

Strategic National Stockpile Overview

Todd Piester

July 1, 2008

Coordinator: Welcome and thank you for standing by. At this time all participants will be in a listen-only mode. To ask a question during the question and answer session you may press star 1 on your touchtone phone. Today's conference is being recorded, if you have any objections you may disconnect at this time.

I would now like to turn the call over to Alycia Downs; you may begin.

Alycia Downs: Good afternoon and thank you for joining us for today's COCA conference call entitled Strategic National Stockpile Overview. We are very pleased to have Mr. Todd Piester present on this call.

We will be using a PowerPoint presentation for this call that you should be able to access on our Website. If you have not already downloaded the presentation please go to www.emergency.cdc.gov/coca; click on Conference Call Information Summaries and Slide sets, the PowerPoint can be found there.

Mr. Piester served on active duty in the United States Army and retired after 20 years of service as a Lieutenant Colonel. He is now a Supervisory Emergency Response Specialist who serves as Branch Chief in the Division of Strategic National Stockpile in the Coordinating Office for Terrorism Preparedness and Emergency Response here at the Centers for Disease Control and Prevention in Atlanta, Georgia.

The objectives for today's call: After this activity the participants will be able to identify the types of items in the SNS formulary and describe the SNS emergency response options.

In compliance with the continuing education requirements all presenters must disclose any financial or other relationship with the manufacturers of commercial products, suppliers of commercial services or commercial supporters as well as any use of unlabeled products or products under investigational use.

CDC, our planners, and the presenters for this call do not have financial or other relationships with the manufacturers of commercial products, suppliers of commercial services or commercial supporters. This presentation does not involve the unlabeled use of a product or products under investigational use.

I will now turn the call over to Mr. Piester; you may begin.

Todd Piester: Thanks very much. It's my privilege to provide this overview this afternoon and I've also been joined by our Associate Director for Science, Dr. Sue Gorman who will also be here through the question and answer period and may be able to provide more insight into specific questions that come up.

If you go to your next slide, I understand that is a disclaimer slide. And on to the next slide. The title should be Strategic National Stockpile Mission.

Our mission is to deliver critical medical assets to the site of a national emergency. That truly drives everything that we do within the program. It's the reason we exist; it's what we focus on every day. We're involved in preparedness and we're involved in response.

The mission statement is short, it's easy to remember, it's something that we all know and can quote verbatim. But it has a lot of meaning behind the simple words. Deliver to us really has a broader context than just what you think of with delivering a package. We want to have a delivery of the right product to the right place at the right time.

The right product for all the right reasons, for all the medical and scientific reasons, maintained in the proper conditions, transported in a timeframe that's relevant to arrive to meet a specific need.

Critical medical assets are more than just the products, more than just the pharmaceutical products, the medical products, the medical supplies, it also involves our folks, our technical assistance, our expertise that we provide both in preparedness mode every day working with states and local communities to help them prepare to receive SNS assets but also what we'll provide in response.

The site of a national emergency, it might be a bio terrorist event, it might be an all hazards type response, it could be a naturally occurring situation such as Hurricane Katrina.

We work within a process that's now been defined by the Department of Health and Human Services, the Public Health Emergency Medical Countermeasures Enterprise that helps determine requirements for assuring that we have the right stuff, the right countermeasures in the stockpile.

We focus on creating the pathways, the mechanisms to move that materiel to where it's needed in the timeframe that's clinically relevant so there's a lot of planning that goes into understanding each particular countermeasure and each circumstance that it would be used under to devise response mechanisms,

transport mechanisms that will deliver the product to the right place in the time that it's needed.

Of course, all response starts at the local level. Medical response is going to be local and we assure that we're integrated with local planning. We do this through states; we do this through cooperative agreements here at CDC as part of the Public Health Emergency Preparedness Program.

As I said, we provide technical assistance; we make sure that state and local jurisdictions are doing everything they can to plan for and prepare to receive stockpile assets and use them effectively.

We've got a dedicated branch of staff that focus every day on helping their counterparts in those states, in the local communities, with their planning and with their preparedness. We also have a training team and an exercise team, both of which focus on supporting state and local needs, again, for preparedness of receiving SNS assets.

And lastly, we maintain the materiel in a manner that's going to ensure that it's in the right shape and the right condition when it gets there, that it's viable when it reaches its destination. And that's a huge challenge for the size and the importance of the assets that we currently have in the stockpile.

It involves a lot of work with the FDA; it involves work with what's prescribed in current good manufacturing practices or CGMP; it involves a lot of work with security, environmental controls, monitoring of those circumstances for both environmental controls and security, rotating product to make sure that the shelf life isn't exceeded, and also working with the FDA on shelf life extension to get the best possible use out of every product that we buy.

Next slide. The background of the Strategic National Stockpile, or SNS, or sometimes just referred to as the Stockpile, the program was created in 1999 and it was started as an organization called the National Pharmaceutical Stockpile or NPS.

Its initial target for readiness was the Millennium celebration, which you may remember, as the world went from 1999 to 2000 and you may recall that there were some terrorist threats or concerns along with that timeframe. But that was the initial target for capability when the program was created.

Currently the Stockpile is valued at approximately \$3.5 billion worth of assets. And it contains antibiotics, medical supplies, antidotes, antitoxins, antiviral drugs, vaccines and other pharmaceuticals. All of those items are what make up what's currently known as the SNS.

Our annual budget is nearly \$600 million at the current time. Obviously a large part of that is for rotating and maintaining product, purchasing new product, making sure that we are staying abreast. The formulary, the contents of the Stockpile, are always being matched to the current situation as new threats or new priorities emerge for the nation.

The Stockpile isn't a first response asset, it's designed to supplement and re-supply what state and local communities will quickly run out of in a medical materiel response.

One item to note is that we were transferred to the Department of Homeland Security when it was formed by the Homeland Security Act of 2002 and we were then jointly managed by the Department of Homeland Security and the Department of Health and Human Services after that time.

The project BioShield Act of 2004 then returned the Stockpile to Health and Human Services. The name was changed from National Pharmaceutical Stockpile to Strategic National Stockpile by the Homeland Security Act of 2002.

Next slide. And the next slide is titled: Putting it Together. Our goal in the Stockpile is to effectively link the pieces. We want to take the science, we want to take the medical science, we want to take that to help determine: what's the right stuff? What do we need? What are our priorities?

There'll always be far too many requirements than there'll be assets to meet those requirements so there's a prioritization; we'll never have enough to meet all the possible scenarios so there are decisions that are made along those priorities, what we should have for what reasons.

We link in to the science; we link into the medical community that help prescribe what those requirements are and prioritize them.

The Stockpile then, we largely control the next two items, the acquisition and storage and the deployment. Those are items within the process that we really control; that we really are responsible for and have a great deal of positive control over.

And then lastly, the product into the people; we provide technical assistance; we provide other support in preparedness to get the product into the people. But largely those are state and local responsibilities; we support them, we get the product there, we help them plan and prepare for it but ultimately that last part is really a state and local responsibility.

So again, our focus is on creating a linkage, making this as effective as possible from the determination of the needs through to the end result of getting the right product into people when it's needed.

Next slide. This is a huge undertaking, this business with a Stockpile of \$3.5 billion worth of assets; it's a huge undertaking, it's not something that any one organization could do on its own. Because of that we rely on our partners and we have Federal partners, we have other governmental partners, we have commercial partners; we rely on many different entities to help make this whole business of the SNS come together successfully.

First of all, our acquisition support is done by the Veterans Affairs. That was really an early decision in the creation of the Stockpile, to leverage the buying power of the VA. They buy in such high volume that they get the very best price for the items that we need in the Stockpile.

You may be familiar or may have heard of the federal supply schedule, the prices that the Federal government buys from the vendors and manufacturers and that, and it's at a reduced price from what's generally available commercially. And again, because of the VA's buying power we're able to buy products at reduced prices even from the federal supply schedule prices.

We also work closely with the Departments of Defense, Justice, Homeland Security and the Food and Drug Administration. We have dedicated support from the United States Marshals Service; we have over 30 US Marshals that are part of our program, that assist us with security every day; they assist us with planning, preparation and then will also be a key component of securing the Stockpile in a response.

We work very closely every day with the Food and Drug Administration. Our science team works very closely, our logisticians work closely to make sure that all of the FDA requirements are maintained throughout the process of acquiring and storing and maintaining our products.

And lastly there, we work with the USDA and the National Veterinary Stockpile. The Veterinary Stockpile is relatively new; they've only been around several years now but we've done a lot of collaboration with them.

And we even meet with them on a semiannual basis so that we can share lessons learned and share techniques, things that have been successful for us that we can help them with as they are establishing themselves, establishing their programs and their capabilities.

Next slide: Commercial Partnerships. We work very closely and rely very heavily on our commercial partners. We contract with third-party logistics organizations; we partner with those vendors and they store and maintain Stockpile materiel.

They have proven to be extremely helpful. They are world-class at what they do and we rely on them significantly to get the job done of storing this vast quantity of materiel, maintaining it in a ready state and the ability to push it out when needed.

We also rely on commercial transport partners, world-class partners again, for rapid deployment of the medical countermeasures. We have contracts in place that allow us to move product both by ground and by air when needed. And we routinely practice and drill and exercise with these partners to make sure that they're ready and that we're ready to work with them.

Lastly, we seek assistance from outside forces to assist us with efficiency; again because of the very important mission that we have and the tremendous resources and assets that we're responsible for, we've got to focus on making sure we're doing things as well as we can.

An example of this would be our ongoing project with an activity-based costing project to better capture and communicate lifecycle costs for particular items and programs within the Stockpile.

It's important to understand for planning and for considering future acquisitions if a countermeasure is to be added to the Stockpile, how can we best project, based on past experience, what the lifecycle cost will be for that item? What does it cost not only to purchase it but what does it cost to store it year after year? What does it cost to rotate that product? What does it cost to maintain it in terms of security, in terms of monitoring, all those things, and ultimately then product rotation, product replacement at the end of lifecycle.

So again, we rely on our commercial partnerships to help make sure not only do we get our job done everyday but that we're focusing on the future and how we can do a job better next time than we do it this time.

Next slide. Just to highlight several other partnerships. We rely heavily on ASTHO and NACCHO for our support of state and local jurisdictions. They are great partners in helping us understand what's important to states, what's important to counties; it helps us, provides us with a means of providing information to those jurisdictions, passing information. It's really a great forum for us to better understand ultimately our customer and to better meet their needs.

The last bullet there is just an item that highlights another example of a partnership, the Business Executives for National Security or BENS. And we've been involved working together on a project with them that has looked at some new alternatives for dispensing for the Stockpile at the state and local level. Dispensing a product in something like a mass prophylaxis campaign is a very, very big challenge.

So we're always looking for ways that we can work with people to help ultimately the local communities with better ways that they can effectively and efficiently dispense product in a response.

Next slide: Formulary Framework. And when we talk about formulary we're talking about the items that are in the stockpile, what makes up the SNS, what are the actual assets.

Our original formulary was developed through subject matter experts working together and they focused on the Category A Threat Agents. And those Category A Threat Agents, those biological threat agents are listed.

After addressing the Category A Threat Agents, within priorities that were established, other items were then looked at for addition to the formulary and ultimately added to the SNS formulary. Those included for a chemical threat, nerve agent antidotes and also radiological threats.

Most recently we've added some non-bioterrorism, non-emergency or non-terrorist response type assets. And those would include our assets that we now stockpile for pandemic influenza. We maintain the Federal Stockpile of antiviral drugs; we have 50 million regimens of antiviral drugs in the Stockpile that will be distributed pro rata across the nation for treatment of symptomatic patients in the case of pandemic influenza.

We also stock and have purchased and maintain for pandemic response, personal protective equipment items and other items that would be needed.

This was the initial work on the framework again - subject matter experts working on Category A Threat Agents, but over time, since '99, the formulary has grown with other threats and other items being added: chemical, radiological and now non-bt with pandemic influenza.

The next slide. We use an acronym, REASON, R-E-A-S-O-N. And this acronym helps us consider the necessary aspects of items for including in the Stockpile. These are considerations that our science team uses; they are considerations we use to help keep us on target, to help us determine the various items that would meet a particular need, which may be best suited for inclusion in the Stockpile.

R - rotation. Can the products be rotated? Can the drugs be rotated? Is there a commercial market? If there's an item that there's a commercial market for it's very likely that we can enter into agreements, arrangements, contracts with vendors and with manufacturers to rotate the product so that product that we may maintain, as it reaches shelf life, could be rotated out into the commercial marketplace and be replaced by fresh dated product.

If there's not a commercial marketplace, there's probably not much of an opportunity to rotate the product in that manner, which means we're really then talking about having to purchase the product, maintain it for the duration of its shelf life and then ultimately replace it with new product; that's generally not as cost effective as opportunities when we can rotate the product.

The next letter of the acronym: E - effectiveness of the drugs for a particular disease. Again, we're looking for what's most effective, we're looking for what's most efficient; we're looking for the best results for the need.

A - availability of items. Can we reach our targeted capability in a reasonable time? There are some items that are determined to be items of interest for inclusion in the Stockpile, however, their commercial production may be so limited that we just can't obtain them quickly enough to reach capability in a reasonable amount of time.

Also if we were to purchase those drugs it might severely and negatively influence the normal commercial market, the availability of that product for its current need. So that's another consideration that's made in looking at new products.

Continuing the acronym: S - storage considerations. Does this item take special or particular environmental controls for storage, or is it stored at ambient temperature? From a Stockpile perspective in terms of cost, in terms of warehousing, certainly anything that's stored at ambient temperature is much more cost effective for us to maintain and also much simpler for us to maintain.

The letter O - other; something such as IND or investigational new drug status, cost; is there more than one use? This is just a collection of other considerations to look at. If we can find an item that's going to be effective for more than one scenario or more than one threat obviously that has a lot of benefit to us and can help us achieve capability in other areas, so that's an important consideration as we're looking at new items.

And the last letter of the acronym: N - the need for ancillary supplies. Are there options that require less in terms of ancillary supplies, something that makes the logistics of all this simpler not only for us, simpler for transport, simpler on the receiving end at the state level and then for use at the local level.

For example, something like a prefilled syringe maybe easier logistically than another alternative that would include product in a vial that required ancillaries, that would require transfer needles, syringes for administration.

So a lot of different factors, a lot of different considerations that our experts look at in determining what particular items to purchase to meet the needs and put in the Stockpile.

Next slide. The Project BioShield Act of 2004 significantly affects the Stockpile now and will continue to do so in the future. It was enacted by President Bush, again, in 2004. And there are already items in the Stockpile as a result of this Act.

The purpose of the Act is to accelerate research development and acquisition of medical countermeasures trying to make that whole effort of getting the next generation countermeasures into the Stockpile, ready for use, ready for the nation's needs.

Legislation has authorized \$5.6 billion over 10 years. Again, the vast majority of the product procured for BioShield will go into the Strategic National Stockpile.

It also established the Emergency Use Authorization to provide access to medical countermeasures after the declaration of a public health emergency, an

EUA would certainly ease some of the requirements and make it faster to administer products that have not yet reached licensure for that use.

Currently for the items in the SNS, FDA, CDC, HHS, are working together to preplan those emergency use authorizations so that they're easier to process, easier to put in place if the items are needed in a response.

Project BioShield also incorporates Homeland Security making the threat determination. This isn't something that's done strictly in Health and Human Services or at CDC, it's something that involves other governmental partners providing what they're best at, helping this all come together.

So Homeland Security helps determine what the threats are, those are then translated through the scientific and medical communities to ultimately be what items are going to be purchased and developed for inclusion in the Strategic National Stockpile.

Next slide. This slide highlights some of those items that are currently in the SNS that have already been procured under Project BioShield: Anthrax Immune Globulin, AIG, will be used for the symptomatic treatment of Anthrax patients.

Calcium and Zinc, DTPA, they are chelating agents for the treatment of internal contamination of radioactive materials. They are already in the SNS.

Liquid Potassium Iodide, a protective agent for nuclear accidents or release.

Heptavalent Botulinum Antitoxin and that is currently in the SNS - we get occasional calls as there are botulism cases in the US. This isn't freely

available; it's not readily available and the SNS holds the product that is available.

And the last item there, Anthrax Vaccine Adsorbed or AVA. And future procurements under Project BioShield will include next generation countermeasures to include next generation Anthrax Vaccines.

So that's just a quick summary of items of what's already in the SNS that have been procured under Project BioShield. Again, in the upcoming years there'll be significantly greater purchases adding to both the size and scope and value of the SNS. So our challenges will continue to grow.

The next slide. There's another entity, the most recent addition to the SNS formulary process is the Biomedical Advanced Research and Development Authority or BARDA. And this was established by the Pandemic and All-Hazards Preparedness Act or PAHPA when it was put into place last year.

This organization, BARDA, is part of the Department of Health and Human Services. They work with the Public Health Emergency Medical Countermeasures enterprise, linked into that at HHS, and also the folks that are part of working Project BioShield, responsible ultimately for the procurement of countermeasures against chemical, biological, radiological and nuclear threats.

They're charged with acquiring the countermeasures that aren't commercially available or those that are only in research or development and not ready for commercial sale yet. One of the challenges for the SNS has been many of the items that are needed in the SNS, there's no other need for.

The instance of these diseases in natural settings is so low that there just isn't the need for these next generation countermeasures. So BARDA, Project BioShield, all of these efforts focus on producing these emergency response medical assets, these countermeasures, that will be needed in a response setting above and beyond what they're needed for in a normal everyday setting.

And just an item of interest: the authorization for BARDA between 2006 and 2008 was \$1.07 billion.

Next slide. Now I'd just like to focus a little bit about how the SNS responds. We've identified and we focus on three emergency response concepts: first being rapid delivery of a broad spectrum of support if there's an ill-defined threat or in the very early hours of a situation.

This is very rapid response, it's not specific items; it's general items, things that may be needed; things that are anticipated in the early hours of an emerging situation that state and local communities will start to run out of.

The next item in our response concept: large shipments of specific materiel when a threat is known. It's not as fast as that broad-spectrum rapid delivery but it's tailored to the specific situation that's present.

And then lastly, again, the technical assistance both for receiving and distributing, using Stockpile materiel during the event; it builds on the preparedness efforts that we're part of every day; that planning, training, exercise and support that we provide.

So the three emergency response concepts are: broad-spectrum support, specific materiel support and then technical assistance as part of an SNS response.

Next slide. A little more specifically, emergency response options; for broad spectrum support 12-hour push packages - and we'll talk more about each of these items in subsequent slides. So for broad-spectrum support, that very rapid initial push of general items that may be needed, 12-hour push packages.

Specific materiel support; we have two types of inventory within the Stockpile, we also have vaccines and we also have our buying power and surge capacity.

So in terms of speed of response, broad spectrum support, 12-hour push packages are our most responsive asset; that's what we can deliver the fastest. Types of inventory, specific materiel support, not as quick, still rapid response but not quite as quick.

And then lastly, the buying power and the surge capacity would be our slowest response. If we have to go out and purchase items that are available commercially because we don't have them in our inventory, that would be the slowest response but it's certainly something that we've done on numerous occasions; we've used that buying power, both in response to 9/11 at the World Trade Center in purchasing respirators literally over night and getting them delivered to protect the workers at Ground Zero.

And we also used this mechanism for responding to Hurricane Katrina when there were many non-formulary items needed and we supported the response with our buying power.

Next slide: Twelve-hour Push Packages. Twelve hours, that indicates the time that we'll deliver from the Federal decision to deploy. So from the Federal decision to deploy we can have a 12-hour push package anywhere in the country in 12 hours or less, from the Federal decision to deploy.

Push, because the items aren't specifically requested separately; it's that general broad-spectrum response; it's a collection of items for an ill-defined threat or in an emerging situation when we don't know exactly what's going to be needed but we want to be very quick in delivering items that we have good reason to believe will be expended very quickly and needed by state and local officials.

Our 12-hour push packages are pre-packaged; they're configured in transport-ready containers. And the next slide will show some pictures that will better illustrate that. We've got these secure facilities located around the country so that we can meet that 12-hour response time anywhere in the country. And those are near major transportation hubs to allow us to move them quickly.

Again, we rely on our world-class transport partners to deliver the 12-hour push packages.

And to assist the state and local officials in receiving these, setting up their supply, setting up their warehouse and then rapidly accessing the items that they need at that particular time, each of the containers is color-coded and numbered and that makes it very easy to identify.

Push packages include, for example, oral antibiotics for prophylaxis for a bioterrorism event, IV antibiotics for treatment, IV fluids, bandages, other medical supplies. It's a general broad-spectrum response that we can get there very quickly.

Next slide titled 12-hour Push Packages shows your three pictures. And I'll start in the top center and that shows an entire 12-hour push package; that's about 130 containers. And you see there those are the actual air deployment containers.

You see that they have Lexan or clear plastic sides so you can see inside and see the contents and identify contents very quickly. You also see hanging off the front of each of those a strap; these containers, each of them, are on casters, they're on wheels, and they all weigh 1500 pounds or less. They're aluminum-frames, aluminum tops, aluminum bottoms so they're all very light and they can be moved easily on a smooth surface floor by two people.

So this makes these very easy to move around the warehouse or once state and local officials actually receive them; they can be moved by individuals, they don't take materiel handling equipment; it doesn't take a pallet jack or a forklift to move these around.

You see them in the top center picture configured as they would be on air movement pallets and you can see how that approximates the cargo hold of an aircraft. One 12-hour push package will take up the entire cargo hold of a large cargo aircraft.

So there's two sized containers, you can see in the center tall containers, and then you can see on either side there are what we call short containers and those are angled a little bit on the side, again, to match the interior dimensions of a fuselage, again, trying to get the maximum product on that one aircraft load.

The picture to the bottom left shows a single container and it's coming off the back of a truck with a lift gate. We can move the containers by air; we can move them by ground or we can move them - ideally you move them from a warehouse to a warehouse with loading docks; they roll on, they roll off with no material handling equipment.

In this case it's just demonstrating how they can be moved by trucks and then moved off the truck, lowered on that lift gate, and then wheeled off from there.

The bottom right picture shows some of our containers on a K-loader, again, our transport partners, on their equipment, being loaded on to a wide-body cargo aircraft.

So again, the 12-hour push package, it's pre-packaged, they stand ready for deployment anywhere in the country. We have a total of 12 of these 12-hour push packages configured, packed, ready to go and they're our most deployable, most responsive asset.

Next slide: Specific Item Support. We'll talk briefly about each of these: managed inventory, vaccines, Chempacks or chemical packs, Federal Medical Stations or FMS then lastly our buying power surge capacity.

Next slide: Two Types of Inventory. Vendor managed inventory and Strategic National Stockpile managed inventory; VMI and SMI. As I said earlier, whenever there's a commercial market that offers us the opportunity to enter into a Vendor Managed Inventory agreement with partners where we pay them to have product on hand for us and then we pay them to rotate that product out into their commercial marketplace before it reaches shelf life and replace it with fresh dated product.

Well, that's a great arrangement and it's very cost effective and it works very well for us. However, the nation's needs far surpass the commercial marketplace for many of our items. So for things like oral antibiotics, the nation, the world just doesn't use enough of the product that would make it possible for us to enter into agreements for vendor managed inventory of our oral antibiotics.

So for everything that we can we prefer to enter into agreements for vendor managed inventory. Whatever we can't, though, we then have in Stockpiled Managed Inventory or SMI. In response, really they're both the same, doesn't matter to the recipient whether a vendor managed it or whether we manage it; it's coming to you, or it's coming to the recipient; it's palletized cargo. It's very large quantities of specific items to meet specific needs.

So that's the important thing to remember about our two types of inventory; it's bulk cargo, it's palletized cargo, specific items for specific needs. It's not quite as fast as a 12-hour push package; it should arrive within 24-36 hours roughly from the decision to deploy. Again, not quite as rapid but it's very large quantities, very specific items for specific needs.

The next slide - and this is entitled Stockpile Managed Inventory. And it just shows one of our warehouses. It shows an aisle at one of our warehouses with Stockpile Managed Inventory. And you can see there the racking where it's palletized cargo, six racks high so we're maximizing the footprint of each of our warehouses through racking that makes this as effective as possible to store all the product that we need.

This also can give you an idea of why it's not quite as quick as that push package to deliver. You can see there that a lot of the product is going to have

to be brought down with high lift forklifts. It's got to be brought down off possibly the fourth, fifth, sixth rack to get down onto the floor. So it takes a specialized piece of equipment to even get it onto the warehouse floor.

And then every one of those pallets has to be moved around by material handling equipment, a pallet jack or a forklift, and that's going to take an operator for each pallet. So it's just not as quick to move.

And then loading trucks, again, with palletized stock is a much slower proposition than what's already in those pre-packaged cargo containers that are in our push packages. But, again, vast volume, and this is where the vast majority of the Stockpile assets are, is in our managed inventory, both Stockpile and vendor managed inventory.

If you look at the value of the Stockpile, \$3.5 billion worth of assets, we have 12 12-hour push packages, each of those push packages weighs about 50 tons each. But the sum total of our push packages makes up less than 5% of the total SNS assets.

Next slide. Another area that we manage, vaccines; the inventory includes the nation's supply of anthrax vaccine. We also have the nation's supply of smallpox vaccine and the ancillary supplies that will go with that. A smallpox response for the nation will be one of our biggest challenges of getting smallpox vaccine out for the entire nation within a short period of time to protect the nation from a smallpox outbreak.

Also, other items like immune globulin plasma and botulinum antitoxin. So within our inventory management, smallpox vaccine is probably our most challenging response because it's the largest volume, it's nationwide but we have other items that will support other response scenarios.

Next slide: Forward Placed Caches: Chempacks We said that our most responsive assets were 12-hour push packages, 12 hours or less. Well if we look at a nerve agent threat, a nerve agent attack, those nerve agent antidotes have to be delivered within minutes; 12 hours doesn't get them there fast enough.

So we were given the challenge and have created a program nationwide for forward placement of nerve agent antidotes. It's integrated into local response plans; it's containerized. We maintain the inventory; we monitor it; we have systems to monitor the storage conditions and the security but it's placed in locations that state and local communities decide, where it can be quickly accessed and integrated into their response when called for.

There are two configurations: there's one that's suited more for hospitals and there's one that's suited more for emergency medical service type locations. The EMS containers are largely auto-injectors; the hospital containers contain a greater proportion of multiuse vials; similar products just different configuration for different settings.

But again, another way of making the right assets available in a relevant timeframe.

The next slide: Federal Medical Stations or FMS. This is an HHS asset; it's managed and deployed by the Stockpile. It provides non-acute and special needs care to patients for three days. So each set is configured to provide 250 bed spaces and it comes with supplies that will last for an estimated three days.

Those 250-bed units can be broken down into 50-bed increments. The supplies include housekeeping, first-aid equipment and also pharmaceuticals. And you see in the picture there an FMS that was set up. These were actually a prototype when Katrina started but again because of the unique requirements of Katrina we went from prototype to actual response deployment in a matter of hours and we've continued to refine it from there.

This is a set of equipment; it needs to go into a building of opportunity. Health and Human Services has a rapid deployment force that would make up the site staff, the medical staff, for an FMS. It also could be put, and has been successfully used at installations that included VA where VA staff would fall in on and actually manage and take care of the patients that would be used there.

Again it's non-acute or special needs care; it's not a hospital; it's not tentage; it's the equipment that would help a building of opportunity be used for non-acute care for medical surge and also special needs patients.

Next slide. Just, again, our buying power/surge capacity, another thing that we offer. Again it's using the Veterans Affairs to get the very best prices. We use prime vendor contracts, emergency spending protocol to replenish. But again, this would be our slowest response if we have to go out and buy it if we don't already have it.

Now I'd just like to briefly talk about our response unit, our technical advisory response unit. It's the technical assistance that we provide to state and local officials in a response. So next slide and if you'll go to the slide that is titled TARU Primary Missions.

Ideally the TARU will arrive at the state to assist the state before our assets do. So if we've got to get a push package anywhere in the country in 12 hours or less ideally we want to get our TARU there in less time than it takes to get the push package.

So they're very deployable; we drill them, we exercise them to keep them ready at all times to deploy. They receive the SNS materiel at the designated location and then facilitate transferring it to state and local authorities. And that's just the start of it.

The next slide: TARU Secondary Mission shows what they continue to do from there. They provide technical assistance: anything that they can assist with related to the SNS they're going to provide. They're going to help break down the materiel; they're going to assist with dispensing and distribution issues; they're going to advise on needs and requests, help with the formulation of re-supply requests; they'll advise on storage, transportation issues; they'll assist with anything they can.

And then also they'll manage any SNS materiel that's not released to state and local authorities. There may be some selected items in a push package or in other assets where the situation doesn't really call for that to be provided to the states and the TARU could hold that under their control rather than signing it over to the state.

Next slide. Again just to highlight some of the things our ongoing efforts for technical assistance for countermeasure dispensing. Homeland Security Presidential Directive 21, HSPD21, there's an incredible amount of effort government-wide, nation-wide, to assist with countermeasure distribution, countermeasure dispensing.

This slide just highlights some of the things that we do everyday in our ongoing technical assistance efforts. First version 10.2: Receiving, Distributing and Dispensing SNS Assets; the planning guide. And this is a document that we prepared to provide assistance to states. And it has undergone upgrades, updates to make sure that it stays current.

We provide technical assistance to 62 project areas. And those are the Public Health Emergency Preparedness Cooperative Agreement project areas, the 50 states, Washington DC, three separately funded cities, several territories and then some island jurisdiction.

We also provide the state and local exercise support and evaluations, also training support that I've mentioned. Both in training and in exercising we have replica SNS materiel that we can provide to help states train and help states exercise.

And this replica materiel will give them a representation of both push package and can also be for pandemic flu items or vendor managed or Stockpile managed inventory items to give them a sampling of what they'll receive; boxes look the same, internal bottles may look the same. And those items can be used both for drills and exercises all the way down to practicing dispensing.

Again we also offer classroom instruction and a number of satellite broadcasts annually all as part of our technical assistance to help the preparedness of state and local officials.

Next slide. Again, just going back, putting it together; in review: we focus on the end result, getting the product into people and we work to maximize each step to get the right stuff to the right place at the right time.

Next slide. That's the conclusion of my presentation and I'd be glad to answer questions.

Coordinator: To ask a question you may press star 1. You may withdraw your question by pressing star 2. Once again to ask a question press star 1 and record your name. One moment please.

The first question; your line is open.

Question: Yes, is there any thought of switching to the DuoDotes instead of the Mark I kits?

Sue Gorman: Yeah, this is Sue Gorman. We are considering that because the Mark I kits will not be available indefinitely. Right now we don't have DuoDote but that's definitely on the table for consideration.

Question Cont'd: Thank you.

Coordinator: Our next question: your line is open.

Question: There's 72 CRI cities, CRI areas across the country of varying size and complexity, yet a push pack handles antibiotics for, as I understand - I've seen different figures but 300,000 people plus or minus. There are 12 push packs. In a multi-CRI scenario event, if the Stockpile managed inventory won't arrive for 24-36 hours and the push pack may be there earlier but 12 hours is a planning interval, how are we to meet the 48 hour deadline for complete prophylaxis if the time to get the materials takes up three-quarters or more of the available hours?

Todd Piester: You've asked a very good question. For those on the phone that may not be familiar with the acronym CRI, Cities Readiness Initiative, really an effort by the government to enhance the ability of localities, cities to dispense prophylactic antibiotics to its citizens within 48 hours of an aerosolized release of anthrax.

And you've asked a very good question. Our general planning figures for managed inventory is 24-36 hours. We recognize the challenges of a CRI response and understand the 48 hour timeline. We believe that the push package, as our most responsive asset, may be of value for its rather limited antibiotic prophylactic capabilities to get first responders and other critical elements started on prophylaxis; that's our most responsive asset.

We are committed to providing the oral antibiotics for a CRI-type setting in enough time that we're going to avoid the problems that you've brought up. So I didn't go into detail with that, but we recognize the challenge that you've described and we have mechanisms in place to make those oral antibiotics deployable to meet those needs. And we continue to look at other alternatives to be able to do it better, faster to meet those needs.

So our general planning figure for managed inventory is 24-36 hours, CRI-type setting, large quantities, enough antibiotics to prophylax the population of the city we're going to get that delivered significantly faster than 24-36 hours.

Question Cont'd: Thank you. I don't know if I can ask a follow-up but you had indicated the push pack might be used for first responders. Those of us at the local level see that as far too slow in terms of a population response and most are planning local caches.

Within that context and given the buying power of the Federal government/VA, the commonality of the drugs, the unit of uses, as well as the Federal program for shelf life extension, is there any thought to being able to extend to the local level through the states the ability to buy unit of use antibiotics so that everything is standardized and costs are minimized and rotation is not - or the need to rotate is minimized as well?

Todd Piester: Shelf life extension, we understand is a huge, huge desire at the state and local level, and the last that I'm aware of it it's been discussed significantly in terms of antiviral drugs for pandemic influenza and it's really the FDA's program. We understand that it is always being looked at; it's highly desirable to assist the nation's preparedness.

We're not aware at this point of indications that it's possible in the near term but we do know that other parts of government, HHS, FDA, are very well aware of how important it is, how important it would be and continue to look at it, but we're not aware of any imminent success in gaining access for cities and states.

And I understand your point, yes, in some circumstances I'm sure many communities aren't planning the push package for first responders based on local caches meeting that need.

Coordinator: Our next question; your line is open.

Question: Yes, when you say that the push packs are designed to be deployed within 12 hours of the Federal decision, who can request the SNS and how - once the request is made how long does it take for that decision to be made?

Todd Piester: The first question, who has the authority to deploy the Stockpile...

Question Cont'd: No who has the authority to request it?

Todd Piester: I'm - well, okay, sorry. Our planning guide says that governors or their representatives can request the Stockpile. Currently by law, the Director of HHS has the authority and also DHS can require HHS to deploy the Stockpile.

How quickly will those decisions be made? I really don't have an answer, there's not a set answer I'm aware of to give you for that other than I believe that there's enough understanding of how rapidly decisions need to be made in an emerging situation such as aerosolized release of anthrax where literally every hour will count towards helping save lives so I believe that decision will be made very quickly.

If we use history as an indication, on 9/11 then the NPS delivered a push package in less than seven hours in that response. So I don't have a good answer to say that there's a standard, "this is how long the decision will take from our exercises," I know that it's been emphasized, the decisions need to take place rapidly to make the product as efficient as possible in saving lives.

Coordinator: Our next question.

Question: Yes, I was just wondering if there was an emergency where botulism antitoxin was needed for a large amount of people? I have to ask then, how much would then be able to be obtained?

Todd Piester: I'm going to let Dr. Gorman answer that one.

Sue Gorman: It really - how fast. It's part of managed inventory so technically that would be the 24-36 hour timeframe, and I'm aware that that isn't really compatible

with how quickly you would like to get the botulism antitoxin to the person. So we're working on ways to make that available faster.

As far as how much we have different types of antitoxin in the Stockpile right now. The only licensed product that we have is the AV antitoxin but we also have E, plain A, heptavalent, so it really depends also on which type of botulism the person is affected with.

And I don't know how quickly those results are going to be available so in an unknown case where we don't really know what one we're dealing with we would most likely want to use the heptavalent. And I can tell you that we have a current contract under Project BioShield for 200,000 doses of heptavalent and that's coming in every month. So we have not achieved all 200,000 yet but that would be what we have on hand when that contract is completed.

Question Cont'd: Thank you.

Todd Piester: And just another note about our response time: those times that we've provided, the 12-hour push package, 24-36 hours for managed inventory, those are from a cold start; those are from no notice. Those are the times that we're counting on that we can accomplish our response in the middle of the night on a weekend, no one's at work; we've literally got to reach everyone from our vendors, our transport partners, our own staff, to crank things up and get things moving.

Well, if we're fortunate that an emergency happens during normal work hours when people are already present our response will be shorter, I mean, we're going to go as absolutely fast as we could possibly go, those are planning figures we provide that take into account the worst case, which is it's the

middle of the night on a weekend and we've literally got to get everything started from scratch; just a note on those.

Sue Gorman: And also in an event unfolding and we have credible information that there's a threat of botulism or - at the sign of the first case of botulism we definitely would be able to forward deploy those types of assets to the area so that would cut down on the time it would take to reach the patient.

Coordinator: Our next question.

Question: My question has been answered. Thank you.

Coordinator: Our next question.

Question: Yes, my question relates to the pandemic antiviral managed inventory. There has circulated on the Internet a document, which may in fact be a draft of the plan for this inventory. And there are three items on it that would be very helpful to know from the local planning viewpoint. I just wanted to know if you can confirm that, in fact, these are accurate.

The first is that within two weeks the 62 areas will receive basically most, if not almost all of the inventory of antivirals and N95 masks. The second point is that the states and locals will be expected to follow the RSS protocol. And the third is that TARUs will not accompany this shipment. And I wonder if you can confirm or deny that?

Todd Piester: Okay, I'll walk through them one at a time. The first, as I understood what you said, within two weeks you'd receive most of your antiviral and N95s. Current Stockpile planning, that's part of the CDC response plan for pandemic influenza, calls for two different deployment options for SNS

countermeasures and each option consists of three parts - one is a sequential item - we would ship all antiviral drugs out first in Part 1, followed by Part 2 with respiratory protective devices, N95s and surgical masks, followed in Part 3 by all other items.

We have another deployment option that's a metered package option where we would ship out in Part 1 25% of the allocations of all assets, in Part 2 the next 25% of all items and followed by Part 3, the remaining 50% of all allocations of all items. So in both options at the two-week mark we're halfway through delivery.

So if it was the sequential item response all antivirals would be out already and the majority of N95s would be delivered by then, there may be some still in process there at the two-week mark. If we're in sequential - I'm sorry, excuse me, if we're in the metered package response option everyone would have received their initial 25% allocation and at the end of two weeks the next 25% would be shipped to everyone.

There may be some locations still in transit, still not receiving it. But the vast majority would have received both their first 25% and second 25%. So I hope that helps you better understand, in more detailed terms, what we're looking at. Within two weeks sequential item, all of the antivirals will be received at that point and the vast majority of the N95s and surgical masks; if it's the metered package option all the first 25% received, the vast majority of the second 25% received with a little bit left in transit.

But at the two-week mark we'll have pushed the first two parts out. The second part, yes, we do plan to ship to RSS (receive, store, stage warehouses). And the third part of the question, you are correct, we do not plan to deploy TARU in a pandemic response.

For us the pandemic response, much like a smallpox response, is nationwide and simultaneous; we don't have the assets to physically put TARU in each state at that point, so we won't be able to. So for pandemic response, yes, we do plan to ship to RSS locations for Stockpile assets.

Now I know that on the vaccine side, pre-pandemic vaccine, which the Strategic National Stockpile doesn't control, doesn't store, doesn't deliver, I know that that's going to vaccine ship to locations that may be separate based on planning from the RSS for the Stockpile countermeasures.

Question Cont'd: That's very helpful.

Todd Piester: Did I--.

Question Cont'd: Thank you.

Coordinator: Our next question; your line is open.

Question: Yes, are there any plans to restart the Chempack program for the hospitals because the last year a number of the hospitals opted not to participate in the program for a variety of reasons, but since then some of the states have stopped restocking their stockpiles in the region so now there's some - the hospitals want to come on board. But at this point in time my understanding is that the program is not active.

So how can we restart that program because our county has a 2.5 million population. And to my understanding there's only one hospital about 25-30 miles away from the main city that has opted to house it. So how can we

restart the program so other hospitals can start stockpiling or participating in the program?

Todd Piester: At all levels of the Stockpile, the Chempack program in the Stockpile continues; it's active, it's current, pardon me, continues every day, product is being sustained where it has been fielded. I believe you're asking about an issue that's within the state of the state possibly needing to take another look at where they've chosen to place those Chempack assets that they were allotted.

So I believe the answer to your question is a discussion with state officials whether it's a Chempack coordinator, an SNS coordinator, someone at the state level to investigate are there going to be opportunities where the state will take another look at where its allocated Chempack assets have been deployed and where they're stored at.

But from our perspective Chempack is alive and well and continuing. There are some discussions at the Department of Health and Human Services of what's being called Enterprise Chempack, growth of Chempack, looking at Chempack models for other areas.

So it is a model that is alive and well, it is a program that at our level is alive and well. I think the answer to your question is discussions with state officials.

Question Conit'd: Okay, I think I already discussed with state officials, I will do it again because their - the impressions they gave me is that the CDC has not started - I mean, they will check with the CDC to see if the program is in restart. So the question is that that I need to get an answer to that and I will talk to the state people again. But thank you for your information.

Coordinator: Our next question; your line is open.

Question: Hi. You had mentioned before that the SNS program uses private sector logistics partnerships for warehousing and delivery, which is, you know, makes a lot of sense. Our county would like to do this to locally, i.e. enter into an MOU with a private sector company, a transport warehouse company that specializes in overnight delivery.

But the stumbling block to the MOU is reimbursement; the county doesn't want to put up that kind of money and get stuck with the bill. So is it memorialized anywhere that in a declared emergency that that sort of MOU with a private sector where you set up an SNS where they do the warehousing and the trucking because that's the most efficient way to get it done, that that would be guaranteed reimbursed by FEMA so that we could show them that when we're trying to talk them into signing an MOU?

Todd Piester: I don't think Dr. Gorman nor I are best prepared to answer your question. I do know that there are states and communities that are using third-party logistics vendors for RSS operations, that are using it for distribution. But I don't think either of us is prepared to really provide the answer you're looking for.

I would suggest that you send that - email that question in; it'll reach us and then we can provide it to the right part of our program that can better answer that.

Question Cont'd: Okay. Thank you.

Todd Piester: Good question, unfortunately, sorry, I don't think either of us can answer it definitely.

Question Cont'd: Thanks.

Coordinator: Our next question your line is open.

Question: Yes, I would like to know how much medicine comes in that initial dispensing that's supposed to be done on the county level? We've received several conflicting amounts; one being that there's a two-day supply, one that there'd be a 10-day supply and then a third that it would be two weeks.

Todd Piester: I believe your question is: What's the configuration of oral antibiotics that we ship out. In a push package that will consist of 10-day unit of use bottles. So that will be a bottle of 20 for 10 days you would use that would then, for a full course 60-day regimen, have to be followed by another 50 days of supply. But the initial push for us is to get that 10-day unit of use bottles out.

How much the state will allocate to your county or to your community is not something that we control; it's a state function. But the configuration of the materiel we send is 10-day unit of use for the antibiotics...

Question Cont'd: Okay.

Todd Piester: ...to get started.

Question Cont'd: And when we dispense that medicine do we dispense 10 days worth of oral meds as well or do they come back through? The guidance that we had gotten from the state were that anyone that required oral meds would get two doses and they would follow-up with a family physician.

Todd Piester: Again I think this is a conversation you've got to have with the state officials. We're going to provide to them enough antibiotics to take care of the needs;

our initial push on that is going to be 10-day unit of use as the start of the number of regimens. Ideally, from our perspective, after 10 days possibly the exposed population has been better defined to determine just a better finite number of people that need to continue to full course and others may not need to and that could reduce the logistical burden on us, transport as well as the state system.

But the question of how to dispense I think is something you need to discuss with your state officials.

Questioner: Okay, thank you.

Coordinator: Your next question comes; your line is open.

Question: Could you tell us what exactly is contained in a push pack?

Todd Piester: I don't think we can tell you exactly; I think Dr. Gorman can give you a generalization.

Sue Gorman: There are oral antibiotics in 10-day unit of use bottles. There are IV antibiotics. There are burn and blast supplies such as bandages and dressings. IV ancillary supplies that you would use to start an IV. There are IV fluids and there and also airway management supplies from bag-valve mask to CO2 detectors to oropharyngeal airways and things you would need to intubate someone.

So it's very general; it isn't specific to a particular threat although it does have the unit of use antibiotics in there that could be used for anthrax, plague or tularemia.

Coordinator: Our next question.

Question: Yeah, yeah, this is a two-part question relating to the formulary framework Slide 9. This country's population at 300 million and you commented that you had 50 million courses of I think the antiviral and that they would be distributed pro rata and I'd like to know what that term, pro rata, means in terms of the availability of only enough for 1 out of every 6 persons.

Keeping in mind that we, at the local level, are required to have a POD system with a guideline that was supposed to be able to prophylax the entire population within 48 hours.

The second part of the question is that there is a debate, at least in the medical and public health circles as to whether the antivirals should be used for prophylaxis or should it be reserved for treatment of people who are already sick. And the importance of that part of the question is that the entire POD system is based on prophylaxis. So I'd appreciate your comments on both pieces.

Todd Piester: Sure. First of all the nation has decided - the national strategy is that we should have the capability to treat up to 25% of the population; that equates to 81 million regimens. Of that 81 million, 50 million were to be in the Strategic National Stockpile, the Federal portion of that; 31 million were to be in state stockpiles. And that was to be purchased under a Federal government contract with a 25% Federal subsidy, so that's the state portion of this 81 million total.

So if 50 million is just the Federal portion that's in the SNS there were to be another 31 million in the state purchased stockpiles. Some states have purchased all of their allocation, some states have purchased more than their

total allocations, some states have chosen to purchase less than their full allocation, so the 50 million is just the Federal portion of that component.

The current Federal plan calls for those stockpiles to be used for treatment. There is discussion of the value of prophylaxis; prophylaxis is mentioned in community mitigation, if you're familiar with that document. There's ongoing discussions, subject matter expert working groups of the next generation or the next version of Federal guidance on the use of antiviral drugs.

Currently it remains as treatment, prophylaxis is certainly being considered. And there's discussion about now that there's increased production of antiviral drugs, increased capacity to produce; that then makes potentially more product available than that opens up the possibility to discuss how it could be used for prophylaxis also.

Currently though that guidance is being worked on. Right now it's still for treatment.

Question Cont'd: I guess I don't understand then why we're doing all this planning for PODS.

Todd Piester: Well PODS, as part of a mass prophylaxis campaign for a bioterrorism event would certainly be applicable.

Question Cont'd: Okay but not for flu?

Todd Piester: At this time not for flu; if they expand the guidelines for use of antiviral drugs for prophylaxis then PODS may be very applicable.

Question Cont'd: Thank you.

Coordinator: Our next question.

Question: Yes, in light of the agreement that was drafted between HHS and the Canadian Ministry of Health and the Mexican Secretary of Health for distribution of medical and non-pharmaceutical products if you had a multi-country event has there been a plan developed of how that would work? And if there is how - where do we find it?

Todd Piester: Planning is ongoing and the work you described is part of SPP, the Security and Prosperity Partnership. There's ongoing discussions and planning with both our neighbors to the north and south. I can't refer you to a place now though that you can see the plan.

We know that at state and local levels there's a significant amount of cross-border planning and actual preparations underway. But the Federal level plan, as far as we're aware, is still being formulated.

Question Cont'd: Thank you.

Coordinator: Our next question; your line is open.

Question: Yes, thanks for the good presentation. When an event occurs we're going to be concerned about really mobilizing our first responders and our first receivers. This is going to be quite a challenge and it seems as though we could accomplish much of this ahead of time by providing a prophylaxis.

Last year the med kit study was completed in Los Angeles area where they pre-positioned antibiotics in households; it seemed to be quite successful with 99% of the kits being returned intact although at the end of the study it mentions it would be up to three years by the time that that could actually be

initiated. Is there any way to accelerate that schedule and is this a feasible project within the CDC?

Sue Gorman: I'll comment on that. It's certainly a feasible project and it's a number one top priority at Health and Human Services right now and work is ongoing on that program to see how we can best market that and do that on a larger scale. So stay tuned, that's a top priority right now.

Question Cont'd: Thanks a lot; that'd be quite helpful.

Coordinator: Our next question; your line is open.

Question: Hi, thank you, Colonel. Question for you, you had made reference to the Federal - the Medical Stations; does the CDC, by chance, have a TO&E list for the equipment in that or is that strictly available through DHHS? The reason I ask is that we're part of a group here that's working on alternative care sites and having - I'm using kind of the model from our old fleet hospitals that we had years and years ago and would like to be able to augment it or at least reference the kinds as far as the equipment that they have on board.

Todd Piester: I think your best avenue for that request is to go to HHS. It is their asset; we manage it and deploy it but truly they're the ones that are designing, as you say, the TO&E, the formulary, the contents. And that's been updated and changed and evolved numerous iterations since it started. So I think your best bet is to contact HHS for that listing.

Question Cont'd: Okay, thank you, Colonel.

Alycia Downs: Mr. Piester, I want to thank you; that was a very informative presentation. And I want to thank our participants for joining us today.

I know there were still a few people who were waiting in line to ask your question but as you can see we've gone past our hour so please send an email to coca@cdc.gov; that is C-O-C-A@cdc.gov and we will try to answer your questions.

The recording of this call and the transcript will be posted to the COCA Web site at www.emergency.cdc.gov/coca as they come to us. You have a year to obtain continuing education credits for this call. All continuing education credits for COCA conference calls are issued online through the CDC Training and Continuing Education online system, www2a.cdc.gov/tceonline.

Please note that the training and continuing education online site is temporarily down; they're doing everything they can to restore the service quickly. If you have questions please email them at ce@cdc.gov or call 1-800-41 TRAIN, T-R-A-I-N.

So thank you again very much, that was a very useful presentation and I think everyone gained a lot of very good information. So thank you again and I hope everyone has a wonderful day.

Todd Piester: Thank you, glad to help.

Coordinator: Thank you for participating in today's conference call; you may disconnect at this time.

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