

# COMBATING TERRORISM: MANAGEMENT OF MEDICAL SUPPLIES

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## 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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## COMBATING TERRORISM: MANAGEMENT OF MEDICAL SUPPLIES

WEDNESDAY, MARCH 8, 2000

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 10 a.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays and Tierney.

Staff present: Lawrence J. Halloran, staff director and counsel; J. Vincent Chase, chief investigator; Kristine McElroy, professional staff member; Jason M. Chung, clerk; David Rapallo, minority counsel; and Jean Gosa, minority assistant clerk.

Mr. SHAYS. Good morning. I'd like to call this hearing to order.

Pharmaceutical and vaccine stockpiles constitute a vital and growing element of the national domestic preparedness effort against terrorism. In the event of a chemical, biological or nuclear incident, local hospitals will need extraordinary quantities of antidotes, antibiotics and sera to treat the victims. If the right medicines do not arrive quickly, thousands could die.

Today, the Department of Health and Human Services' four National Medical Response Teams are available to deploy with medical supplies to treat up to 5,000 casualties each. The Marine Corps' Chemical/Biological Incident Response Force also maintains a supply of pharmaceuticals and equipment that could be used to support local first responders. A larger National Pharmaceutical Stockpile is being assembled by the Centers for Disease Control.

To be useful, medical stockpiles must be carefully maintained and well managed. So we asked the General Accounting Office to assess the accuracy of current inventory tracking and the adequacy of internal controls over critical stockpile assets.

GAO found inventory shortfalls, recordkeeping discrepancies and security lapses that compromised the ability to respond to the chemical or biological incidents.

The fundamental cause of the problems was not the complexity of the terrorism threat, or the logistics of a multi-event response scenario, but the lack of the most basic management controls. GAO found a critical national program running on little more than Post-It notes and a spreadsheet. The Marine Corps isn't even willing to concede their cache is a "stockpile" that needs to be managed like the others.

Terrorism poses any number of extremely difficult challenges to our national security. Accounting for medical stockpiles should be the easy part. Well recognized principles of program design, inventory management and internal control should be applied immediately to transform the current cottage industry of stockpile management into the national enterprise Congress intended.

The threat of domestic terrorism demands we amass, and preposition, costly medical supplies we hope never to use. We hope the very existence of stockpiles will deter terrorists. But in the tragic event we are called upon to open the national medicine cabinet, it must contain the types and amounts of supplies needed to save lives.

In addition to testimony from GAO, we will hear today from those responsible for management of the Nation's stockpiles. To varying degrees, each has acknowledged GAO's findings and pledged reforms. We look forward to their testimony.

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

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## Statement of Rep. Christopher Shays

March 8, 2000

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Today, the Department of Health and Human Services' four National Medical Response Teams (NMRT) are available to deploy with medical supplies to treat up to five thousand casualties each. The Marine Corps' Chemical/Biological Incident Response Force also maintains a supply of pharmaceuticals and equipment that could be used to support local first responders. A larger National Pharmaceutical Stockpile is being assembled by the Centers for Disease Control (CDC).

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Mr. SHAYS. Our first panel, and we have two, is GAO, Ms. Cynthia Bascetta, Associate Director, Veterans Affairs and Military Health Care Issues, U.S. General Accounting Office, accompanied by Mr. Ronald Guthrie, Assistant Director. And Martin Eble, Senior Evaluator, Accounting and Information Management Division of GAO.

If you would rise, we'll swear you in and we'll get started.

[Witnesses sworn.]

Mr. SHAYS. Ms. Bascetta, it's my understanding you will give testimony and then we'll ask questions and all three will respond to the questions we might ask.

Ms. BASCETTA. That's correct.

Mr. SHAYS. Great to have you here. Thank you.

Ms. BASCETTA. Thank you.

Mr. SHAYS. And also let me say to you, what we'll do is we'll do 5 minutes but we'll roll it over. So you'll see the first 5 minutes red light and then we'll roll you over again.

**STATEMENT OF CYNTHIA BASCETTA, ASSOCIATE DIRECTOR,  
VETERANS AFFAIRS AND MILITARY HEALTH CARE ISSUES,  
GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY RONALD  
GUTHRIE AND MARTIN EBLE**

Ms. BASCETTA: Mr. Chairman, thank you for inviting us to discuss our report on the Federal medical stockpiles that would be used to treat civilian victims of a chemical or a biological terrorist attack. My testimony today will highlight weaknesses in management at the stockpiles, the results of our count of stockpiled supplies, and the progress the agencies have made since we issued our report about 3 months ago.

At that time, we reported that OEP, VA, and the Marine Corps unit known as CBIRF did not have basic internal controls in place to manage their stockpiles. As a result when we counted the inventory, we identified discrepancies between what should have been on hand and what was actually there. We found excesses of supplies such as sterile gloves, as well as shortages of some antidotes and antibiotics. For example, in one location we found 1,000 fewer diazepam injectors than required. Diazepam, also known as Valium, would be administered to calm victims and control convulsions. Although VA contends that it stockpiled a substitute for these injectors, it could not produce written documentation of OEP's approval at the time of the substitution. At another location, the entire supply of amyl nitrate—an antidote for cyanide poisoning—had been expired for 8 months. We also found incorrectly recorded expiration dates and lot numbers, which are necessary to keep supplies current and to respond to potential manufacturer recalls. At one location this information was wrong for 250 doxycycline tablets and 100 cipro tablets, two antibiotics used to prevent the onset of symptoms in people exposed to anthrax.

To improve stockpile management, we recommended that VA, OEP and CBIRF each establish fundamental internal controls, which serve as the first line of defense in safeguarding assets like these stockpiles. Incorporated in OMB Circular A-123, internal control is essential to managing an organization and it compromises the plan, methods and procedures used to meet missions,

goals and objectives—in this case, the critical mission to save lives in the event of biochemical terrorism.

We identified the lack of internal control as the root cause of the inventory discrepancies we found in our review. Until this is corrected, the responsible agencies cannot provide reasonable assurance that all the stockpiled items will be current, accounted for, and available for use. For example, at the time of our review, the systems lacked basic information required for sound recordkeeping, including documentation of back orders, replacements, and the shipment and receipt of pharmaceuticals and medical supplies. Further, none of the agencies conducted periodic inventories of the stocks they had on hand to compare them with required amounts.

Moreover, security was lax at some locations. We found commingling of stockpiled items with other VA Medical Center pharmaceuticals, sometimes in unsecured refrigerators. While CBIRF's overall security was much better, it could not ensure that proper access was maintained because no logs were kept for recording access to its warehouse and trucks where the working stock is stored.

Mr. Chairman, we're encouraged that OEP, VA, and CBIRF concurred with all our recommendations and have committed to improving stockpile management. In fact, the current memorandum of agreement between VA and OEP appears to incorporate much of our advice for improving stockpile management. So does VA's new agreement with CDC, which as you know is responsible for a new and vastly larger pharmaceutical stockpile. Specifically, CDC's agreement includes provisions for unannounced inspections and specific remedial actions with timeframes for completion if VA's performance is unsatisfactory. In addition, VA told us that it has prepared a plan indicating its commitment to conduct risk assessment of its vulnerabilities, to arrange for annual inventories, to implement the tracking system for the complete documentation of all transactions, and to rotate supplies properly. CBIRF is working on a list of required items but it needs to expedite this because it is pivotal to implementing our recommendations.

In conclusion, we believe the agencies should be able to turn this situation around and, because of the criticality of this mission they should do so expeditiously. Since this is not, in my view, an expensive problem to fix, how quickly and effectively they will be able to depends less on resources and more on their commitment to implement an organized and disciplined response to our findings. Placing higher priority on this effort at the highest management levels will be essential to ensuring better stewardship of the stockpiles and, as a result, mitigating as best as possible the potential consequences of a terrorist attack.

This concludes my remarks. We'd be happy to answer any questions you might have.

Mr. SHAYS. Thank you. It's my understanding that your investigation didn't look at what supplies should be there, but how the supplies were being maintained.

Ms. BASCETTA. That's correct.

Mr. SHAYS. Did one of the three of you, or all of you, visit all four sites?

Ms. BASCETTA. We visited five sites.

Mr. SHAYS. Right.

Ms. BASCETTA. The four NMRT sites.

Mr. SHAYS. Four VAs?

Ms. BASCETTA. Yes. And also the CBIRF site.

Mr. SHAYS. Describe to me what the—I don't even know what the site would look like.

What is the—describe to me, I mean is it a small room, is it a large room? Do we have trucks with supplies? Just describe to me what it looks like.

Ms. BASCETTA. There is some variability. I have been at one of the sites and it's located at a VA Medical Center. I'm not sure, but—

Mr. SHAYS. Which State?

Ms. BASCETTA. Washington, DC. I'm not sure of the dimensions of the stockpile, but it's a secured area. It's called a cage, and inside this cage are a number of pallets that have boxes on the pallets, and they're all shrink-wrapped. They're on pallets so that they can be moved easily.

I don't know if Ron or Marty would like to describe what some of the conditions are like in some of the other areas.

Mr. SHAYS. I'd like to have it all. I'd like you to contrast some of the sites and so on.

Ms. BASCETTA. OK.

Mr. EBLE. Mr. Chairman, I visited the Hines location. This is also a VA facility. This is in Chicago, just outside of Chicago at Hines, IL. And it's set up very much like Ms. Bascetta is describing within—in this case within a pharmaceutical facility, a large, caged, locked room. And the pharmaceuticals for this purpose are segregated from the other items there and locked.

Mr. SHAYS. I'm just trying to get some basic area of what you're talking about. It seems to me like that this is not a big deal in terms of being able to store this and to keep records, and it strikes me that obviously there are some of the pharmaceuticals that may expire and you have to replace them.

Mr. EBLE. Right.

Mr. SHAYS. I would imagine some would have to be cooled.

Ms. BASCETTA. That's correct.

Mr. SHAYS. And I just want to know if you saw a consistency in all five sites. I want to know if we're talking about a small room, 10x10, if we're talking about a very large place, with some already on trucks. I just want to have a sense of what—

Mr. EBLE. This would be small location, perhaps 10X10 or 15X15.

Mr. SHAYS. I mean, you could almost store it in one of these public storage spaces?

Mr. EBLE. In a garage. Right, that's correct.

Ms. BASCETTA. That's about the dimension.

Mr. GUTHRIE. Essentially, Mr. Chairman, there are essentially six to eight pallets. And pallets are typically 4x4 or 5x5 and the goods are stacked perhaps 3 to 5 feet high on each one of these pallets. So if you can envision an area that's perhaps as large as the space in front of us here, it's a caged area usually with solid masonry walls behind and a screen, like a screen fencing, a fairly rigid fencing with a locked screen door. That's rather typical. It's kind of a warehouse feeling environment to it. And it typically would

have a small refrigerator inside that space to house pharmaceuticals that must be refrigerated.

Mr. SHAYS. We don't need to know the exact location of these sites since, actually, security is important. But I want to also get a feeling for the number of different types of things that we have to record. Are we talking about 100 items, are we talking about 5,000 items, what are we talking about?

Ms. BASCETTA. About 200,000 items is the denominator in the counts that we did, in the inventory counts that we did.

Mr. SHAYS. And 200,000 items and there are groupings within each so are you—

Ms. BASCETTA. Three of the sites have 35,000 items of primarily medical supplies. Not antidotes or antibiotics. Those are in smaller quantities.

Mr. SHAYS. I'm just trying to now get a sense of what your major concern is and then what your second biggest concern would be and just go down.

What's your first—and let me ask you, when you were doing your investigation, are we talking about things in the margin, or are we talking about some very serious problems?

Ms. BASCETTA. In terms of the specific significance of the shortages that we found, we didn't make a judgment as to the criticality of those specific shortages to the mission. Our concern was that because of the failure in the underlying systems to be able to track what's in the stockpiles and to be able to assure currency and their availability for use, that we wouldn't be able to tell from time to time how adequately maintained those stockpiles were.

That's our major message. It's less a message that focuses on the specific findings of our inventory count, which we consider symptomatic of the more serious underlying problem of the need to have systems in place that can track the stockpiled items.

Mr. SHAYS. Are you saying that we were not—did they have records of what they have, but they simply didn't have the quantities they needed? Or did they not even have the records to say what was actually in the cage?

Ms. BASCETTA. Sometimes they didn't have the correct quantities, but the bigger problem was that they didn't have, for example, historical documentation of what had been replaced. And so there was no way over time to track how the stockpile had been maintained.

Mr. SHAYS. Just tell me the method you used to examine the inventory in the stockpile material. What was the method?

Ms. BASCETTA. Sure. I'd be happy to and this might help give you a sense of how manageable these stockpiles are in terms of their size and dimensions.

I'm also glad that you asked this question because the agencies, although they concur with our recommendations, do take issue with our count.

What we did was, of course, because of our timeframes, we wanted to go onsite immediately, but VA was uncomfortable with that. They wanted a few weeks to do some pre-inventories before we arrived.

Mr. SHAYS. I don't understand that at all. Why wouldn't the best way of knowing the condition have been to go in right away and just check it out?

Ms. BASCETTA. Well, it would have been and that certainly would have been our preference, although we were concerned more about the systems again than the actual counts. So we were willing to accommodate them on their request to give them a little bit more time.

When we arrived onsite we did a 100 percent count of every single item in the stockpile. We did not use a sampling approach so that—

Mr. SHAYS. In all five sites?

Ms. BASCETTA. Yes, that's correct. So, there you know that if we were able to do it in a matter of days, it's a manageable task.

Mr. SHAYS. Right.

Ms. BASCETTA. We also ensured that VA program staff were present at every location while we were counting. And when we noted discrepancies, we brought them to the attention of the VA personnel onsite with us. And in all cases they recounted except in California, where toward the end of our work they chose not to recount.

In no instance did they inform us that we had counted incorrectly while we were onsite. It was only after our report was issued that they raised some questions about substitutions and nomenclature issues that they think might have caused us to miscount.

And the final issue that I want to clarify for the record is that while the agencies believe that our count of errors is inflated, we want to explain that that is truly the accurate way to measure deficiencies in the systems. What we did was count multiple errors for a single item. And that's because if an item had, for example, a wrong expiration and a wrong lot number, that would require two corrective actions to make the system accurate.

So, our discrepancy rate does account for multiple errors for a single item, but we believe that's the correct way to measure the systems.

Mr. SHAYS. Now, for the record just tell me how the lack of management controls affects management of the stockpiles.

Ms. BASCETTA. How a lack of management—

Mr. SHAYS. How the lack of the internal controls affects the management of the stockpile.

Ms. BASCETTA. Well, there are several dimensions of internal controls that need to be in place to give stockpile management the appropriate attention. First, you need to establish an environment in which the staff who are involved place an appropriate priority on stockpile management and not in a singular fashion, but in a continuous fashion. It's an iterative process that needs to have a high level of attention over an extended period of time.

In addition, all of the policies and procedures that you would have in place, such as those that are reflected in our Standards for Internal Control and in OMB Circular A-123, pretty much spell out what you need to do to ensure that your inventories are accurately maintained.

Mr. SHAYS. This may seem like somewhat of a digression, but I'm having a hard time understanding why it is we would have any

problems whatsoever. I mean, when I go and get my car repaired, I go the parts desk of the automobile dealer and they can, on their computer, tell me what they have. They can show me pictures of it. They can decide they only have three left or two left or they're going to order it and they're going to get it in a few days. I mean, so this is not rocket science-kind of management skills, is it?

Ms. BASCETTA. No, it's pretty straightforward inventory control. I agree with you.

Mr. SHAYS. To what extent have the agencies tried to implement your recommendations?

Ms. BASCETTA. Well, right now what we have is their letters to us concurring with our recommendations. And our best evidence of their actions are the agreements that they've signed with VA. And those appear to be much better than the previous agreement that VA had with OEP. As you know, this is CDC's first agreement with VA and they quite proactively incorporated many of our recommendations to prevent the kind of problems that we had identified in the VA OEP situation. I'd say that if they implement what is in those current agreements and they give it appropriate management attention, they ought to be able to fix the problems that we identified.

Mr. SHAYS. What internal controls did you find in place to ensure that the requests and draw-downs for the medical supplies from national stockpiles were properly authorized?

Ms. BASCETTA. I don't think we—

Mr. GUTHRIE. Mr. Chairman, I don't know that there have been draw downs per se. These are pretty static stockpiles and it would be the rare event where they would draw down on these stockpiles.

Mr. SHAYS. If a draw down were to occur, how would they record it?

Mr. GUTHRIE. I don't know that we covered that during the course of our review, sir.

Mr. SHAYS. Is this the same—I've asked you about the four VA facilities, but how about the Marine facility, describe to me how it would compare.

Ms. BASCETTA. The Marine—

Mr. SHAYS. Do they stockpile the same basic pharmaceuticals, and so on?

Ms. BASCETTA. They have similar types of items in their stockpile, emergency supplies and a variety of antidotes that would be used. They refer to their stockpile—they refer to their supplies as a working stock. They object to the word "stockpile." But it seems to us—

Mr. SHAYS. Why would they object to that?

Ms. BASCETTA. Well, we're not sure, to be honest. It seems to us to be a semantic difference. And to us the important part is that whether they call it a working stock or a stockpile, they agree that it needs to be managed in accordance with the standards that we laid out.

Mr. SHAYS. Does a working stock mean they continually roll over and take things out? I mean, what's the significance of that? I'll ask them, but what is your sense of the significance?

Ms. BASCETTA. The way we understand it, the supplies would be handled similarly to the NMRT sites in that they're deployable

supplies. So we really don't see much of a distinction. The other issue that they raise is that their working stock is internal to their unit. They have primarily a military mission rather than a civilian mission. But on the other hand they do acknowledge that in the event of an emergency, if they show up onsite and the locals don't have supplies, they will treat civilians in those situations.

Mr. SHAYS. Do they have supplies that are just for, say, children?

Ms. BASCETTA. They do.

Mr. SHAYS. So that would strike me—as they don't have children in the Marines, so they obviously have some supplies for civilians. And that makes sense.

Ms. BASCETTA. It seems that way. And they also appear to have thousands more of certain items than they would need for their own internal use.

Mr. SHAYS. Great.

Mr. Tierney, nice to have you here.

Mr. TIERNEY. I want to thank the members of the panel for coming forward today. And I apologize for my tardiness. I have read your testimony in addition to listening to what you have to say, and I don't have very many questions in addition to the chairman's. I think he covered the ground pretty well.

But I am curious to know, when you were dealing with the folks that are responsible for these measures, did you find any glaring lack of training or glaring lack of unfamiliarity with your standards?

Ms. BASCETTA. Yes, I'd say that we did. We're not certain whether the reason is that there simply wasn't enough attention put on the kinds of skills that a person would need to have to handle this kind of an effort, but we did notice that people with financial background or with any kind of accounting were not in the picture and that had those skill sets been brought to bear, we don't think that this would have happened or certainly not to this degree.

Mr. TIERNEY. And was that right across the board, VA, the Marines?

Ms. BASCETTA. Yes.

Mr. TIERNEY. How about the management skills on that, did you find that the people that were responsible overall for it had the skills and just lacked the individuals beneath them having those appropriate skills and training, or do you think the management skills needed to be improved?

Ms. BASCETTA. I don't think that it was a problem of management skills as much as a problem of lack of attention. I simply think this wasn't given high enough priority. It just didn't seem to be on everybody's radar screen at an appropriate level.

Mr. TIERNEY. I was a little concerned about what appeared to be in your testimony, a lack of internal oversight or mechanisms to assure that they were doing what they ought to be doing. And so nobody was watching anybody else and sometimes somebody was doing all the functions instead of dividing them so that you make sure errors would be caught.

Ms. BASCETTA. Right.

Mr. TIERNEY. Have you noticed any marked improvement in those areas since your report in dealing with those companies?

Ms. BASCETTA. We see that they have policies and procedures in place to follow those standards, but we haven't been back to verify that, in fact, that's what's happening.

Mr. TIERNEY. When will you go back for that?

Ms. BASCETTA. We haven't been asked.

Mr. TIERNEY. OK, fair enough. Thank you very much.

Mr. SHAYS. I just have one other question in terms of the draw downs. I understand they haven't drawn down, but did you look the procedures of how they draw them down? Did you ask them what they would do and how they would do it or did you just not?

Ms. BASCETTA. We really focused only on what was actually physically in the stockpile. I suppose that if there had been those kinds of procedures in place we would have reviewed them as well. And certainly they should be spelled out in their new policies and procedures.

Mr. SHAYS. You weren't asked to do this, but were you—I mean, these are four sites in the country that then may go somewhere else.

Ms. BASCETTA. Right.

Mr. SHAYS. Did you have a sense intuitively when you saw these sites that they were in a reasonable location, near an airport, so that we could get these to where they needed to go in a few hours, not days?

Ms. BASCETTA. I think that's fair to say, yes. That they were appropriately positioned.

Mr. SHAYS. OK. Thank you very much. You've given us an opportunity now to meet with the next panel. Thank you.

Our second panel is Dr. Frances Murphy, acting Deputy Under Secretary for Policy at the Department of Veterans Affairs, accompanied by Mr. John Ogden, Chief Consultant, Pharmacy Benefits Management Strategic Health Group, Department of Veterans Affairs; testimony from Dr. Robert Knouss, Office of Emergency Preparedness, Public Health Service, Department of Health and Human Services; Dr. Steven Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases, Center for Disease Control and Prevention, accompanied by Mr. Steve Bice, Branch Chief, National Pharmaceutical Stockpile Branch, Department of Health and Human Services, and our fourth testimony is from Colonel Carlos Hollifield, Chemical Biological Incident Response Force, U.S. Marine Corps, Department of Defense, accompanied by Captain Warren Rich Dalton, M.D.—so, Doctor, Biological Incident Response Force, with the Marines as well.

Do you have everybody at the table?

Now, let me just say, I'm going to swear you all in, but I just have to first take care of some procedural things from the committee, unanimous consent, and we're going to welcome your testimony and have it basically be as long as you need it to be.

I ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that the record remain open for 3 days for that purpose. Without objection, so ordered.

And I ask further unanimous consent that all witnesses be permitted to include their written statements in the record. And without objection, so ordered.

Again, we'll do the 5-minutes, we'll roll it over again for another 5 minutes, but if you feel that you need to say something and can't do it within the 10-minutes I want it part of the record and am happy to have you do that.

Dr. Murphy, we're just going to start with you and then we'll go to Dr. Knouss and go right down the line, Dr. Ostroff, and then Colonel Hollifield.

You're on.

**STATEMENTS OF FRANCES MURPHY, M.D., ACTING DEPUTY UNDER SECRETARY FOR POLICY AND MANAGEMENT, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY JOHN OGDEN; ROBERT F. KNOUSS, M.D., OFFICE OF EMERGENCY PREPAREDNESS, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHEN M. OSTROFF, M.D., ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ACCOMPANIED BY STEVEN BICE; AND COLONEL CARLOS HOLLIFIELD, U.S. MARINE CORPS, CHEMICAL BIOLOGICAL INCIDENT RESPONSE FORCE, ACCOMPANIED BY CAPTAIN WARREN (RICH) DALTON, M.D., U.S. NAVY**

Dr. MURPHY. Mr. Chairman and members of the subcommittee, I am pleased to have this opportunity to address GAO's recent report concerning managements of chemical and biological medical supplies. I am accompanied by Mr. John Ogden, Chief Consultant—

Mr. SHAYS. We swear in everyone who testifies, even Members of Congress. Actually I didn't, Senator Byrd came and we didn't administer the oath to him. I chickened out, but everyone else who has come before us has.

I'm sorry, I'm going to have you start over again. My apology.

[Witnesses sworn.]

Dr. MURPHY. I'd like to enter my entire testimony in the record if that would be possible, but to shorten the statement this morning if I could.

As you know, VA's primary mission is to provide health care and benefits to veterans; however an additional VA role is to ensure health care for eligible veterans, military personnel, and the public during Department of Defense contingencies, natural, man-made, and technological emergencies. VA has assigned lead responsibility for this mission to the Emergency Management Strategic Health Care Group, which is headquartered in Martinsburg, WV. The primary responsibilities and authorities governing VA's program implementation are to serve as a VA/DOD Contingency Hospital System backup, which requires VA to serve as the primary backup to DOD medical services in times of national emergencies.

We also act as part of the National Disaster Medical Defense System. VA operates to provide capability for treating large numbers of patients who are injured in major peacetime disasters in the United States and its territories, or to treat casualties resulting from conventional military conflict overseas.

In addition, Presidential Review Decision Directive 62, Combatting Terrorism, which was issued in May 1998, tasked the U.S. Pub-

lic Health Service to work with VA in ensuring that adequate stockpiles of antidotes and other necessary pharmaceuticals are maintained nationwide and to have the ability to train medical personnel in NDMS hospitals.

Under the provisions of this plan over the past 9 years, VA has deployed over 1,000 health care personnel, and provided medical supplies, and equipment, including mobile health clinics, and facilities.

In addition, under the Presidential Decision Directive and as part of the NDMS system, VA has an agreement with the U.S. Public Health Service to maintain the four caches that were talked about in the GAO testimony this morning, at strategic locations throughout the United States, that may be needed for treatment of victims of an event involving weapons of mass destruction. If such an event occurs, these caches would be deployed to the site of the incident. These pharmaceuticals would be used and could provide supplemental capability to local medical caregivers and facilities to treat the victims of the weapons of mass destruction.

VA also has entered into a recent agreement with the Centers for Disease Control and Prevention to assist with procurement and maintenance of the National Pharmaceutical Stockpile that would also be located in specific cities throughout the United States. In both of these instances VA receives funds from the agencies involved to procure and maintain these stockpiles for those respective agencies.

In response to the GAO Report on Management of Medical Supplies, I am pleased to have an opportunity to discuss with you VA's role and activity as a partner with HHS in procurements, inventory storage and maintenance and delivery of medical supplies that are needed for these responses.

The development and maintenance of these stockpiles are integral parts of the Nation's ability to provide needed health care following an emergency. We recognize the key and strategic nature of this mission.

OEP officials determine the contents of those inventories; they provide the funding for the procurement, maintenance and deployment of the medical supplies; and they determine the locations of the stockpile at these sites across the United States. The partnership with the Office of Emergency Preparedness and VA began in late 1995 and evolved into a formal agreement by 1997.

This partnership has been extended now to a partnership with CDC to maintain the National Pharmaceutical Stockpile program.

With that background, I'd like to give you a sense of how VA has responded to the GAO report recommendations. As you've already heard, Mr. Chairman, we concurred with the GAO recommendations and have taken action to correct the problems that they identified. GAO recommended that OEP, CDC, and the Marine Corps, and VA establish sufficient systems of internal control over their chemical and biological stockpiles of medical supplies and pharmaceuticals maintained for responding to a terrorist incident. Management needs to reasonably make certain that personnel conduct risk assessments to ensure efficient and effective administration of the stockpiles and to organize those program activities to identify and

mitigate any risks. That way, when needed, the stockpiles can be provided as planned.

To implement this recommendation, OEP has contracted with the Logistics Management Institute to evaluate the program, to conduct a risk assessment, and to advise VA on areas for improvement. We look forward to utilizing their expertise and input and are moving ahead briskly to get this evaluation done.

Second, the GAO recommended that the agencies arrange for periodic, independent inventories of the stockpiles. I'm happy to report to you that VA has already conducted full inventories of all of the stockpiles at every location. Complete stockpile inventory will be done on a quarterly basis from this time forward. And at completion of the December 2000 inventory, the team will review the lessons learned and make any further improvements that we feel are necessary in looking at the processes in place during that year.

Third, GAO recommended that VA implement a tracking system that retains complete documentation for all supplies which are ordered, received or destroyed. While a tracking system was in place at the time, obvious deficiencies were noted. We recognized that improvement needed to be made and we arranged for a more comprehensive and consistent tracking system to be in place on a continuous real-time basis that will be accessible to VA, OEP, and CDC staff.

Fourth, the GAO recommended that supplies be properly rotated. It is important that the system be updated and provide reports about future expiration dates, and that the ordering, receiving, shipping and rotating of stock at each site be done on a timely basis. We've put systems in place to ensure that this will occur.

Mr. Chairman, I would like to close with a quick description of some additional actions that have been taken since the GAO review process took place, and that is that, as you've heard, we have new memorandums of agreement with both OEOP and with CDC which address all of these issues. We feel that we have moved forward very rapidly to correct the problems that were identified.

Second, VA employees who were responsible for managing this program previously did this as an ancillary duty. Obviously, while the resource need is not great, it is important to have dedicated staff to maintain these stockpiles and to carry out the periodic activities that are necessary to ensure that these functions are being performed in a consistent and reproducible way. Those full-time personnel have been put in place. There is now a permanent full-time director of the emergency pharmacy activities, and a total of six full-time staff will be assigned to this activity.

Third, all the refrigeration issues have been dealt with.

Fourth, some communication issues were raised. The communication between our partners and VA has been improved. There have been numerous meetings and conference calls and we intend to continue that schedule of routine meetings and activities into the future.

Fifth, all the stockpiles have been replenished. And in addition, during the week of December 27, 1999, full inventories were conducted and the amount of diazepam on hand at each stockpile was revalidated. We do feel that we need to take issue with the statement that 1,000 doses of diazepam were missing. In fact, they were

not missing, they were replaced with substitutes when the original auto-injectors were not available for purchase. And I am pleased to report that we can account for all of the Valium/Diazepam stores that were necessary for that stockpile.

Mr. Chairman, I believe that the efforts of both the HHS staff and the VA staff to develop, maintain, and deploy emergency supplies, while they have had limitations in the past, have been improved significantly over the last several months. And we believe we now have systems in place that address the GAO concerns and will ensure that these stockpiles are available should they be necessary in the event of a national emergency.

I'd be happy to answer questions for the committee.

Mr. SHAYS. Thank you very much. We appreciate it a lot.

[The prepared statement of Dr. Murphy follows:]

STATEMENT OF  
FRANCES M. MURPHY, M. D., M. P. H.  
ACTING DEPUTY UNDER SECRETARY FOR POLICY AND MANAGEMENT  
VETERANS HEALTH ADMINISTRATION  
DEPARTMENT OF VETERANS AFFAIRS  
BEFORE THE  
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL  
RELATIONS  
COMMITTEE ON GOVERNMENT REFORM  
HOUSE OF REPRESENTATIVES

MARCH 8, 2000

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Mr. Chairman and Members of the Subcommittee:

I am pleased to have this opportunity to address GAO's recent report concerning management of chemical and biological medical supplies. I am accompanied by Mr. John Ogden, Chief Consultant, Pharmacy Benefits Management Strategic Health Care Group.

**BACKGROUND**

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:

- VA/DoD Contingency Hospital System, PL 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 in the United

States and its territories, or to treat casualties resulting from a conventional military conflict overseas.

- Federal Response Plan, required by Pub. L. 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 (PHS), 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. VA receives funding from the PHS to cover the costs of maintaining the pharmaceutical stockpiles.

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 nine 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), and as part of the NDMS, VA has an agreement with USPHS to maintain four 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 with the NDMS National Medical Response Teams (NMRTs) that are maintained and directed by the Department of Health and Human Services' Office of Emergency Preparedness (OEP). In addition, these pharmaceuticals would be used by the NMRT's and could 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 National Pharmaceutical Stockpile that would also be located in specific cities throughout the United States. 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 discuss VA's activity as a partner with 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.

Mr. Chairman, the partnership of HHS's OEP and VA's EMSHG and Emergency Pharmacy Services (EPS) is, for pharmaceutical stockpile management, a relatively recent one. (Note: EMSHG has overall VA responsibility for emergency management activities. The EPS is

directly responsible for managing the pharmaceutical/medical supplies stockpiles and works in coordination with EMSHG.) From the inception of the partnership, all parties attempted to meet the requirements of the program with very limited staffing. Until recently, VA managed its program using only one and one-half staff nationwide. It was apparent to VA officials and also to the GAO review team that this staffing was insufficient to maintain these stockpiles up to the necessary standard. The lessons learned to date in the program, coupled with the implementation of GAO's recommendations, and additional staffing resources will enable us to not only build a better system for OEP, but also a better system to support VA's new partnership with the Centers for Disease Control (CDC) in the National Pharmaceutical Stockpile Program.

With the above background, what follows is VA's plan to address each of the four recommendations from the 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. Management needs to reasonably make certain that personnel conduct risk assessments to ensure efficient and effective administration of the stockpiles and to organize program activities to identify and mitigate risks. That way, the stockpiles will be provided as planned when needed. To implement this recommendation, OEP has contracted with Logistics Management Institute to evaluate this program, conduct a risk assessment, and advise us on areas for improvement. We look forward to utilizing their input. After that, we will conduct ongoing risk assessments as an integral part of OEP's program to assure that these supplies will be provided on time when requested. CDC is contracting independently with LMI to conduct a similar evaluation.

Second, GAO recommended that the agencies arrange for periodic, independent inventories of the stockpiles. In January 2000, VA conducted full inventories at each cache site. Complete inventories, using personnel from EMSHG, EPS and the Office of Acquisition and Material Management, will also be conducted on June 1, 2000, September 1, 2000, and December 1, 2000. OEP staff will be invited to participate in these inventories. At the completion of the December 2000 inventory, the team will review lessons learned, and decide on the frequency of future audits and the need for onsite staffing dedicated to managing the stockpiles.

Third, GAO recommended that VA implement a tracking system that retains complete documentation for all supplies that have been ordered, received or destroyed. While a tracking system was in place at the time of the audit, it is clear that the staffing to properly maintain the system was insufficient and the data systems needed upgrading. Based on lessons learned from the prior system, in December 1999, VA included additional staff in the pending Memorandum of Agreement (MOA) with OEP to maintain the tracking system. Furthermore, VA is now using an updated tracking system for use in the OEP and CDC's National Pharmaceutical Stockpile Program. The updated system provides documentation for activities associated with the inventory management of the stockpiles. When fully implemented the new system will also allow continuous, real-time access (read only) by OEP and CDC staff. In addition, inventory reports will be available and provided to OEP and CDC officials on a regular and ad-hoc basis.

Fourth, GAO recommended that supplies be rotated properly. The updated system provides reports indicating future expiration dates. These reports allow for improved planning for ordering, receiving, shipping and rotating stock at each location on a timely basis. These capabilities enable EPS officials to keep stockpile manipulations to a minimum and assure

effective and appropriate dating of the supplies.

Mr. Chairman, I would like to close with a description of additional actions taken since the GAO review was in process. First, a new MOA between OEP and VA has been developed and is in the clearance process by VA. The MOA incorporates the recommendations from the GAO audit report. Second, the VA employee who had responsibility for managing this program previously did so as an ancillary duty. In October 1999, VA selected a permanent, full-time director of emergency pharmacy activities. In addition, the staffing of the program has been increased under agreement with HHS by five positions. Third, all refrigeration issues cited in the GAO report have been addressed. Fourth, numerous meetings and conference calls between OEP and VA officials have occurred to address the issues raised by GAO and the new MOA. Fifth, in September 1999, all stockpiles were replenished based, in part, on information from the GAO review. In addition, during the week of December 27, 1999 and also during the full inventories conducted in January 2000, the amount of diazepam on hand at each stockpile was revalidated. (This action was taken due to the statement by GAO that 1,000 diazepam autoinjectors were missing and our concern that diversion of a controlled substance may have occurred. I am pleased to report that all diazepam is accounted for and our review does not substantiate any missing diazepam.) Sixth, we have reviewed space needs at each site based on the expansion of the caches and will soon relocate two caches to more suitable storage locations. Seventh, to improve security of each cache, we will install locking devices at the access point that will record date, time and the individual gaining access. We are seeking technology that will provide remote monitoring of the same. Eighth, in February 2000, all ordering activities were assigned to VA's National Acquisition Center; therefore, meeting one of the GAO's recommendations regarding separation of duties.

Mr. Chairman, the efforts of OEP and EPS staff to develop, maintain, and deploy emergency supplies have been adequate but with the limitations identified by GAO. However, the EPS functions will be more successful in the future with the actions that VA and OEP are taking to strengthen our programs. 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.

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

Mr. SHAYS. Dr. Knouss.

Dr. KNOUSS. Thank you very much, Mr. Chairman. I want to thank you again for the opportunity to appear before the committee and for previous appearances where we've discussed the whole of the National Disaster Medical System and our approach as to trying to be prepared to assist the civilian population should one of these awful events occur. But I would like to put into context these teams and these stockpiles because these are just a part of the total system of the National Disaster Medical System in which we partner with the Department of Veterans Affairs and the Department of Defense and the Federal Emergency Management Agency.

I'd like to spend a few minutes this morning just highlighting my testimony. I've provided my complete statement for the record.

Today I'm here to discuss the recently released GAO report of the complete audit of four of our specialized pharmaceutical caches that are used by our special National Medical Response Teams.

These stockpiles were designed to be deployed with these four specialized teams in responding to a weapons of mass destruction event and providing medical care to its victims. Of course, we use our system for many other things. And in fact, we're just now today completing some of our work with the Air Alaska crash out in California in identifying the victims that died in that accident. The stockpiles that we maintain for the National Medical Response Teams contain specialized pharmaceuticals to treat up to 5,000 victims of a chemical exposure to nerve agents, among other medicines and medical supplies.

The NMRT stockpiles are designed primarily to provide additional supplies to local areas that have depleted their own pharmaceutical resources in the initial hours after a chemical attack, when time is of the essence. The NMRT stockpiles have also been used to preposition supplies for designated special events, including here in Washington, DC, for State of the Union addresses and other activities.

The Department of Veterans Affairs is one of the four partners in the National Disaster Medical System and manages one of the largest pharmacy systems in the country. Consequently, we approached VA with our proposal for the purchase, management and deployment of these stockpiles. VA was able to purchase the pharmaceuticals and supplies through their purchasing system and store the stockpiles in locations from which they can be deployed with our teams.

The report recently issued by GAO raises important concerns about the manner in which these stockpiles were managed and the oversight provided by our office. We've taken GAO's efforts and report seriously, and we're taking immediate steps to ensure proper internal controls are in place and that we are in compliance with all regulations. I want to note that we have carefully reviewed the results of GAO's audit and do not believe that any of the issues cited degraded our ability to respond to a chemical attack should it have occurred over the last 2 years.

Based on the result of the GAO audit, however, we have signed a new interagency agreement with the VA that spells out each agency's responsibilities and activities, including assurance of appropriate storage and physical security of the stockpiles; strength-

ening of internal controls, including audits by both our staff and VA staff, as well as independent reviews; establishment of a schedule of regular communications, inventory updates and reports; and regular and recurring management oversight by our office.

We certainly understand GAO's concerns that insufficient management and oversight controls do not provide any assurance that, even if the audit had been 100 percent correct on 1 day, there are no absolute assurances the same would be true the next day, or at the time of deployment. However, we do not agree with the implication that we would not have been able to respond effectively to a WMD incident. A "12 percent error rate" has to be put in the context of the type of items that were included in the calculation, and how the error rate was determined. An excess of large gloves is not a significant problem and it is our understanding that an individual item could have been produced up to three errors if it was over or under the count, if the lot number was recorded incorrectly, and if the expiration date was not the same as the inventory listing.

But since being provided the audit results we have been working with the VA to assure that these errors, regardless of level of significance, are corrected. Our office and VA will ensure implementation of a far more effective control environment, including stricter inventory control and monitoring and regular reporting and feedback; ensuring that information is recorded properly and the inventory is kept up to date; ensuring additional and regular onsite monitoring of the stockpiles, including announces and no-notice inspections of each stockpile; and ensuring that risk assessments and control activities are implemented.

In conclusion, I want to reiterate that we are working very diligently within our own office and with our VA partners to correct the problems that GAO found, to do a 100 percent inventory, to ensure that current stocks and recordkeeping are accurate and up to date, and to develop and implement the proper management controls and oversight to ensure that the stockpiles are ready to deploy and that we are in compliance with all laws and regulations.

Mr. Chairman, that concludes my testimony. I will be pleased to answer any questions that you may have later on.

Mr. SHAYS. Thank you very much. We've heard from the VA and from HHS and now we'll hear from CDC.

[The prepared statement of Dr. Knouss follows:]

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STATEMENT OF

ROBERT F. KNOUSS, M.D.

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL  
RELATIONS

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

March 8, 2000

Mr. Chairman and Members of the Committee,

I am Dr. Robert Knouss, Director of the Department of Health and Human Services' (DHHS) Office of Emergency Preparedness (OEP). I appreciate the opportunity to appear before you once again to discuss our program's activities.

Last September, I appeared before this Committee and spoke about OEP and the National Disaster Medical System (NDMS), its teams and activities. Today, I am here to discuss the recently released General Accounting Office (GAO) report after an audit of the four specialized pharmaceutical caches used by our National Medical Response Teams (NMRTs), and the cache used by the Marine Corps' Chemical Biological Immediate Response Force.

#### **Background and Purpose of the Pharmaceutical Caches**

In Fiscal Year (FY) 1997, the Congress appropriated \$1.8 million to OEP for the creation of four stockpiles of specialized pharmaceuticals, and in FY 1999, an additional \$1.4 million was provided with the funds appropriated to the Centers for Disease Control and Prevention (CDC) to increase the stocks to be able to treat more victims. These stockpiles were designed to be deployed with our four specialized disaster teams in responding to a weapons of mass destruction (WMD) event and providing medical care to its victims. Three of the teams (California, Colorado and North Carolina) can be deployed anywhere in the country. The Washington, D.C. team does not deploy outside of the Washington, D.C. metropolitan area. The stockpiles contain specialized pharmaceuticals to treat up to 5,000 victims of a chemical exposure to nerve agents such as sarin and VX; vesicants, such as mustard gas; and pulmonary agents such as phosgene. In addition, each stockpile has medicines to protect the team members from cyanide poisoning and antibiotics to begin to provide prophylactic treatment to team members should they be exposed to a biological agent. Each stockpile will also accommodate treatment of the team for radiation exposure.

As you know, OEP is also working with metropolitan areas across the U.S. to create Metropolitan Medical Response Systems (MMRS). Part of the purpose of these systems is to ensure that each metropolitan area has specialized pharmaceuticals on hand to protect and treat responders and to be able to begin to treat WMD victims. We knew that an individual metropolitan area might not be able to afford to keep all the stores of pharmaceuticals on hand that it might need in the event of a WMD attack. We also knew that it would take up to 12 hours to deploy the National Pharmaceutical Stockpile that CDC is developing. Therefore, we designed our stockpiles to be able to deploy with our NMRTs. The three deployable teams and the associated stockpiles can be at an airport (commercial or military) and be ready to board within four hours of notification. The NMRT stockpiles are designed primarily to provide additional supplies to local areas that have depleted their own pharmaceutical resources in the initial hours after a chemical attack, when time is of the essence. The NMRT stockpiles have also been used to pre-position supplies for designated special events.

In FY 1997, when we began developing the NMRT stockpiles, we did not want to develop new and expensive systems, and we looked for systems that were already in place, on which we could build. The Department of Veterans Affairs (VA) is one of the four partners in the National Disaster Medical System (NDMS) and manages one of the largest pharmacy systems in the country. Consequently, we approached VA with our proposal for the purchase, management and deployment of the NMRT stockpiles. VA was able to purchase the pharmaceuticals and supplies through their purchasing systems, and store the stockpiles at facilities in strategic locations near the NMRTs (Los Angeles, CA; Denver, CO; Winston-Salem, NC; and the Washington, D.C. metropolitan area).

### **GAO Report**

The report recently issued by GAO raises important concerns about the manner in which these stockpiles were managed and the oversight provided by OEP. We have taken GAO's efforts and report seriously, and we are taking immediate steps to continue to ensure proper internal controls are in place and that we are in compliance with all regulations. Before commenting on the specific steps we are taking, however, I want to note that we have carefully reviewed the results of GAO's audit and do not believe that any of the issues cited degraded our ability to respond to a chemical attack should it have occurred over the last two years.

Based on the result of the GAO audit, however, we have signed a new interagency agreement with the VA that spells out each agency's responsibilities and activities, including:

Assurance of appropriate storage and physical security of the stockpiles. The stockpiles will be in secured locations, with restricted personnel access. In addition, controlled substances will be ordered, received, stored and issued according to applicable DEA and OMB regulations.

Strengthening of internal controls. OEP and VA personnel, with possible assistance and oversight from the HHS Inspector General's office, will conduct an initial 100 percent inventory and will be matched with inventory records. All out of date pharmaceuticals will be replaced, and we will assure that lot numbers are recorded correctly. Regular and no-notice audits will be conducted.

Establishment of a schedule of regular communications. VA will provide inventory updates on a regular and recurring basis and will also provide reports on inventory replacements and changes. OEP will provide regular and recurring management oversight.

The FY 2001 President's budget includes resources for the stockpile management activities that the VA will now conduct and four our additional activities.

### **Ability to Respond**

We certainly understand GAO's concerns that insufficient management and oversight controls do not provide any assurance that, even if the audit had been 100 percent correct on one day, there are no absolute assurances that the same would be true the next day, or at the time of deployment. However, we are concerned with GAO's implication that we would not have been able to respond effectively to a WMD incident. A "12 percent error rate" has to be put in the context of the type of items that were included in this calculation, and how the error rate was calculated. An excess of large gloves and an

undercounting of medium size gloves is not a significant problem. And it is our understanding that an individual item could have produced up to three errors – if it was over (or under) the count, if the lot number was recorded incorrectly, and if the expiration date was not the same as the inventory listing. Substitutions of an equivalent product also do not affect response capacity. To reiterate, we recognize the significant concern is not whether there is a 100 percent inventory accuracy, but whether the principles of quality control, quality assurance and inventory management have been utilized.

GAO has provided us with the spreadsheets from their audit of each cache. We have taken a serious look at the audit of each of the VA caches. We found that, for the most part, the errors occurred in the number of medical supplies, and that most of the errors were because of surplus quantities, not shortages. We focused our activities on the pharmaceuticals and controlled substances, and found that most of the missing pharmaceuticals at the time of the audit occurred at one location. Since being provided the audit results, we have been working with the VA to assure that these errors, regardless of level of significance, are corrected.

Security is a principal concern. As a result, we will be moving the location of one of our stockpiles so that it can be more readily monitored. In doing so, we want to be particularly careful, however, that we not increase the time that it would take to mobilize our team with its medical supplies and pharmaceuticals.

#### **Further Actions**

With the signature of the new agreement, we will accomplish the following:

Have a more effective control environment - Requirements for stricter inventory control and monitoring, as well as for regular reporting and feedback, are included in the new agreement. In addition, VA officials have informed us that there are now clear lines of command and assignments for stockpile management. The new agreement includes the funding of additional staffing at the VA for close stockpile management.

Properly record information and communicate with management - OEP will provide funds for additional staff and improved computerized inventory records at the VA to help ensure that the information is recorded properly and kept up to date. In addition, OEP and VA are instituting a monthly reporting system and periodic meetings with management.

Ensure monitoring - VA staff is providing additional and regular on-site monitoring of the stockpiles. OEP staff or appropriate contractual staff, will conduct announced and no-notice inspections of each stockpile.

Conduct risk assessments and implement control activities that are linked to the results of a mission risk assessment - The agreement provides that VA, with an OEP representative present, prepare a risk analysis of each location of storage. This analysis includes estimation of the risk's significance, assessment of the likelihood of its occurrence, decisions and recommendations on managing the risks and actions. Based on these analyses, OEP and VA will ensure appropriate risk management.

**Conclusion**

In conclusion, I want to reiterate that we are working very diligently within our own office and with the VA to correct the problems that GAO found, to do a 100 percent inventory, to ensure that current stocks and record keeping are accurate and up to date, and to develop and implement the proper management controls and oversight to ensure that the stockpiles are ready to deploy and that we are in compliance with all laws and regulations.

Mr. Chairman, this concludes my testimony. I will be pleased to answer any questions you may have.

Mr. SHAYS. Dr. Ostroff.

Dr. OSTROFF. Thank you, Mr. Chairman.

We appreciate the opportunity to discuss the development of the National Pharmaceutical Stockpile or NPS, which is one of the components of our overall public health response to the threat of bioterrorism.

Today I am accompanied by Mr. Steven Bice, who is Chief of our CDC National Pharmaceutical Stockpile Branch located in the National Center for Environmental Health.

In 1998, CDC issued Preventing Emerging Infectious Diseases: A Strategy for the 21st Century, our plan for preventing emerging diseases. It focuses on four goals, each of which has direct relevance to preparedness for bioterrorism: disease surveillance and outbreak response; applied research; infrastructure and training; and disease prevention and control. This plan emphasized the need to be prepared for the unexpected—whether it be a naturally occurring West Nile Virus outbreak or the deliberate release of anthrax by a terrorist.

A 5-year strategic plan for bioterrorism that CDC has been developing with its partners will soon be published. It defines activities necessary to ensure that the public health community is prepared to recognize and respond to a threat or actual act of bioterrorism.

However, CDC has already moved forward in multiple critical areas using funds appropriated by Congress beginning in fiscal year 1999. One of these areas was the development of a National Pharmaceutical Stockpile which can be called upon in response to an episode caused by a biological or chemical agent. The mission of CDC's NPS is to ensure the availability of life-saving pharmaceuticals and other medical supplies for prompt delivery to the site of a biological or chemical terrorist event anywhere in the United States. While the first response to an incident will come from local and State emergency medical and public health personnel, few local governments have the resources to create sufficient stockpiles on their own.

CDC has used an ongoing deliberative process to guide purchasing decisions for the NPS. Fiscal year 1999 decisions were based on the recommendations of two multispeciality expert working groups and the Department's operating plan, which was submitted to Congress.

A subcommittee of the Advisory Committee to the Director of CDC also is involved in this review process. Because acquisition priorities may change over time as threats change, these committees will continue to provide input and oversight. CDC has also established relationships with the national security agencies to ensure that the stockpile reflects current concerns and information.

The expert working groups convened by CDC prioritized the following six biological agents and diseases as concerns in civilian settings: smallpox, anthrax, pneumonic plague, tularemia, botulinum toxin and viral hemorrhagic fevers. Because anthrax, plague and tularemia can be treated with currently available antibiotics, purchasing these products for the NPS formulary was given top priority for fiscal year 1999. Presently there is no additional smallpox vaccine or botulism antitoxin to procure. However, efforts to rectify

this situation are a high priority for the Department and our partners in the Department of Defense.

The working groups also identified chemical agents that could be used in a terrorist incident, including nerve agents such as sarin, and respiratory irritants and vesicants such as sulfur mustard and cyanide. Obtaining antidotes for these agents was also given high priority in fiscal year 1999.

The NPS has two basic components. One consists of four pre-assembled sets of supplies which are called "12-hour push packages," ready for quick delivery and use in the field. And in response to your questions to the previous panel, we've brought pictures so that you can see what one of these actually looks like in the warehouse. There are also Vendor Managed Inventory packages [VMI], which will be activated if the incident requires a continued response. The VMI packages will be shipped to arrive at 24 and 36 hours after activation and will comprise material that would be delivered from one or more pharmaceutical manufacturers or prime vendors with whom we will contract to hold inventory that can be released at the time of an emergency.

The decision to deploy the stockpile will be based on the best epidemiologic, laboratory and public health information regarding the nature of the threat. This is one of the reasons the development of the public infrastructure for bioterrorism response is so important. When a biological or chemical terrorist incident is suspected, CDC will enhance surveillance activities, laboratory confirmation procedures, notification of the Office of Emergency Preparedness and appropriate Federal agencies and provide pertinent technical support. With regard to the stockpile, the Director of CDC, in consultation with the Assistant Secretary for Health, will direct its mobilization. If CDC stockpile components are needed, 12-hour push packages will be rapidly deployed. CDC will then begin the process of tailoring subsequent deliveries of stockpile components from the Vendor Managed Inventory as indicated by the specific biological or chemical threat.

In regard to the GAO-identified weaknesses in internal controls and management structure, there are three aspects of our NPS which are critical in addressing these concerns. First, there is direct coordination and management by CDC staff. CDC is an active partner in all aspects of the NPS. This includes providing guidance, oversight, operational control, and evaluation. After an intensive systematic deliberative process, which included valuable input and support from GAO and others, CDC chose the VA as the acquisition partner to work with on the NPS and feels that carefully planned management steps and close oversight will prevent future problems such as those identified by GAO.

The second point is that there will be continuous monitoring, quality assurance, and evaluation. We've taken steps to assure that the memorandum of agreement between CDC and the VA is explicit, comprehensive and precise. And CDC's tradition of oversight, technical assistance, and onsite presence is an integral part of the NPS. Through its real-time access to the VA's electronic inventory record system, CDC will monitor the purchase of stockpile pharmaceuticals and medical equipment, rotation of stock, and disposal of items for which there is not comparable civilian use.

CDC will physically verify the records of stock maintenance and transactions as part of its periodic unannounced site visits. Since the memorandum of agreement was signed CDC has already made multiple visits to inspect the 12-hour push packages, including two visits which were unannounced. Security measures will also be in place to safeguard NPS pharmaceutical supplies and equipment.

The third aspect of our management plan is partnerships, collaboration and communication. The responsibility for managing the NPS requires that we partner with OEP, other Federal agencies and State and local governments. CDC is planning training to fully prepare our State and local partners and will provide technical assistance to State and local governments that wish to purchase pharmaceuticals, chemical antidotes, other medical supplies and medical equipment to augment their current emergency response capabilities.

In summary, we believe that these components of the NPS will address the management concerns identified by GAO and assure provision of medical supplies, pharmaceuticals and other stockpiled equipment in a timely fashion.

This concludes my comments and we, too, will be happy to answer any questions.

Mr. SHAYS. Thank you. This is very interesting and it will be interesting for me to see how all of you interface with each other.

[The prepared statement of Dr. Ostroff follows:]

TESTIMONY OF

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BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS,  
AND INTERNATIONAL RELATIONS

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

March 8, 2000

Good morning, Mr. Chairman, and Members of the Subcommittee. I am Dr. Stephen M. Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied by Steven D. Bice, Chief of the National

Pharmaceutical Stockpile Branch, in CDC's National Center for Environmental Health. I appreciate the opportunity to testify before the Subcommittee about the plans for and management of the National Pharmaceutical Stockpile Program (NPSP), one component of CDC's overall public health response to the threat of bioterrorism. An appropriate response to a potential bioterrorism threat requires unprecedented partnerships among security agencies, first responders, and the public health community at all levels of government.

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 explosion 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 the strategic plan that CDC is developing with its partners to define the specific activities that will need to be conducted over the next several years to continue 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 most likely include county and city health officers, hospital staff, members of the outpatient medical community, and a wide range of response personnel in the public health system. Thus, protection against terrorism requires investment in the public health system. This point is underscored in a report, commissioned by the Department of Health and Human Services Office of Emergency Preparedness (OEP) and recently released by the Institute of Medicine and the National Research Council, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, which stresses the need for long-term public health improvements in surveillance and epidemiology infrastructure.

Increased vigilance and preparedness for unexplained illnesses 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 five areas, including model preparedness planning, developing of national biological and chemical agent laboratory diagnostic capacity, strengthening surveillance and epidemiologic investigation capacity, and enhancing communications systems, particularly at the local level. The fifth integral component of public health preparedness has been the development of a National Pharmaceutical Stockpile (NPS), which can

health preparedness has been the development of a national pharmaceutical stockpile (NPS), which can be called upon in response to an episode caused by a biological or chemical agent. Today I will be discussing CDC's approach to development and implementation of the pharmaceutical stockpile, but it should be emphasized that this must be developed in concert with the other segments of the public health infrastructure.

The mission of CDC's NPS is to ensure the availability of life-saving pharmaceuticals, vaccines, antidotes, other medical supplies, and equipment for prompt delivery to the site of a biological or chemical terrorist event anywhere in the United States. The NPS is not the first response to an incident of biological or chemical terrorism. That response will come from local and state emergency, medical and public health personnel. However, few local governments have the resources to create sufficient stockpiles on their own. Therefore, a primary purpose of the NPS is to provide critical drugs and medical material that would otherwise be unavailable. Key elements of the stockpile program include: procurement and logistics management; monitoring, quality assurance, system testing and evaluation; contract management; training and education; operational research and evaluation; and coordination of emergency response efforts. CDC will manage the NPS in collaboration with a number of important partners, as I will describe in detail later. In particular, CDC has chosen the Department of Veterans Affairs (VA) as our primary acquisition partner. This decision was reached after a systematic assessment of all available information and exploration of alternatives.

This morning, I am going to discuss the stockpile's relationships to other national pharmaceutical stockpiles, its contents, its deployment, and its overall management.

#### Relationship to and Coordination with Other National Pharmaceutical Stockpiles

CDC's NPS is a unique resource available to all United States public health departments. However, there are other national pharmaceutical stockpiles, and it is essential that the NPS coordinate with these resources for the most cost-effective protection of the American people.

OEP has established four National Medical Response Teams (NMRTs), which have stockpiled enough antidotes and equipment to treat an affected population of up to 5,000 people each when responding, particularly to the release of chemical agents. CDC has been collaborating closely with OEP to make sure CDC's stockpiles complement the NMRT stockpiles. CDC will continue to collaborate with OEP in FY 2000 through co-inspections of stockpiled items, and OEP will continue to be involved in CDC's program planning and expert working groups.

The Marine Corps' Chemical and Biological Incident Response Force (CBIRF) may be deployed to assist civilian communities; therefore interagency coordination is critical. CDC has met with CBIRF staff to begin coordination of our efforts.

#### Contents of Stockpile

CDC has implemented an on-going deliberative process to guide the purchasing decisions for the NPS. The process involves enhancing preparedness for biologic and chemical agents that would be catastrophic if released into the population. The process involved extensive input from experts including representatives from the intelligence community, DHHS, academic experts, and state and local health authorities. The experts met in two working groups in June 1999. CDC's FY1999 purchasing decisions were based on the recommendations of these groups and the FY1999 DHHS operating plan. A sub-committee of the Advisory Committee to the Director, CDC, will be convened to continue this process, and because priorities will change over time, will continue to meet at least once annually. In

addition, CDC has established relationships with various national security agencies so as to facilitate continuous updates and analyses of threat agents and ensure that the stockpile reflects current needs.

The expert working groups convened by CDC prioritized the following biological agents: smallpox, anthrax, pneumonic plague, tularemia, botulinum toxin and viral hemorrhagic fevers. Because anthrax, plague and tularemia can be effectively treated with antibiotics that are immediately available, purchasing these products for the NPSF formulary was given first priority in the stockpile section of the DHHS FY 1999 operational plan. Smallpox and botulism require materials that are not immediately available and will require a series of additional research, FDA regulatory, and production steps before these can be procured. These efforts are a high priority for DHHS and the Department of Defense (DOD).

The working groups also identified chemical agents that could be used in a terrorist incident, including nerve agents such as sarin, and respiratory irritants and vesicants such as sulfur mustard and cyanide. In addition to medications and supplies for intravenous administration, CDC proposes to include medical equipment that would be essential for treatment, including airway supplies, bandages and dressings, other emergency medications, and a back-up supply of chemical antidotes. These are items that local clinicians may find in short supply in the event of a biological or chemical terrorism incident.

#### Components of the National Pharmaceutical Stockpile

The National Pharmaceutical Stockpile (NPS) has two basic components. The first component consists of four 12-hour push packages for immediate response. A 12-hour push package is a pre-assembled set of supplies, pharmaceuticals, and medical equipment ready for quick delivery to and use in the field. These packages will permit emergency medical staff to treat a variety of different agents, since the actual threat may not have been identified at the time of the stockpile deployment. The packages will be color-coded on aircraft pallets, positioned in environmentally-controlled and secured warehouses, and ready for immediate deployment by the contract carrier to reach the affected area within 12 hours of the federal decision to deploy.

The second component, Vendor Managed Inventory (VMI) packages, will be activated if the incident requires a larger or continued response. The VMI packages will be shipped to arrive at 24 and 36 hours after activation. The VMI packages will comprise material that will be delivered from one or more pharmaceutical manufacturers or prime vendors, who, per a contractual arrangement with VA and CDC, will hold inventory that can be released at the time of an emergency, and will be tailored to provide medications, supplies, and/or products specific for the suspected or confirmed agent(s).

#### Deployment of the Stockpile

The decision to deploy the stockpile will be based on the best epidemiologic, laboratory and public health information regarding the nature of the threat. This is one of the major reasons that development of the public health infrastructure for bioterrorism response is so important. One scenario for deployment of the NPS begins with an overt bioterrorist act, resulting in a state governor requesting assistance from the President. The Federal Response Plan would be put into effect, under which CDC is responsible for the management of public health issues surrounding biological and chemical terrorist events. A more likely scenario would be that CDC, at the request of a state health department, would begin investigating an unusual pattern of illness and conclude that the outbreak might be the result of a bioterrorist event. When a biological or chemical terrorist incident is suspected, CDC will begin or enhance surveillance activities, laboratory confirmation procedures, notification of appropriate Federal agencies and provision of pertinent technical support. With regard to the stockpile, the Director of CDC, in consultation with the

Assistant Secretary for Health (ASH), will direct the mobilization of NPS assets. If CDC stockpile components are needed, 12-hour push packages will be rapidly deployed to best address the needs of the stricken population. CDC will then begin the process of tailoring subsequent deliveries of stockpile components from the VMI as indicated by the specific biological or chemical agent.

#### Mobility of the Stockpile

CDC is taking steps to assure the mobility of the stockpile by negotiating a contract with a commercial cargo carrier to transport the stockpile on a moment's notice. Any operational airport in the country could be used as a potential offload and distribution site for the NPS. If a terrorist incident occurs, the NPS will be delivered to a secure site proximate to – but outside of – the affected area. CDC will be working with the carrier to ensure that the stockpile can be moved by either land or air for delivery to any US location.

#### Stockpile Management

The GAO report on the management of existing stockpiles identified weaknesses in internal controls and management structures. Over the past year, CDC has worked closely with GAO to address these coordination, oversight, and partnership concerns as they relate to the NPSP. Three aspects of the NPSP management plans are critical in this regard: (1) direct coordination and management by CDC staff; (2) on-going monitoring, quality assurance, and evaluation; and (3) partnerships, collaboration and communication.

#### **1. Direct coordination and management by CDC staff**

The stockpile's pharmaceuticals, vaccines, antidotes, other medical supplies, and equipment will be managed by highly-trained professionals, who will complement state and local public health teams' efforts. This team of professionals is vital to the stockpile's effectiveness. Each member of the program has a clearly defined role that results in increased accountability.

#### The Role of CDC

CDC will provide guidance, oversight, operational control, and evaluation elements as the designated executive manager for the NPSP. CDC staff members are hired for their technical expertise and professional backgrounds and will be retained on the basis of demonstrated competence in the performance of their duties. The NPSP staff is functionally organized so that a single staff member has the lead for ensuring that all monitoring, quality assurance, and evaluation responsibilities are carried out with diligence and efficiency, and every NPSP staff member has some level of supportive responsibility for each of these areas as part of his performance work plan.

CDC chose the VA as the acquisition partner to work with the NPSP. At the time the decision was made, CDC was aware that GAO had identified problems in a similar collaboration. Therefore CDC considered other options, including DOD and CDC self-management. However, after an intensive deliberative process, using the best information available, CDC feels that the VA is the best partner and that following carefully planned management steps can prevent the problems identified by GAO.

First, CDC will continually monitor the status of NPS inventory at both VA and VMI locations. One of the strengths of the CDC-VA partnership will be the development of a real-time look-down inventory monitoring system. This system will track inventory levels, the ordering and receipt of all products, the

status of all NPS transactions, and the scheduled rotation of stock to maintain current expiration dates on medications and devices. This monitoring will be done through direct access to the inventory systems of all partners to the NPSP.

Second, each year CDC will conduct no fewer than 3 periodic "no notice" or unannounced inspections of facilities that store NPS pharmaceuticals and other response material. CDC staff will carry out these visits using a standardized protocol covering all aspects of NPSP responsibility, including storage, security, and deployment procedures. These facilities will need to register under the Food, Drug, and Cosmetics Act and will also be subject to FDA inspection. CDC staff will also conduct operational capability inspections at the contract carrier's shipping locations. CDC staff will cite any deficiencies identified during inspections and hold partners accountable for prompt corrections.

Third, CDC staff will carry out no fewer than 2 periodic exercises each year to test various aspects of the NPSP. CDC and external monitors will be used to observe and record how CDC staff and its partners perform in a simulated deployment. These monitors will rate performance using a combination of objective and subjective rating criteria. A follow-up report of such exercises, citing strengths and weaknesses, will be accompanied by specific actions that partners and CDC must take to correct any system defects.

#### The Role of the VA

The VA was selected to serve as the primary acquisition partner for the stockpile while CDC will manage and provide oversight of all aspects of the stockpile program. The VA was selected as this logistics and purchasing partner due to its experience with large pharmaceutical purchases on behalf of the U.S. government and its strong willingness to partner with CDC to ensure successful implementation of the NPS. The NPS has a logistical team that will be working closely with the VA and medical suppliers and vendors throughout the country. The VA has a staff member who will serve as a single point of contact on stockpile issues and is fully dedicated to the NPSP. This person is directly responsible for VA's stockpile duties and will provide continuous management. In addition, each push package will have a dedicated VA pharmacist on staff.

The 12-hour push packages will be stored separately from normal operating stock in a secured section of either a commercial or VA-owned warehouse approved by CDC. The 12-hour push packages will be managed with CDC oversight in the form of scheduled and unannounced inspections that are part of the NPSP quality assurance activities.

The VA, with CDC concurrence, will award the VMI portion of the stockpile's supplies to a medical products distribution or manufacturing company or a combination of both. The VMI material may be co-mingled with the contractor's normal operating stock and continuously rotated to insure potency of government-owned and reserved material. The VA will ensure compliance with the VMI contract and will provide quarterly reports to CDC on compliance and internal control issues. In addition, CDC staff will conduct periodic unannounced inspections of sites where stockpile VMI is being stored.

#### **2. Monitoring, quality assurance, and evaluation.**

CDC has taken steps to ensure that the Memorandum of Agreement (MOA) between CDC and VA is explicit, comprehensive and precise. In addition, CDC's tradition of strong oversight, technical assistance, and on-site presence will be an integral part of the NPSP. A thorough monitoring and evaluation loop will include any remediation needed to quickly fix identified gaps. CDC will utilize the ongoing partnership between FDA and VA to assure the quality of the NPS contents.

between FY 2000 and FY 2001 to assure the quality of the NPS products.

#### Inventory and Record-Keeping

The VA will procure medical material contained on the NPS requirements list. It is anticipated that there will be several CDC procurement cycles during each year. The VA will update procurement records to ensure timely status of orders and expected delivery dates. Each product shipped to the VA distribution center must have a minimum of 95% of its shelf life remaining at the time of receipt. Products received with insufficient shelf life remaining will be returned to the manufacturer. Any exceptions to this 95% requirement dictated by limited market availability must be approved by CDC.

All NPS material will be stored in a secure, well-lighted, temperature-controlled warehouse or distribution center. The 12-hour push packages will be stored separately from operational stock and kept in a limited access area. Inventory management records will reflect a CDC ownership code for both the 12-hour and VMI packages and will facilitate the rotation of medical material prior to its expiration.

Through its real-time access to the VA's electronic inventory record system, CDC will routinely monitor the purchase of stockpile pharmaceuticals and medical equipment, rotation of stock, and disposal (or shelf-life extension) of items for which there is no comparable civilian use. CDC will physically verify the records of stock maintenance and transactions as part of its site visits. CDC's MOA with the VA specifies the prompt and proper recording of transactions because it is the intention of CDC to monitor this information through the VA system of electronic inventory control. From this documentation, CDC logistics staff will provide periodic reports and analyses on the status of stockpile products.

#### Security

Security measures are or will be in place in FY 2000 to safeguard NPS pharmaceuticals, supplies and equipment. The NPS demands that storage areas for general medical supplies be appropriately secured; that access to warehouses be confined to a limited number of personnel; that internal documents be updated frequently to reflect personnel turn-over; and that keys or combinations are changed when personnel leave the agency. All medical controlled substances shall be ordered, received, stored, and issued in accordance with all applicable Drug Enforcement Administration (DEA) regulations; and all controlled substances shall be stored in a safe or vault with a combination lock with a combination that is known by only the primary and alternate responsible staff. The review and tightening of these physical security measures will be a prominent part of CDC's unannounced inspections. Since CDC staff are not security experts, we are seeking technical assistance from the U.S. Marshals Service to provide a security assessment of our 12-hour Push Package sites.

#### Stockpile Deployment Exercises

CDC must ensure that the stockpile can be deployed quickly and effectively before it needs to be used in a biological or chemical terrorist incident. As noted earlier, CDC will conduct periodic exercises to test all aspects of stockpile deployment. These exercises will begin in FY2000.

CDC, in conjunction with its partners, will develop scenarios for situational field exercises to evaluate the capabilities of the stockpile deployment and distribution mechanisms. These exercises will range from tabletop scenarios to full-scale, real-time simulated operations that will incorporate multiple jurisdictional partners and federal agencies. A full system exercise will take CDC to the point of hand-off to state officials and will review their distribution plan and their performance as part of the overall system.

### **3. Partnerships, collaboration and communication.**

The responsibility for overseeing and managing the NPS requires that CDC partner with state and local governments and coordinate with OEP and other federal agencies. This is necessary to provide US citizens with the maximum protection available. In addition, CDC is learning from and utilizing the expertise of many partners, including drug and equipment manufacturers, transportation companies, the FDA, and the VA to ensure production, maintenance, security, and delivery of NPS items.

#### Partnering with federal agencies

The responsibility for oversight and management of the NPS requires CDC to partner and coordinate with other federal agencies as well as state and local health departments in order to provide a comprehensive protection program. In addition to the VA, other key federal partners involved in issues related to the management and deployment of the NPS include OEP, FDA, DOD, FBI, and FEMA.

#### Partnering with state and local agencies

CDC will work with state and local health agencies to provide, distribute, and administer the products in the stockpile. In order for the stockpile to be deployed quickly and effectively, CDC must provide technical assistance to aid in the development of state and local capacity to receive and distribute the NPS.

Local organizations at the city, county, and regional level will be essential in the effort to reach all citizens who need medical help after a terrorist incident. However, these partners need to become fully aware of the NPS to ensure that they are able to most effectively plan for and use this valuable resource. To meet this need, CDC is now planning extensive training, including use of the Internet and a continuing education effort, to fully prepare our state and local partners. Other private or industry organizations will also have important roles to play in the local or state deployment of the stockpile. For example, organizations such as nursing home associations, private ambulance services, and trucking companies all provide services that could be critical to the timely deployment of the stockpile.

CDC is also prepared to provide technical and scientific assistance to state and local governments who wish to purchase pharmaceuticals, chemical antidotes, other medical supplies, and medical equipment to augment their current emergency response capacities.

In summary, we believe that these components of the National Pharmaceutical Stockpile Program will prevent the stockpile management concerns identified in the GAO Report and will provide medical supplies, pharmaceuticals, and other stockpile equipment in a timely fashion

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 am happy to answer any questions you may have.

Mr. SHAYS. Colonel, it is so wonderful to have you here and you have the floor.

Colonel HOLLIFIELD. Thank you, sir. I'm very pleased to be here. I have the opportunity today to address the management of medical supplies within the Chemical/Biological Incident Response Force. With me today is Commander Warren R. Dalton. Commander Dalton is a U.S. Navy Medical Officer and board-certified emergency medical physician and serves as my Senior Medical Officer.

Commander Dalton dealt directly with the GAO representatives who visited our command and is here to provide any additional insight you may desire relative to that visit or the management of our medical supplies.

As you're aware, sir, during the summer of 1999 the GAO undertook a study to evaluate the readiness of our Nation's "stockpile" of chemical and biological medicines designed to treat civilian casualties. As originally envisioned no Department of Defense Activities were projected to be a part of that study. However, the GAO did visit our command at CBIRF, Camp Lejeune, and had some valuable insight for us.

Although CBIRF maintains medical supplies as part of routine inventory, we've never considered those supplies to fall into the category of being a "stockpile," basically because we don't view those supplies as being held for further distribution. We view that our medical supplies are held for internal use, primarily for the treatment of the Marines and sailors assigned to the command; that is to say, sir, that the medical supplies that are stocked are not stocked for distribution to civilian care providers or for routinely treating civilian casualties, except where emergency lifesaving care is required.

Accordingly, we view the supplies that we hold as being held by the end user as opposed to distributor. Nonetheless, where the GAO recommended we strengthen our internal control measures, we think that we've taken appropriate action to comply with the guidelines set forth in OMB Circular A-123.

First they asked that we conduct risk assessments and look at our program activities and organize those to identify and mitigate those risks.

I conducted a risk assessment in December 1999, and as part of this risk assessment I asked for a formal independent external physical security evaluation. We just received the results of that evaluation late in February of this past year and we're taking appropriate action to implement the measures contained therein.

Specifically, we'll be looking at improving our access control under that portion of the warehouse where medical supplies are stored, setting up positive lock and key control procedures.

In addition, we will be providing crime prevention and loss awareness training for all personnel performing supply related duties.

Additionally, as part of this risk assessment I asked my Supply Officer to conduct a total review of the medical supply operating procedures in effect at my command. His charter was to ensure that the procedures that we have in place are consistent with governing Marine Corps directives and the policy as set forth in the

Marine Corps Consumer Level Supply Policy Manual, Marine Corps Order P4400.150E. Since the Department of Defense is not formally a participant in the National Pharmaceutical Stockpile Program, it is this directive that we use to manage our medical supply operations.

Second, the GAO recommended that CBIRF arrange for periodic independent evaluations. The Marine Corps Field Supply Maintenance Analysis Office, an independent agency that operates outside of my influence and outside of my command, routinely conducts external reviews of all Marine Corps supply related accounts.

Following the GAO's visit I coordinated and arranged with my higher headquarters for an independent evaluation by an external agency having specific knowledge of Navy medical logistic procedures. The Medical Logistics Company of the Second Force Service Support Group was tasked to conduct a review of our operating procedures, and that review was just completed approximately 1 week ago.

Pending the written results of that review, when received, we will take appropriate action to implement any findings and recommendations that they make.

Further, I directed that my Supply Officer conduct periodic spot checks of our inventory and have arranged for a quarterly reconciliation of the medical supply account. I've asked him to ensure that the medical supply account receive special emphasis during all future supply related inspections and audits.

Third, the GAO recommended that we implement a tracking system that retains complete documentation for all supplies that were either ordered, received, or destroyed.

We have recently evaluated our existing data base and to be quite honest, sir, there's room for improvement. And we're working to modify that data base to improve the fields of data this captures so that we will have better tracking and visibility.

Additionally, in light of the fact that our medical supply account is maintained on a daily basis by Navy medical personnel as opposed to supply personnel, my Supply Officer has been directed to ensure that the medical personnel tasked with the daily operation receive adequate training in supply related functions.

Finally, the GAO recommended that we rotate supplies properly. It is my intent to publish specific written policy that addresses the overall management of our supply medical account when we receive the results of the Medical Logistics Company's independent evaluation. This policy will address not only the proper rotation of medical supplies, but will further ensure that we are being consistent with the existing Marine Corps and Department of Navy regulations.

I believe that all these actions will significantly improve the internal control over my medical supply account.

Before I conclude, sir, I would like to address a few additional issues raised in the GAO Report.

The GAO noted that CBIRF did not have an authorized allowance list of supplies that it was authorized to maintain.

Mr. SHAYS. If you talk a little slower—I think you're well trained to get it all done, but I'm going to try to listen carefully here.

Colonel HOLLIFIELD. Yes, sir.

The medical supplies that I maintain, sir, are those that my staff and I feel were necessary to be able to execute our mission. The supplies were quite typical in terms of types and quantities to the types of medical items that would be held by most any military medical organization.

Within the Department of the Navy the types and quantities of supplies and equipment that a unit is authorized to hold is set forth in a standardized, authorized medical allowance list, commonly referred to as an AMAL. An AMAL exists for every type of military organization, however, none have yet been developed for chemical or biological response units such as CBIRF. To this end we have taken the lead in trying to identify what we feel is an appropriate stockage level of medical equipment and supplies that we should retain to be mission-capable. This has been submitted to our Marine Corps Systems Command at Quantico, VA, which is currently working to standardize an allowance list.

In the interim it is my intent to publish a standardized allowance list as a CO's allowance list until such time as an AMAL is fielded. This allowance list will serve as the baseline for our inventory.

In addition to those general medical care items that we hold, sir, my unit stocks three medications specifically designed for the treatment of chemical or biological casualties. These medications, 2 Pam Chloride, atropine, and diazepam, are held first and foremost as part of my own force protection program. Since CBIRF Marines and sailors risk potential exposure when sent to respond to a chemical or biological incident, this is a measure that any prudent commander would take. However, I also recognize that during any response there is a potential that we may have to provide care for either local first responders or civilian casualties. And while the medications are not stocked or held expressly for this purpose, they could be so used in emergency situations.

However, in such circumstances it has never been envisioned these supplies would be turned over to local medical care providers, but rather that they would be administered by my medical personnel only when lives were genuinely at risk and where no reasonable alternative exists.

Sir, I'm here today not to offer any excuses, but to provide an explanation of the actions that we've taken since GAO visited. GAO provided a very important aspect for us because they brought a viewpoint that was beyond the pure military bounds and they've caused us to take an internal look at our operations and look for methods and means within our resources and capabilities to improve our process.

We do feel, however, that in the characterization of CBIRF's medical supply as a kind of "stockpile," the GAO does not truly provide an accurate depiction of the holdings that we possess. We're keenly aware that we are a unique unit with a very important mission, and accordingly my staff and I have made every effort to implement the recommendations within our power and capabilities.

Mr. Chairman, we stand ready to answer any questions that you may have today, just as your Marines and sailors within the unit stand ready to respond when this Nation calls. Thank you.

Mr. SHAYS. Thank you, Colonel.

[The prepared statement of Colonel Hollifield follows:]

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STATEMENT BY

COLONEL CARLOS R. HOLLIFIELD

COMMANDING OFFICER,

CHEMICAL BIOLOGICAL INCIDENT RESPONSE FORCE (CBIRF)

UNITED STATES MARINE CORPS

BEFORE THE

HOUSE COMMITTEE ON GOVERNMENT REFORM

43

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS,

AND INTERNATIONAL RELATIONS

ON

8 MARCH 2000

CONCERNING

COMBATING TERRORISM:

MANAGEMENT OF CHEMICAL AND BIOLOGICAL

MEDICAL STOCKPILES

NOT FOR PUBLICATION UNTIL

RELEASED BY THE HOUSE

**ARMED SERVICES COMMITTEE**

Mr. Chairman, members of the subcommittee, I appreciate the opportunity to appear today to address the management of medical supplies within the Marine Corps' Chemical Biological Incident Response Force (CBIRF).

I command CBIRF, having assumed that responsibility in August 1999. During my 25 years' of Marine Corps service I have had the privilege of leading Marines in several operational commands. From that perspective, I can assure you that the Marines and Sailors assigned to CBIRF are both professional and mission ready. And, as an officer with training and assignments in law enforcement, force protection, physical security, and combating terrorism, I fully appreciate the nature of the threat that now confronts us.

With me today is Commander (Captain select) Warren R. Dalton, a U.S. Navy Medical Officer and board certified emergency medical physician who serves as the Senior Medical Officer for CBIRF.

Prior to commenting on the matter before us today, I would like to offer some background for members of the subcommittee who may not be familiar with CBIRF. The command was activated in April 1996 in response to Presidential Decision Directive 39. Since that time, the unit has evolved from a concept to an operational response entity. Comprised of an average of 340 Marines and Sailors, CBIRF includes over 43 different military occupational specialties. These individuals have supported numerous national security level events, including Presidential inaugurations, State of the Union addresses, the Atlanta Olympic Games, Summit of Eight meeting, the Papal visit to St. Louis, and the NATO 50<sup>th</sup> anniversary celebration. Additionally, the unit has deployed personnel in support of our combatant commanders for nine theater level exercises or operations.

The Government Accounting Office (GAO) visit to CBIRF prompted me to take a close look at procedures used to manage our medical supply account. While our supply and medical personnel are well versed in the requirements mandated by existing military directives, I fully recognize the inherent benefit of being reviewed by an external set of eyes.

As you are aware, in July 1999, representatives of the GAO visited CBIRF at Camp Lejeune, North Carolina. As a result of this visit, the GAO noted some concerns regarding our medical supply account operations. Appropriate action has been undertaken to address management areas highlighted by the GAO's visit. These actions, either completed or planned, are addressed in subsequent portions of this statement. I think to understand the approach we have taken, it is important to provide the background surrounding the GAO's visit to CBIRF.

GAO's visit to CBIRF was in conjunction with their effort to assess the readiness of our Nation's "stockpile" of medical supplies held for the treatment of chemical and biological civilian casualties. My staff and I understood that the intent of the GAO effort was to focus on the readiness of those entities operating under the parameters of the National Pharmaceutical Stockpile program, a program in which the Marine Corps is not a participant. As originally conceived the GAO study was not projected to look at any Department of Defense agencies. Specifically, the GAO undertook to *"review the accuracy and currency of the inventory tracking systems for federal medical stockpiles that would be used to treat the civilian population following a chemical or biological terrorist attack"*.

As the GAO team conducted its evaluation of CBIRF's medical supply account, it became apparent to CBIRF medical personnel that a difference in perception existed regarding the nature of the medical

supplies held by CBIRF. GAO personnel regarded all of the medical items held by the unit as a "stockpile," thus making the entire unit medical supply account subject to the standards applied to those participants formally operating under the parameters of the National Pharmaceutical Stockpile program. Navy medical personnel made attempts to explain that the medical items held by CBIRF did not constitute a "stockpile" as these items were held for organic unit use. As such, these items are more appropriately viewed as working stock used primarily for the general medical care of personnel assigned to the unit and to ensure the ability of the unit to execute its response mission.

In my view, the very concept of a "stockpile" implies that items within that category are held for the purpose of further distribution. While portions of CBIRF's medical supplies could be used in emergency response situations to provide lifesaving care for chemical or biological casualties, the bulk of items held are used in general medical care treatment programs.

The unit holds only three items that can be categorized as specifically for the treatment of persons exposed to chemical or biological agents. These three medications – 2 Pam Chloride, atropine, and diazepam – are held primarily for the purpose of protecting unit personnel who, in their response role, face the potential of exposure. Nonetheless, such items could also be used to treat civilian casualties at the scene of a chemical or biological incident. CBIRF medical personnel deploy with a sufficient quantity of such items to provide emergency lifesaving care in the event local medical authorities lack ready access to such medications. However, it has never been envisioned that these items, nor any other routine care medical items, would be released from military control or turned over to local medical personnel. Referring to CBIRF's medical supplies as a "stockpile" for simplification does not alter the fact that we truly do not possess a stockpile, but simply a "working stock" used to provide care for assigned personnel as well as to respond to any emergency situation.

One of the concerns raised by GAO was that there were some 2,300 "missing" items within CBIRF's medical supply account, of which 1,500 were listed as missing antidotes. This finding resulted from two factors, a duplicative database entry and the classification of consumed medical supplies as missing. One container of atropine (1,500 doses) was mistakenly entered into the computer database twice. While this duplicative entry highlights the need for greater attention to detail on the part of personnel making clerical entries, it was simply a database entry error. This error, which would have been noted during the next scheduled inventory, was identified and documented during the GAO visit and corrective action was immediately taken. This clerical entry accounted for 1,500 of the 2,300 "missing" items. These items were not "missing", as they never existed. With regard to the remaining 800 "missing" items, the GAO did not provide a breakdown of the items. However, Navy medical personnel present during the audit reported the items were mainly in the category of consumables (bandaids, alcohol pads, tongue depressors, etc.), none of which could be specifically classified as items unique to the care of chemical or biological casualties. These 800 items, out of over 38,000 counted, constitute a 2% error and we have undertaken various steps to tighten our procedures. I believe that a 2% deviation in routine consumables does not adversely affect the ability of CBIRF to perform its incident response mission.

It should be noted that of the 38,000 medical supply items inventoried at CBIRF by the GAO, only approximately 7,000 items, which includes both initial response and follow-on medical supplies, are specifically related to the treatment of chemical or biological casualties. The remainders are standard medical supplies typically maintained by any military medical unit and are routinely consumed to support day-to-day operations. In addition to being prepared to provide emergency medical care as part of the unit's chemical and biological response mission, assigned medical personnel provide care for Marines and Sailors assigned to CBIRF. Accordingly, consumable items are expended in the course of routine medical care and replenished as needed. The consumption of expendable items for routine medical care does not

adversely impact upon the ability of CBIRF to execute its incident response mission.

The GAO further noted that CBIRF did not have an approved list of medical supplies which it was authorized to maintain. As this new and unique unit transitioned from a concept to a viable response force, one of its inherent responsibilities was to develop standardized techniques, procedures, and equipment. To this end, CBIRF was confronted with the need to develop standardized medical equipment and supply lists. As the unit has matured and exercised its response concepts, adjustments have been continuously made and we have gained a better understanding of exactly what types and quantities of medical equipment and supplies are needed for the unit to remain mission ready.

Existing military units know what medical equipment and supplies they must maintain as those items are set forth in a standardized Navy Authorized Medical Allowance List (AMAL). As a relatively new unit with responsibility for an emerging threat mission, no AMAL currently exists for chemical and biological response forces such as CBIRF. Accepting responsibility to standardize this area, CBIRF has submitted a proposed chemical-biological AMAL to the Marine Corps Systems Command at Quantico, Virginia, that will eventually serve as an approved list for our medical equipment and supply holdings.

Since its inception, the unit has sought to stay abreast of technology while at the same time eliminating non-essential property. During the past six months, many medical items found to be excess have been returned to the supply system. The 5,700 excess items cited by the GAO were part of this effort, an undertaking that was already underway when the GAO visited in July 1999. Our total medical inventory has been reduced by approximately 25% over the past six months.

Further, the GAO noted that Marine Corps officials have not required reports on our "stockpile". This is an accurate statement since no one within the Marine Corps has ever regarded our medical supply holdings as a stockpile, rather as a working stock. The scope of medical items held by CBIRF is similar in terms of items and quantities to that found in the medical supply account of any deploying military unit conducting battalion level aid station operations. With the exception of the three medications held specifically for treatment of chemical or biological casualties, CBIRF holds medical supplies that could be found in most any operational military organization. No requirement exists to report medical supply account status for any of these units, to include CBIRF.

The management of CBIRF's medical supply account is conducted per Marine Corps Order P4400.150E (Consumer-Level Supply Policy Manual) which requires that medical supplies be handled in the same manner as organic property. The GAO noted that CBIRF was not following management control guidelines set forth in Office of Management and Budget Circular A-123. However, this does not obviate the fact that as a Marine Corps organization we have conducted our supply operations in accordance with existing military regulations. Our medical supply account was subject to a review by the Field Supply Maintenance Analysis Office (FSMAO) just prior to the GAO's visit and no significant problems regarding medical supply operations were noted.

While I do not think that CBIRF should be held to higher supply management standards than those required of any other military unit, I recognize that the unique nature of our unit and mission make consideration of GAO's observations prudent. To this end, my staff and I have carefully reviewed the recommendation of the GAO to institute additional management and control procedures. The GAO specifically recommended that CBIRF:

- a. conduct risk assessments and organize program activities to identify and mitigate risks;

- b. arrange for periodic, independent inventories;
- c. implement a tracking system that retains complete documentation for all supplies that have been ordered, received, and destroyed; and
- d. rotate supplies properly.

In response to these recommendations, the following actions have either been completed or are programmed for completion in the immediate future.

- a. The Commanding Officer completed a written risk assessment on 16 December 1999. This risk assessment considered the physical security of medical supplies as well as control and accountability factors. Additionally, a formal evaluation was completed on 20 January 2000 by a trained physical security specialist to identify any improvements that could be made to enhance the security and control of the warehouse area housing our medical supplies. Specific actions that will result from this evaluation include enhancing access control procedures for the medical supply storage area, implementing key and lock control procedures; and the conduct of annual crime and loss prevention training for personnel performing supply related duties. It is envisioned that physical security of our supply warehouse will be enhanced as a result of CBIRF's relocation to Naval Surface Warfare Center, Indian Head, Maryland, during the fall of this year as the warehouse facility will be located within a designated "restricted area".
- b. During the first quarter of this calendar year, the Supply Officer reviewed the operating procedures for our medical supply account. As a result of the review, which was completed on 28 February 2000, modifications are planned for the existing database used to account for our medical supplies. These modifications will enhance tracking and control for the 7,000 unique chemical and biological medical supply items by documenting consumption, rotation, and disposal actions. The medical supply account holdings are subject to periodic spot checks by the unit Supply Officer and the database will be reconciled quarterly. These actions will validate the effectiveness of operating procedures, check accountability, and identify any areas requiring corrective action. Further, the Supply Officer will ensure that medical supply procedures and accountability are reviewed as a part of all supply account inspections or audits and will further take action to provide specific focus on medical supply procedures during regularly scheduled FSMAO evaluations.
- c. The Senior Medical Officer submitted a request to our higher headquarters on 17 December 1999 soliciting an independent inventory by an external agency having knowledge of Navy medical logistics procedures. On 11 February 2000, the Commanding Officer, Medical Logistics Company, Second Force Service Support Group was tasked to conduct this assessment. The assessment is presently ongoing and I expect written results to be provided within the next month. Once received, we will implement appropriate action to ensure that our medical supply account operations are in full compliance with all applicable Naval Bureau of Medicine, Naval Medical Logistics Command, and Marine Corps Supply System directives.
- d. The Supply Officer has been tasked with three additional initiatives that will be considered upon completion of the independent review of our procedures by Medical Logistics Company. First, to ensure that Navy medical personnel performing supply actions for the unit's medical supply account are properly trained. Second, to develop, in concert with the Senior Medical Officer, an authorized medical supply allowance list. This list will be approved by the Commanding Officer and serve as the baseline for account holdings until such time as a chemical-biological AMAL is fielded. Finally, the Supply Officer will develop written policy for approval by the Commanding Officer that specifically addresses medical supply

procedures to include rotation and disposal of medical supplies.

In conclusion, while I do not believe that the medical supplies held by the 31<sup>st</sup> AIRF truly constitute a stockpile, and as such do not specifically fall under the parameters of the GAO's view of national stockpile readiness, my staff and I nonetheless recognize the value added by GAO's observations. The external review has provided a different perspective beyond the bounds of a purely military viewpoint and served as a catalyst for the unit to reevaluate its operating procedures. This review not only afforded us the opportunity to ensure compliance with existing military directives, but also a means by which to implement measures within our capabilities to enhance our existing procedures.

Mr. SHAYS. This is very helpful to have all of you here and it will be interesting for me, one, to see how you interface and, two, to understand a few things that this raises really beyond the GAO report that will help us in our continual oversight. And I'll say from the outset that our view is that sometimes GAO is always easy to come in and find things wrong and it's always easy for Congress to come in and condemn and say why is it wrong. But if you see what GAO has suggested as making sense, and agree with the criticisms, see that their recommendations make sense and that people are implementing those recommendations, we're happy to get on to the next issue and not throw stones.

But there are some things I just don't quite understand, so there are going to be some general questions at first.

First, Colonel, I understand the Marines are usually the first in, they always want to be the first in, but the Army feels sometimes they're going to be the first in in some instances. But bottom line, you're usually first in and so I'm making an assumption that that's why you have a stockpile. But I don't understand, one, if you're the only branch that has the stockpile—if you have any knowledge of this I'd like you to share it with me, but I can ask others—one, why do you have this stockpile? And two, if you're the only branch to have it, why you and not the other branches?

Colonel HOLLIFIELD. Mr. Chairman, I would default back to saying that we've never considered what we hold as stockpile. If you look at the quantities of items that we hold and the types of items that we have in our inventory, they're very typical to what you would find in almost any operational military command. So accordingly, if the quantities and items that we hold are truly a stockpile, in essence almost every military organization holds a stockpile.

We are not a part of the formal cache program that you were briefed on earlier. However, we do stock a small quantity of 38,000 medical items and hold approximately 7,000 items that would be specifically designed for first response to a chemical or biological event. The remainder of the items that we stock are primarily general medical care items. So we don't view this as a stockpile. We really view it as a response stock. Primarily we hold these supplies for our own individual use. We've never envisioned that we would distribute those to anyone outside of our organization or outside military control.

Mr. SHAYS. So it basically is your testimony that you suspect the other branches are doing the same thing you're doing?

Colonel HOLLIFIELD. Sir, I couldn't speculate on whether they're doing that. I know that we have been a test bed, in essence, to develop techniques and procedures and I'm sure they face the same challenge as we have in terms of an authorized list of what they should have.

Mr. SHAYS. Is this a directive from the Secretary of Defense that you do this? In other words, if I'm asking a question you may not know, I understand, because it's not really the primary focus of this hearing, it's just a logical question to ask for our understanding this whole process.

Colonel HOLLIFIELD. There is no basis, sir, that tells me what I'm authorized to hold. The items that we hold now are those that we held when the unit was first activated in 1996. Since that time

we've developed to come up with an understanding of what we feel is appropriate to have in order to be able to effectively execute a response.

Mr. SHAYS. I'll come back to this.

My understanding—I'll ask anyone here to correct me—we in Congress asked that the VA stockpile, HHS and VA—well, actually, maybe HHS and then they contracted with VA, so I'll have that clarified—but we had four sites. But we also said that CDC would have a stockpile as well. I get the sense that it really—I mean, the way I was beginning to see it, I was beginning to think the Marines would be first, maybe, they might be the first to a particular site, but this is probably just military.

Colonel HOLLIFIELD. The event that would get us to the site would be a request from another Federal agency, such as FEMA.

Mr. SHAYS. My sense, though, is that the primary sites are the four for the earliest, that those are primary sites for the fastest call, and then my sense is the CDC sites will be larger and then will respond on a more long-term basis. Dr. Ostroff, am I right? Kind of give me a picture here. Give me the sequence of how this works.

Dr. OSTROFF. Right. I think I'll let Dr. Knouss also respond.

I think one of the things that is important to point out is that there are different types of events which are possible. And we look at chemical events as being quite different from biological events. When chemical events occur, the timeframe between when the release occurs and when people start getting sick is really quite brief, whereas with most of the biological agents the time interval between the exposure and when people will become ill for some of these agents can be days to weeks. And so the events will play themselves out quite differently. And how these events get recognized will clearly be quite different as well.

The stockpiles developed by OEP—and I think I'll leave that to Dr. Knouss to further elaborate—are largely around the deployment of teams that will be responding to chemical events. We have developed our stockpile to be able to supplement in larger numbers those materials if the chemical event is larger that can be handled with the stockpiles developed by OEP. But ours is principally developed around being able to respond to biological events.

Dr. KNOUSS. Support function No. 8 of the Federal Response Plan under FEMA deals with the consequence management responsible agency if there should be one of these events in the United States. Our part of that is that the health and medical response and the four national response teams that we have put together are meant to be able to deploy to an incident site or to be prepositioned out at the site in which there is a threat, a known threat, a significant threat, in order to deal with the most immediate consequences. So most of the cache that we carry with us is meant to deal with the immediate consequences of a chemical exposure, where time is absolutely of the essence to get to the scene and to be able to offer antidotes. And frankly, by the time we reach the scene a lot of our supplies are meant to be resupply of what we are trying to already preposition through metropolitan medical response systems in the major metropolitan areas themselves.

And then we would come in with our stockpiles and our caches.

Mr. SHAYS. Those being—

Dr. KNOUSS. OEP, HHS.

Mr. SHAYS. The four VA stockpiles?

Dr. KNOUSS. Yes. They would accompany our teams in and we have designed those caches so that they can be split into five pieces, readily. One piece could go to an incident and four other pieces could go to resupply up to four hospital facilities. And once we arrive at a scene we could immediately separate those caches into those five pieces, or we could manage it a little bit differently. We could send two to one place or three pieces to another, but they are manageable pieces of an overall cache and designed to be tactically responsive to whatever the situation might be.

If we need more to treat 5,000 people we can bring in a second cache from another location to reinforce that. But frankly, at some point the limiting factor becomes the number of professionals that are available to be able to administer the caches in a pharmaceutical—on a rapid basis.

Mr. SHAYS. So technically you think you have basically the ability to respond to 20,000?

Dr. KNOUSS. Exactly. At the maximum. Now, that response needs to occur in hours, so time is really of the essence. The CDC stockpile is meant to deal with reinforcing some of that chemical supply if we need to for very serious exposures. But is primarily geared to meeting the very large pharmaceutical requirements where up to millions of people might be exposed to a biological attack. And so therefore the cache that you see there illustrated as part of CDC's cache is far larger than the size of the cache that you will see—the number of boxes that you would see at one of our warehouses.

Mr. SHAYS. Dr. Ostroff, how many sites are you going to be developing?

Dr. OSTROFF. The actual number of sites is still under discussion. There will be four sites for the 12-hour push packages.

Mr. SHAYS. Four different sites than with the VA?

Dr. OSTROFF. No, one of the sites is the VA warehouse in Hines, IL. The other three have yet to be prepositioned. There are still discussions about how to most efficiently locate them.

Mr. SHAYS. So the one in Hines has basically yours and HHS's. I just want to make sure I'm not—I want to be clear here. We have four VA sites. CDC has mandated to establish a bigger cache.

Dr. OSTROFF. Right.

Mr. SHAYS. Are you also using some of the VA sites as well as other sites?

Dr. OSTROFF. Well, it's conceivable. For instance, the Vendor Managed Inventory, which is the longer-term supply, will be a virtual inventory through either the manufacturers themselves or through what's referred to as Prime Vendor, essentially a middleman who would be able to provide a variety of different agents. And that inventory may be in a number of different locations. We are seeking to try to minimize the number of different locations.

Mr. SHAYS. I'm going to go to Mr. Tierney. But just let me ask this question then I'll be coming back. Is it conceivable that we would just pay manufacturers to have an excess supply? I would think one of the advantages is that then they could then keep ro-

tating it out so it never becomes useless, and they can still get into the marketplace potentially.

Mr. OSTROFF. That's correct. You're absolutely correct and that is far and away the most efficient way to have the vendor managed—

Mr. SHAYS. And I'm going to come back and ask the VA and HHS if you let—the shelf life runs out, but do you try to, maybe if you have weeks or a month left or something, try to get them out so they can be used somewhere where there's a need. I know for instance that Ameri-Cares, based in my community of Canaan, has given out billions of dollars worth of drugs around the world. And what they do is, they get close to terminated vaccines and so on and then use them up within the time period. So I'll ask VA if they just throw away these pharmaceuticals or whether we're still able to utilize them.

Mr. Tierney said I could just jump in and ask you that. Is this a little beyond the point now? I'm not trying to rush you because I first want to make sure you manage the pharmaceuticals well, but this is when we get beyond the good management, and I'm just hoping that we're not wasting the products.

Dr. OGDEN. It's possible to return some of the items. Some of the items we can't return because that's part of the agreement between, let's say, the manufacturer and the Department of Defense for those items that we specifically buy for the Department of Defense, but some items we can return and we have returned and do have credits received for those outdated products.

Mr. SHAYS. We can get into this later. Thank you.

Mr. TIERNEY. Thank you, Mr. Chairman. I really don't have a lot of questions in here. I think that you've all addressed the GAO's report in a fine manner.

I do have one question for the Colonel, to try to get an understanding. Do you have any knowledge about whether or not the other branches have units similar to yours?

Colonel HOLLIFIELD. Mr. Tierney, I don't have any knowledge of a unit exactly like mine. I know that they are developing the Weapons of Mass Destruction Civil Support Teams within the Army National Guard. The parameters of that program I'm not familiar with in specific detail.

Mr. TIERNEY. Thank you. Other than that I think I understand pretty much what's going on and what's transpired here. I do want to make the comment without at all seeming patronizing or anything that I think it was refreshing to hear people acknowledge the GAO's value in the report that they did and address it. And I think everybody reserved whatever questions and issues they wanted to raise on that, but I think it's a very high level of professionalism and response and I just want to commend you all for doing that and it's impressive to us and I think it's going to benefit the country. And thank you very much.

Mr. SHAYS. I have just one question. I wanted to read the testimony that I had on the Marines.

Colonel, I want you to put this in some perspective because on the surface it doesn't make me feel comfortable. I think there is an answer for it so you say, "While I do not think that CBIRF should be held to a higher supply management standard than those re-

quired of any other military unit, I recognize that the unique nature of our unit and mission make consideration of GAO's observations prudent."

I've always thought that the military actually has a higher standard than the private sector and the implication there is not comforting.

Colonel HOLLIFIELD. Sir, we have a set procedure for the management of our supply account as set forth in our Marine Corps Consumer Level Supply Policy Manual. As it was pointed out when the GAO visited, some of the systems that we use, our data bases for example, do not capture all of the exact data fields that would be necessary to adequately ensure that we're tracking and properly getting the visibility to the degree that was lacking when GAO visited. Those data bases that we use are data base systems that are prescribed for us. Certainly, however, there's nothing preventing us from looking at or modifying those and adding additional fields so that we do capture stuff such as consumption data, rotation dates of supplies, shelf life expiration, et cetera. Those right now are not captured with the existing data base system.

Mr. SHAYS. Those are not what? I'm sorry.

Colonel HOLLIFIELD. Those are not captured at this time by the existing data base. So in addition the data base captures only the very basic information in terms of the type of item, its stock number, et cetera. But we have to go in and manually track shelf life expiration. So when we say that we don't feel that we should be held to a higher supply management standard, my intent there is to say, we think we have pretty good guidelines already in existence with our existing policy. But we do need to go back and make some minor modifications to enhance our control mechanisms.

Mr. SHAYS. I'm trying to understand why when GAO looked at your facility, they were basically directed by DOD Health Affairs to look at your facility as a stockpile facility, and so it's—we're going to try to understand the Marines, not Army, why Marines. In one sense maybe it's a compliment to you all that you all may be doing something a little different than the other branches. But let me just state what I think I'm hearing and then I want to be corrected because we're almost done here.

The bottom line, the first responders are going to actually be the local communities themselves, that's going to happen. They're going to have some supplies. And the next response is going to be—and I'm not sure how the logistics work—but we're going to get supplies from one or more of our four locations. Is that going to be done by the military, is it going to be done commercially, is it going to be done in a combination? And is HHS basically, is the VA just responsible for the stockpile once, but that's it and then HHS takes over? I've asked a few questions.

Dr. KNOUSS. To get back to our system, the National Disaster Medical System is made up of four components. We have HHS's components which are mainly the teams that are going out and providing care at the scene of a disaster. Our partners in the Department of Veterans Affairs also assist us with that, but also are responsible for operating a part of the system that would be used to hospitalize people that need care in which the local communities resources have been overwhelmed and DOD—

Mr. SHAYS. DOD using the VA facilities locally?

Dr. KNOUSS. Well, no, actually it's a system of 100,000 hospital beds in civilian hospitals that we have organized under Federal Coordinating Centers operated by the VA and by the three branches of DOD. And that's a partnership arrangement where we have mainly to deal with two problems, military contingencies—

Mr. SHAYS. The "we"—sometimes I hear "we", and your "we" might be different than my "we."

Dr. KNOUSS. All right. "We" as the Federal Government. We and HHS.

Mr. SHAYS. Who is the "we" that makes sure this happens, is it HHS?

Dr. KNOUSS. The partnership is the Department of Health and Human Services; the Assistant Secretary for Health chairs the group that manages this system. The Under Secretary for Health of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs at DOD and the Director of FEMA. That partnership operates the system. DOD is responsible for transportation of patients in that system. And the Department of Veterans Affairs and DOD are responsible for the maintenance of the hospital beds in that civilian contingency bed system, with 2,000 hospitals around the country participating.

Mr. SHAYS. How do the pharmaceuticals get to the sites?

Dr. KNOUSS. The way we would do that is under the Federal Response Plan. The first step is for FEMA as responsible for transportation to move our team to the disaster site and they would depend on DOD resources. If we're not able to use that system, our backup is a direct call to the Director of Military Support in the Pentagon. And our third backup is to piggyback onto the civilian contracts that CDC will have for the larger stockpile movement.

So we have three steps that we can use to back up movement of our teams and smaller supplies.

Mr. SHAYS. I've learned just in my own small office if I have two people responsible, nobody is responsible.

Dr. KNOUSS. We are.

Mr. SHAYS. So, I always have one person ultimately responsible.

Dr. KNOUSS. Our office.

Dr. MURPHY. Chairman Shays, we would get a call from OEP that a disaster has been declared. They need the cache. That call would go out; VA would go to the cache, transport it and deliver it to the team, the NMRT, and they would take it to the disaster site. That's how the pharmaceuticals would be transported and that would be VA's part of the role.

Mr. SHAYS. I think I'm pretty clear about that. I'm pretty clear that the VA is basically taking the recommendations of the GAO and implementing them. You have an objection to one area dealing with what you had in supply and not. So you take issue with one area of their report, correct?

It's my understanding that basically you, Dr. Ostroff, are still deciding how much is going to be held by the manufacturer, what sites to have and so on. But I'm sure the GAO report is helpful for you to just make sure.

And Colonel, the sense I'm getting from you is that you view your stockpile differently. I just want to be certain so we don't have

to deal with it later. Is it possible that DOD views your stockpile as unique and that you aren't to service the needs the other three branches?

Colonel HOLLIFIELD. Sir, I have no knowledge if that's the view that they hold.

Mr. SHAYS. Well, then I don't want to imply that it is. I just want to make sure I asked the question.

Colonel HOLLIFIELD. I know that in your previous analogy, sir, the two steps, we count that in between the incident and when the 12-hour push is going to show up, we're there not primarily for that purpose, but we certainly have some medications with us, that in the event that there is a time gap to be bridged between the time that the first responders act and may not have those medical supplies they need, and OEP and CDC can push from their stockpiles, we can bridge that gap on a very moderate basis.

Mr. SHAYS. Let me say this is the first hearing that's been helpful for us to get this knowledge and it's also to make you aware that we are interested and will be watching, in part because I think there's a temptation to think you may never be utilized, and yet you may. But we're also going to just make sure that you're living up to all your goals and objectives. And then we're also going to be looking to see if the system can be improved and if we in Congress can play a part.

Is there any comment that any of you want to make before we adjourn this hearing?

Mr. Ogden, you look like you want to say something.

Mr. OGDEN. No, thanks. Thank you very much, Mr. Chairman. Just thank you.

Mr. SHAYS. Well it's wonderful to have you here. Thank you for your good work.

The hearing is adjourned.

[Whereupon, at 11:35 a.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

