.

Mr. SHAYS. Let me ask you, are there other units like yours? I mean, I'm really showing my ignorance.

Colonel HOLLIFIELD. There is no unit exactly like mine, sir, at the Federal level. The National Guard is sending up units, the civil support teams.

Mr. SHAYS. The response teams, and so on.

Colonel HOLLIFIELD. Yes, sir. But they are designed to provide the support for the State and local response under the State adjutant general.

My unit comes in and provides support specifically focused on chemical and biological, in addition to the medical stabilization piece that we could bring to the table.

Mr. PUTNAM. We don't want to go to the Army or the Air Force to do this, we're going to your unit to do it, aren't we?

Colonel HOLLIFIELD. Yes, sir, and other—there are other entities. The Air Force has a radiological assessment team that provides support.

Mr. SHAYS. Right, for radiologic.

Colonel HOLLIFIELD. Yes, sir.

Mr. SHAYS. OK.

Colonel HOLLIFIELD. We have an oversight and coordination command and control coordination structure in place with the joint task forces that we'll support.

Mr. KUCINICH. And you have the capability to now go to Dayton and—excuse me, Columbus and Dayton and Chicago and Miami? Or can we only be at one place?

Colonel HOLLIFIELD. Sir, I have the capability to provide an initial response primarily to a single location; however, I could provide a followon response to another location. But I only have 372 personnel in my unit, so the level and depth of what we can do is limited.

Mr. SHAYS. I just don't want to have an over-expectation of what we have available.

I think this issue is huge. I mean, I truly do. I think it is kind of like everybody will be asleep. You all aren't, but the general public and the lot may not fully realize that there will be a chemical or biological attack some time, maybe nuclear, and that's why you all are doing what you're doing.

I'm still not really getting a great answer from my standpoint. I know that you're going to be going to a site. I want to ask——

Colonel HOLLIFIELD. If I could draw an analogy, Mr. Chairman?

Mr. SHAYS. Sure.

Colonel HOLLIFIELD. I'm kind of like the ambulance guy, you know. I have some limited medical supplies.

Mr. SHAYS. Right.

Colonel HOLLIFIELD. I'm the ambulance. I show up at the scene and I provide some stabilization care so that these agencies and the medical supplies they provide the local responders can take over that surge of patients and be able to follow on and provide the long-term care.

Mr. SHAYS. It's just basically you're a one-scene primarily focus, so I sure as heck we know soon enough to get you there before we see the chemical contamination spread or the biological agents.

Colonel HOLLIFIELD. We try to preclude that, sir, by two methods. One is we look and rely very heavily on intelligent information.

Mr. SHAYS. Right.

Colonel HOLLIFIELD. So if we anticipate that there is a credible threat for a major event, we can pre-stage forces at that scene, which we have done repeatedly in the past.

But, more importantly, we keep about one-third of the unit on a 1-hour tether, 365 days a year, which means if something happens, within 1 hour we can recall that response force in. All their equipment is pre-stage packed and mobile loaded. And then it's just a matter of air lift and getting us to the destination before we can have impact.

Mr. SHAYS. Thank you. Now, the national medical response teams, how many do we have?

Dr. KNOUSS. Four.

Mr. SHAYS. So does that mean that we could get to those four sites?

Dr. KNOUSS. At the beginning what's going to happen is that the State of Ohio is going to be responding, and, in fact, we are developing systems in those cities, so—and we've also worked with the State to link those cities in a network so that we have some response capability in the State of Ohio to begin with, which was the example you started with.

Then we have the opportunity to move those four teams. The first three teams would be the ones positioned on the west and the central and the East Coast. The one here in Washington, DC, will probably stay here in the event that we have a continuing or additional——

Mr. SHAYS. Right.

Dr. KNOUSS [continuing]. Threat here in the Nation's Capital.

We have constructed our stockpiles so that we can split each one into four pieces, and that means that we can move—we actually have a great deal of mobility. Obviously, at some point the response may require such a large requirement that it is going to exceed what we have pre-positioned, but we think we have a very substantial capability when it comes to chemical victims.

Mr. SHAYS. Mr. Chairman, I'll come back. Thank you for your patience.

Mr. PUTNAM. You're certainly welcome, Mr. Chairman.

Dr. Mather, your testimony states that the caches have been successfully deployed and returned to storage. Why were they deployed?

Dr. MATHER. As a test case. We did deploy the capital—the cache here for the inauguration and the State of the Union address, as you are aware.

Mr. PUTNAM. OK. And do we have any mobile stockpiles overseas?

Dr. KNOUSS. We do not, not for any of the programs that we operate. Those are all domestic and really have been committed to domestic uses. That question has come up on a frequent occasion.

Now, there are some instances in which we have assisted AID in actually purchasing some additional pharmaceuticals for other governments, but it has really been part of a foreign assistance package and not as a part of our immediate response capability.

The one thing that we can do that is new is that, in response to the bombings that took place in Nairobi and Dar es Salaam, we now have a capability of immediately deploying a civilian team from a very fine surgical care institution in Massachusetts that we can use to stabilize U.S. employees that may be immediately at risk from those kinds of events again.

Mr. PUTNAM. When an event or evidence of an event begins to pour in to CDC and HHS, who makes the final call? Who is ultimately responsible for identifying this scenario as an event and therefore triggering your response plan?

Dr. KNOUSS. Well, the initial event would be the FBI and FEMA. In terms of the actual response in terms of management within our department, our current Secretary has made it very clear that he is going to be directly responsible for the responses of the Department of Health and Human Services.

Mr. PUTNAM. So when you are communicating with urban hospitals and first responders and reports begin to come in, and, as we've heard earlier, everything looks like the flu in the beginning, it's up to the FBI to determine what they're really looking at?

Dr. KNOUSS. No, that's when it's looking like an emerging infectious disease, and that's a public health problem, and that really is a CDC issue. It's once it becomes clear that it is a terrorist incident that the lead agency is the Department of Justice and the Federal Bureau of Investigation.

Mr. PUTNAM. But I guess in this murky world that we live in it may not be clear that it is a terrorist incident, and that's why I asked who sifts through the data and makes the recommendation that it is—it looks enough like a terrorist attack to deploy your plan? Is that you, Dr. Hughes?

Dr. HUGHES. Well, that's where the Nation's public health system comes into plan and its linkage with clinicians, health care providers who—in a biological event, it is the health care providers that are going to initially see these patients. They need to have a high index of suspicion, if they're seeing one or two patients, that this may be part of a much larger event occurring in their community or maybe in many communities. So an index of suspicion, prompt recognition, notification of local and State public health authorities who would then, in turn, notify us at the national level.

There is a need for alertness and rapid communication at all levels, as is the case in recognition of any infectious disease outbreak.

There then needs to be an index of suspicion, depending on the nature of the illness, the initial clues related to the epidemiology of the event. There are certain triggers that would alert you to the possibility that you might be dealing with a terrorist event.

Mr. PUTNAM. What is the level of awareness in the local health care community of—why would a public health official in a mid-sized midwestern city like Oklahoma City, why would they think that anthrax is in their community? What training or preparation would they have had given them that would alert them to look for and consider such an outlandishly sounding eventuality?

Dr. HUGHES. I think the good news is they're more likely to consider that possibility today than 2 to 3 years ago, with the publicity, the heightened awareness, the efforts at training, the establishment of strengthened surveillance in laboratory networks, and dissemination of information about the clinical nature of anthrax.

Anthrax is a disease that should not occur at all in the United States in humans, so a single case should raise the possibility of a terrorism event. It doesn't mean a single case will be the result of a terrorist event, but a single case should raise a red flag.

I think, although we have a long way to go, that's more likely to happen today than it was 2 to 3 years ago.

Mr. PUTNAM. Who decides—in these stockpiles that are around the country, who decides what eventualities those stockpiles need to be prepared for? And how often does that threat analysis change, or how often is it reviewed to make sure that we're prepared for the proper eventualities?

Dr. KNOUSS. There are a variety of different processes that we go through to do that. I think Dr. Hughes is in a position to describe a lot of the things that CDC does to decide what is the most likely mass-casualty-producing organisms that might be used and that we have to be prepared to respond to.

From a chemical standpoint, we rely a good deal on what DOD has decided are some of our most important chemical weapons threats, and it boils down to some things that really have a lot of common antidotes to them so that we use that as the basis for the stockpile.

Mr. PUTNAM. Dr. Hughes.

Dr. HUGHES. Roughly 2 years ago we assembled an expert group of individuals representing the private sector, the Department of Health and Human Services, the intelligence community, and we talked about candidate agents. The Department of Defense had representatives at that, as well. We talked about candidate agents that we should be most concerned about, considered a number of parameters, one of which is the ability that we've alluded to already of an organism to spread from person to person, cause severe disease, have a high mortality rate. Those kind of things went into the equation.

It was that process that led us to definition of what we call "category A" agents that are the ones that we are most concerned about because of their potential catastrophic impact.

The category A agents include smallpox, anthrax, plague, tularemia, botulism, and several of the viral hemorrhagic fevers such as ebola.

So we have a pretty good idea of those agents that would have the most devastating consequences. The two bioterrorism incidents, though, that have been perpetrated in the past in the United States successfully involved common diarrheal pathogens—salmonella in one case and shugella in another. So you've got to be prepared for a broad range of possibilities.

Mr. PUTNAM. And how many eventualities does our stockpile prepare us for?

Dr. HUGHES. Well, I can speak to the CDC stockpile currently. What we've done is focus on the category A agents that I mentioned. In those push-packs that I mentioned and in the vendor-managed inventory, the push-packs currently are supplied to adequately deal with plague and with tularemia. More work needs to be done to get them fully up to the level they should be to deal with anthrax.

And, of course, when you get to smallpox and the viral hemorrhagic fevers, there aren't effective therapies currently available for those so that becomes a research issue. So it's very complicated.

Dr. KNOUSS. Could I just add to that, though, that the stockpile that we do have in terms of antibiotics includes what are called "broad spectrum antibiotics," and they can be used against a large number of different organisms that might be susceptible. So what we are now putting in the stockpile is not necessarily limited to treating just plague or tularemia or anthrax, it can be used for a variety of other illnesses, bacterially caused illnesses, as well.

Mr. PUTNAM. Let me get back to what we were discussing earlier in terms of the line of authority, the chain of command. To follow-up on the chairman's line, there is a disturbing amount of evidence emanating from the Chicago metropolitan area and in Dayton and in Cincinnati, so you all move into action and begin to deploy assets to that area. Who makes the determination of holding back assets or preparing for a second outbreak or a far-removed outbreak in Miami or New York or San Francisco so that we're not deploying all of our assets to the first line of attack and, in effect, depleting our ability to respond to the secondary effects? Who handles all of that decisionmaking? Does that make sense?

Dr. KNOUSS. Yes. I'm not aware of any situation in which we've actually said, "We're going to keep a reserve force that's going to be available in case there's another incident," with the one exception that here in Washington, DC, we are committed to keeping specific kinds of resources available here in case this—I mean, I just consider this as a secondary target, regardless of where something else may be happening.

But it is like everything else. When you see a particular threat—if we are faced with—and this is a highly theoretical kind of discussion at this point—I don't think there is any formula for good judgment as to what you can commit to one kind of incident or another incident, and every one of those incidents—and we've been involved in a variety of responses to rather cataclysmic natural disasters, as well as pre-positioning resources for some kinds of these incidents, potential threats. There's no exchange for good judgment and there

is no formula for what has to be kept in reserve and what needs to be committed.

Dr. HUGHES. Let me pick up on this a little bit, and maybe Mr. Bice.

Mr. SHAYS. You know what I'd like to suggest, if I could, Mr. Chairman?

Mr. PUTNAM. Certainly.

Mr. SHAYS. That anyone who wants to participate, if they have been accompanying, if they just sit right on the side up here where the mics are. Just come on up here, anyone else who would like to add to this dialog. So you can just wait, but anybody else.

I'm sorry.

Dr. HUGHES. I know that Mr. Bice will want to amplify on this, but, from the CDC standpoint, in terms of the stockpile, we have—it's a two-component situation where we have these push-packs. There are seven right now. There will be an eighth this summer. But obviously——

Mr. PUTNAM. Is that enough? Let me just stop you right there.

Dr. HUGHES. Well, It depends on the magnitude of the situation. If the situation that we're talking about occurs in 20 different cities, obviously the eight push-packs wouldn't cover 20 cities.

There's a second component, though, to the CDC stockpile, and it's what we call the "vendor-managed inventory," which can't be mobilized as rapidly but it can be mobilized within 24 to 36 hours of activation.

In contrast to the push-packs, which are an attempt to be all things to all agents, the vendor-managed inventory can actually be tailored so that if you know you're dealing with anthrax you can call on the medications and supplies that you need to deal specifically with cases of anthrax.

Mr. PUTNAM. Mr. Bice, I think you wanted to followup on that?

Mr. BICE. Yes. Thank you, Mr. Chairman. I just wanted to ensure that all understand that, while there's no magic to eight, we dealt specifically with Defense Intelligence Agency, Central Intelligence, FBI, our own colleagues in our own department and other departments who are experienced with strategies for defense and response. There is no magic to eight, but the fact that each of the push packages can treat in the hundreds of thousands of people for a week or thereabouts gives us breathing room to mobilize the prodigious amount of supplies and equipment that we have held back in the vendor warehouses across the United States.

So therein is our tactical scenario that we play out, we exercise according to that plan. So we would never commit all eight push packages, for example, to Dayton or to any one location. They would stage according to what we would see as evidence by laboratory and epidemiologic evidence the need for those.

And one other caution. None of what we do is to respond—none of what the national pharmaceutical stockpile is to do, we're not a first response element. We would only go when Governors of States requested assistance, and in that sense we're not a primary or first response element.

Mr. SHAYS. But it conjures up this concept of the scene. I mean, the scene that I visualize, unless the technology isn't there for terrorists to do, is Atlanta Delta flights. All of a sudden, you know,

there's some contamination at the airport and there's all these—if you've ever been there—you've been there.

Dr. HUGHES. I have the pleasure of constantly, sir.

Mr. SHAYS. And so there could be potentially 40 sites like that. So I'm not comforted that somehow the national government doesn't—you know, is kind of responding in invitation. I mean, I could see a for instance where we literally have to say, "No flights. No one is allowed to get on the highway. No one is allowed to move from their office to home. You have to be stationary." I mean, I can see that. Is that an unrealistic——

Dr. HUGHES. That's very realistic. Let me just comment. In the Operation Top Off exercise that occurred last year that involved three components, the most complicated one was the plague outbreak that was said to have occurred in Denver, exposing a very large number of people, and all of these issues that you've brought out and many more came up.

There was thinking in terms of when Colorado asked for a push-pack to provide initial treatment to people that were initially felt to have and then confirmed to have plague. A push-pack was notionally sent.

There were reports of other States who were concerned about potential exposures of their population, requesting a push-pack to be sent, and the decision was made not to send it along the lines of not spreading one's assets too thin.

But then all the questions that you are just alluding to immediately came up, as well—issues related to quarantine, stopping interstate movement, closing the airport. Actually, we recommended that Denver International Airport be closed in the exercise, and then we recognized that caused problems in terms of mobilizing the push-pack, which had to be flown into Denver. So these are very real concerns.

Mr. SHAYS. Right, they are, and this committee has been working on this for years—correction, we have been involved in this process for years and trying to get caught up to speed, and I feel like I have a long way to go, but I don't have a terrorist mind. But you closed the Denver Airport too late. That's another hub, I believe, and so planes are everywhere.

I could see that the first indication is you had some of the ticket agents who all of a sudden came down with an illness and died, and you all are trying to sort it out. Do we have the authority—do any of you have the authority to recommend to the President or someone the ability to just shut down all traffic, to close everything down, to ask for no movement whatsoever so this doesn't spread?

Dr. HUGHES. Of course we could recommend such a thing. In terms of authorities, I can't speak to——

Mr. SHAYS. But who would—I want to identify. I'm not playing a game here. I want to identify who most likely would be—you know, I have this vision of a former Secretary of State saying, "I'm in charge here." I want to know who ultimately is accountable for that recommendation.

Dr. HUGHES. Well, I cannot definitively answer your question, but I can say that in the aftermath of the Operation Top Off and lessons learned there is an ongoing review as we speak looking at

interstate quarantine authorities, looking at State laws for quarantine of infected individuals. It has raised many, many questions.

Dr. KNOUSS. I'm not sure that we're the best people to answer that question. The people to answer that question that have been working on it and chairing the task forces looking at those issues has been the Department of Justice.

When we're talking about the quarantine issues and looking at quarantine laws at the present time, a lot of them are dependent on exactly what State law is and they vary from State to State.

Mr. SHAYS. It's just that, you know, we have this comfort level that, you know, you're the group that's going to be responding, and I had this sense before I came to this hearing that this is kind of a complete picture, and I hear "scene" rather "scenes." I have a sense that we will try to catch up to the contagious elements and we'll be—you know, if it's nice and neat and pretty we'll be doing fine, but otherwise we'll have some——

Dr. KNOUSS. Mr. Chairman, I think that we're just one part of a very large response that is going to be taking place, and that's what I was trying to allude to at the very beginning in terms of this being one part of the Federal response plan and the issues that will be tackled really at the highest level of our government.

Mr. SHAYS. Then let me just make this statement—did you want to say something, Dr. Hughes, first?

Dr. HUGHES. I was just going to say that your comments I think are very well taken. One thing they bring out is the urgency and the importance of having surveillance systems in place, strong public health surveillance, so that an event can be very rapidly recognized because things can spin out of control very, very quickly potentially.

Mr. SHAYS. Yes. I mean, I'm left with the feeling that, just as it relates to all of you and the wonderful work you're doing and the efforts you're making, you could potentially never get caught up to it. It will be identified too late, it will have spread too quickly, and we won't have the resources, even though it seems like we might.

If I could, could I ask about smallpox?

Mr. PUTNAM. Certainly.

Mr. SHAYS. Why don't I——

Mr. PUTNAM. Well, I just wanted to—I think that your line of questioning highlights the theme of this subcommittee since January, which is, when it comes to homeland security, Department of Justice points to the CDC, the CDC points to the Department of Justice, and there really isn't anybody willing to stand up and say, "I'm in charge here," and that reflects sort of an institutional crisis of identifying how to respond to these types of threats.

I would hope that you all would recognize the threat before a lot of Governors would, much less have to wait on the Governors to type up the proclamation to invite you down for tea.

I think what this highlights is that it reinforces the need for us to have a better-integrated system of homeland defense and address the questions of when it is appropriate for CBIRF or equivalent or similar type units to be deployed domestically and respond to these types of crises and have pre-positioned stockpiles in the right places, in the right amounts and things of that nature.

That's all I wanted to say, Mr. Chairman.

Mr. SHAYS. Just quickly about smallpox, the "Stars and Stripes" had a story on the 26th that we're going to get 40 million doses of vaccine against smallpox. Who would respond to that? Is that you, Dr. Hughes?

Dr. HUGHES. Yes.

Mr. SHAYS. OK. Tell me the genesis of why that decision was made. The stories that preceded it, to my knowledge, is that the United States has the last and the Soviet Union, and we don't know quite what the Soviet Union has and who it could give it to. What do you know that we don't know that's not classified?

Dr. HUGHES. OK. You've asked several questions.

Mr. SHAYS. Right. We want to give you a range of choices.

Dr. HUGHES. Let me start and you guide me and I'll do the best I can.

Mr. SHAYS. OK.

Dr. HUGHES. There are two authorized supplies of smallpox virus in the world. One of those—or stocks, I meant. One of those is stored at CDC. The other is stored at the Institute Vector in——

Mr. SHAYS. And this is the disease, not the vaccine?

Dr. HUGHES. This is the virus that causes the disease.

Mr. SHAYS. Right.

Dr. HUGHES. Correct.

Mr. SHAYS. Yes.

Dr. HUGHES. There are concerns in the intelligence community about given the fact that the Soviet Union, from all we know, clearly had a very aggressive offensive biological warfare program. They included development of smallpox virus as a weapon.

Mr. SHAYS. Right.

Dr. HUGHES. There are concerns that perhaps all the remaining smallpox virus that the former Soviet Union had is not currently stored in the facility in Novo Severe. So that leaves—there is the possibility——

Mr. SHAYS. At least you can't be certain of it.

Dr. HUGHES. We can't be absolutely certain.

Mr. SHAYS. OK.

Dr. HUGHES. But the officially declared stocks and the ones that come up when you hear talk about destruction, discussions related to future destruction of known stocks, the virus, those relate to the virus stocks at CDC and the ones at Vector and Novo Severe.

Mr. SHAYS. And can I make an assumption at CDC it's strongly guarded?

Dr. HUGHES. It's stored in a secure—under secure conditions. Yes.

Mr. SHAYS [ASSUMING CHAIR]. I feel rudderless at the moment, here. The gavel is over there and I'm here. You could really abuse me here. [Laughter.]

Dr. HUGHES. The storage conditions at both——

Mr. SHAYS. I'm in charge here now.

Dr. HUGHES. I sensed that. The storage conditions at both institutions, both CDC and Vector, have been reviewed by a team of experts from WHO and have been deemed to be adequate.

Mr. SHAYS. And what would happen if we saw an outbreak? We would try to vaccinate as many people in the area as possible?

Dr. HUGHES. Well, if we saw an outbreak of febrile illness with skin lesions consistent with smallpox, the first thing we would do is try to rapidly confirm the diagnosis.

Mr. SHAYS. Right.

Dr. HUGHES. And because of ongoing research programs we have pretty good molecular diagnostic tools now, better than we would have had a year or two ago, to make the diagnosis. Once the diagnosis is made, here's a good example of agent. I mean, if we see cases of smallpox, either that's a lab escape or that's a terrorist infecting himself by manipulating the virus that he had, or it's a terrorism event, so that gets you very—that would get you very quickly into the terrorism arena.

In terms of what you would do, you would mobilize stocks of smallpox vaccine, which is not smallpox virus, you know, it's the smallpox vaccine.

Mr. SHAYS. You don't need the virus to make the vaccine?

Dr. HUGHES. That's correct. The current vaccine and the next generation that's currently being developed involves a related pox virus called "vaccinia." It's the——

Mr. SHAYS. But in creating the vaccine you aren't creating the potential for the disease?

Dr. HUGHES. No. The other thing that you would be rapidly doing is characterizing this smallpox virus that these hypothetical patients are infected with because there would be concerns about the possibility that this virus might have been genetically modified by people who were interested in having——

Mr. SHAYS. Weaponizing it.

Dr. HUGHES. Weaponizing it and having it be able to work around the existing vaccine.

Mr. SHAYS. And so that's a crap shoot. OK.

Dr. HUGHES. I mean, you can imagine scenarios that are beyond the capacity to manage.

Mr. SHAYS. How about with anthrax? If we think our military personnel need to be protected, are we stockpiling anthrax for civilians?

Dr. HUGHES. Well, we—the colonel might want to comment here also.

Mr. SHAYS. Don't feel you have to, Colonel. It's dangerous. You know what a mine field is like.

Colonel HOLLIFIELD. I'm current on my anthrax vaccines, Mr. Chairman.

Mr. SHAYS. You don't want to get in this debate, Colonel.

Colonel HOLLIFIELD. Thank you, sir.

Mr. SHAYS. It's not a pleasant conversation.

Dr. Hughes, are we developing or stockpiling anthrax vaccines in case the public is exposed to anthrax?

Dr. HUGHES. What we're doing with anthrax vaccine, at CDC we actually have an ongoing research program looking at the currently available anthrax vaccine, looking to see if it can be given in fewer doses, looking if it can be given by a different route of administration that might result in a——

Mr. SHAYS. To develop a new——

Dr. HUGHES [continuing]. In less side effects.

Mr. SHAYS. To do what we asked the military to do, which is to develop a modern generation of vaccine, anthrax vaccine?

Dr. HUGHES. Well, there's ongoing research, not research that we're doing, but there is ongoing research looking at improved anthrax vaccines, but what we're trying to do is look at the available vaccine, see if it can be given in fewer doses, different route, and then assessing its——

Mr. SHAYS. Right.

Dr. HUGHES [continuing]. Effectiveness to prevent inhalation anthrax in non-human primates that are exposed.

Mr. SHAYS. Don't you see a gigantic disconnect? The military, to my knowledge, isn't focused on giving a smallpox vaccine to its military, but it has decided, in its wisdom, and based on the facts as they see it, to have anthrax, and yet domestically you all are saying we're going to look at smallpox and you're not—we don't have developed anthrax. So it just to me calls into question the wisdom of what the military is doing. Either the military is right and you're wrong or you're right and they're wrong. They don't jibe. It's not a trick question; it's just an observation that we've had 4 years or 3 to 4 years of very frustrating dialog with the military about this.

It is hard for me to imagine how, if we think we need to protect our military forces from anthrax, we don't think we need to protect the public. I'd just make—I throw it out there and it will dangle out there for a future hearing.

I'd be happy to have the counsel ask some questions.

Mr. HALLORAN. Just to clean up the record a little bit here, Colonel Hollifield, has anybody in your unit read your AMAL kind of side-by-side with the contents of the push packages or the stockpiles to look and see what's the same, what's different? And let me ask all of you, in terms of the transparency of these things, in terms of if he's there first, you fall in after, are you going to be giving the same material—bringing the same material and the same doses in the same color packages, or are we going to have some kind of a bridging transition problem as each asset arrives?

Colonel HOLLIFIELD. I don't think there's been any attempt, to my knowledge at least, to compare the AMAL contents with anything that's a part of the national pharmaceutical stockpile program.

In the military the authorized medical allowance list is basically what I would call "type specific." Each type of military organization, be it an infantry unit, mechanized unit, or an aviation unit, has a specific authorized medical allowance that is tailored to its unit's mission. If you look at the quantity of the medications that we have and the number of victims that we're designed to be able to render care for, which are primarily the size of own force, and compare that with the scope and depth of what the other agencies have in the stockpile program, you know, we're very, very minuscule.

So I'm not so sure that there is a necessity to do that. I understand that it would be nice that if we're all showing up, we're showing up with the same type of items and supplies, but our missions are different, so the care items that I have are really designed to provide protection for my people who go into the contami-

nated environment and risk exposure, and I have very limited quantities.

So I don't think there is a connection. I'm not necessarily sure that—and maybe they can comment in terms of what type of supplies the national medical response team has and if they're similar, but I'm sure that the vaccines and stuff that we carry for care are all similar in nature, whether they're manufactured or the process by how we acquire them are the same.

Dr. KNOUSS. I'd like to just mention that for the pharmaceutical purchases for the cities, as well as those that we make for our teams, that we want to review all those purchases before we actually support them at the city level, and we have an interagency group that looks at that so that we try to achieve as much consistency as we can, as well as the fact that our teams and our cities know what we have in our stockpiles for chemical responses.

So it's not true for—that we do not do that with the Marine Corps' stockpile, but we do try to do that with all of the metropolitan stockpiles and the ones that we hold for our teams.

Mr. HALLORAN. OK. That brings me to—there's a reference we have to metropolitan medical strike teams, which are not on the GAO chart, but yet they seem to be an HHS-funded asset; is that correct?

Dr. KNOUSS. Well, what we have done is that term is somewhat obsolete at this point——

Mr. HALLORAN. I see.

Dr. KNOUSS [continuing]. Because we've migrated to some new concepts. That was a concept maybe 5 years ago, 4 or 5 years ago. But what had then been called a "metropolitan medical strike team" has become now our four national medical response teams, because they are the Federal teams, the civilian Federal teams.

The metropolitan medical strike team concept at the city level has become really a response system concept because we're looking at not just a few people trained to respond; we're looking at the entire capability of the cities' public safety, public health, and health services communities to be able to respond to one of these massive events. And so we're really looking at this from a systems point of view, not a team point of view.

Mr. HALLORAN. Yes.

Dr. KNOUSS. So we've migrated far beyond that original concept that we held in 1996 and 1997.

Mr. HALLORAN. But do you have the same kind of attempt at consistency and transparency with what they might acquire? I mean, the question arises—I was reading through their—I guess it is old now, but their field operations guide, and they give fairly specific instructions about packaging and color coding of what they bring, so is everybody bringing antibiotics to a scene going to have them in red packages, or are they going to open them up and figure out what's inside?

Dr. KNOUSS. No. I think we're trying to standardize that now. One of the things that we're doing, for example, on our chemical push packages, we're putting them in the same kind of containers that CDC is using for its eight stockpiles. We are giving diagrams to the cities and to the teams as to where in each one of those containers they can find what chemicals. So it's not just a matter of,

"Here's what's the content of the stockpile," but here, in a three-dimensional diagram, is where, in our material that we're sending out to you, you can actually find each one of these products. So we're getting far more specific and far more user friendly in what we're sending out there so that we can—I mean, we're very sensitive to the time issues. I'm not sure we've solved all the time problems, but we're very sensitive to the fact about the sooner we can respond the more lives we can potentially save.

Mr. HALLORAN. Yes.

Dr. HUGHES. From the standpoint of CDC, let me ask Mr. Bice to comment on that.

Mr. BICE. The standardization amongst the eight push-packages is, as you can well imagine, very, very consistent. As we go to standardize and mirror what locals have, we come prepared to deliver in bulk and oftentimes locals will deliver or have at their access smaller doses. They won't exactly look alike, but the basic medications will be the same. They'll be the same general medication types, so in that sense that's the answer that we would give.

Mr. HALLORAN. Back to the chairman's question, once the bulk push package arrives, who decides how to break it out and disburse it?

Mr. BICE. We send a technical advisory response unit with each of the push packages. They assist the locals on the scene as for points of distribution, how much needs to be broken down and for how many victims or potential victims.

Dr. KNOUSS. As we enter into our contracts, if I could just add to that, at the local level we are trying to encourage every metropolitan area that we're working with to develop a specific distribution plan, both in terms of location, as to where they would receive the material, and how they would actually do points of distribution for the affected population.

That's a very extensive planning process and a lot is dependent on what the organizational arrangements are at the local level, as Mr. Bice was saying.

Mr. HALLORAN. Was Top Off the first time that the biological scenario was exercised down to that level?

Dr. KNOUSS. I can't think of another time in which it was done like that.

Mr. HALLORAN. OK. And then, finally, the GAO report referenced 17,897 expired items in your inventory that you were looking for FDA shelf life extensions on, so my question is: to what extent do you believe your entire inventory could be subject to that kind of extension activity? And do you inventory systems, are they equipped to account for that? You've put in shelf life. You've put in expiration date. DY have—just reset the expiration date, or do you set the new one, or is there a penultimate one? How do you track extensions?

Dr. KNOUSS. I'm not sure exactly which particular products they're referring to, but there are a variety of shelf life requirements. Our involvement with FDA on the chemical stockpiles has been really to identify and work with them to look at whether or not any of the things that were temperature damaged might be able to be kept, and we've made a decision, because GAO is referring to the stockpiles in the midwest or central locations, specifi-

cally, but we have made a decision that we're just going to replace materials and we're not going to look for a lot of shelf life extension.

For the CDC's stockpile, if I may just add, a lot of the—as you saw in the report, is that there's actually a pre-planned rotation to cut costs to the stockpile, and I think Mr. Bice might want to describe specifically those activities.

We don't have the same luxury for the chemical stockpiles because the products that we use, like atropine and pralodoxime just do not have the same quantities used in the civilian sector except in these kinds of dire circumstances, so there isn't the opportunity for rotation and re-entry into the commercial sector.

Mr. Bice might want to comment further.

Mr. BICE. Dr. Knouss, I'll just add that we are pioneering a concept we call "rotation in place." It is through our private sector colleagues that we've learned that technique, and we are applying it, and I believe you would have to agree that it's successful since we are at least able to rotate product currently.

There are products in all pharmaceutical stockpiles which are not—that don't lend themselves to rotation or that, in the sense of military-unique items, such as mark one auto injectors, we work very closely with our DOD colleagues. Actually, they pioneered the whole swapping out and extension and working with the private manufacturer of those items to reconstitute. While there's a new auto injector on the market and some of this rotation will not be possible, we're looking at all avenues to mitigate against actually having to destroy product. I mean, that's the bottom line. That's the most terrible thing that we could do. But in some cases, unfortunately, that will probably be the case, but at very minimal amounts.

Mr. HALLORAN. And, Colonel, on that same thing, you mentioned the pharmaceutical return program. Could you elaborate on that a little bit?

Colonel HOLLIFIELD. Yes, sir. The pharmaceutical return program is a program that we just recently became aware of. Our medical logistics company at Camp Lejeune has been using this for some time now, and it has worked out very well. It is basically a vendor-managed type program where the medical supplies that you acquire through that vendor program, once they reach a certain mark toward disposal and shelf life expiration, can be returned and put back into the system. As a result of that, the purchaser receives a credit, so you no longer realize an opportunity to let the vendor do your disposal action for you. As well, you realize some cost savings in terms of reorder.

Mr. HALLORAN. And ATLASS-II can track and mark this kind of early ship-back date?

Colonel HOLLIFIELD. Yes, sir, ATLASS-II+ should give us the capability not only to look at what our current inventory is but to see shipping status on replenishment supplies, as well.

Mr. HALLORAN. Thank you.

Mr. SHAYS. I thank you. I think we'll conclude here. I would like to just say that it is obviously easy for us to look at what all of you are doing from the outside and see ways that you might be able to break through the system, and it may look like we're kind

of throwing stones here, but I feel the responsibility of this committee is to look at all the different parts in place and to just use our imagination to see, you know, what has happened.

I always in my office put someone in charge of everything so if something goes on we actually—someone knows if it goes wrong it is really their responsibility. I see—I think our committee could make a constructive role in trying to learn from what you're telling us and see where there seems to be some areas of concern.

The concern that I clearly have is that there won't be one scene, one site, there will be many, and that I do see the Federal Government needing to step in and maybe shutting down the regions of the country until you all get a handle as to how far the disease or the chemical agents have spread.

But I know that you all are working overtime to try to deal with this issue, and I'm certain that you all realize that what you're doing is for real and that some day you may be on CNN responding to TV questions about how we're dealing with a particular crisis, and hopefully we'll be able to feel like we've done a good job.

Colonel, we want you to get on your way to your family. Thank you again for being here. Thank all of you. Thank our previous panel.

With the power vested in me, I'll close this hearing. Thank you all.

Excuse me, I haven't hit the gavel yet. I do want to make sure there's not a question we should have asked that you had prepared for that needed to be asked, or something in the course of this hearing that you think you need to make a statement about? I'd welcome any of those who have accompanied you if you want to.

[No response.]

Mr. SHAYS. It's a sincere invitation. Is there any last comment from anyone?

[No response.]

Mr. SHAYS. OK. Well, with that we'll close the hearing. Thank you.

Are you all set?

Dr. HUGHES. Well, I was tempted. Prevention is key. CDC is the Nation's prevention agency. But I think this discussion has brought out the complexity of dealing with the—some of these scenarios, so prevention is key and, absent prevention, early rapid recognition and response is absolutely critical.

Mr. SHAYS. It sure is.

Thank you very much. This hearing is adjourned.

[Whereupon, at 3:55 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

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