



THE HOUSMAN GROUP

WHITE PAPER

**FORWARD DEPLOYMENT OF MEDICAL COUNTER-MEASURES:
THE ROLE OF THE STATES AND THE AVAILABILITY OF FEDERAL FUNDING©**

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**I. BACKGROUND ON STATE-BASED FORWARD
DEPLOYMENT OF MEDICAL COUNTERMEASURES**

In response to a recent *60 Minutes* segment concerning the federal government's lack of progress in deploying an available counter-measure to a radiological or nuclear attack, a number of states have begun efforts to procure this drug from their own funds. A similar dynamic has played out around the threat of an H5N1 pandemic; a number of states have already appropriated funds to stockpile antiviral drugs. These states are, in essence, seeking to leapfrog stalled federal biodefense efforts, in particular the Bioshield procurement process, and more effectively and swiftly protect their citizens.

At the same time, some of the leading biodefense companies are so frustrated by the direction of the Bioshield Program that they have begun to consider the states as an alternative, perhaps even more reliable, market for some medical counter-measures. This newly emerging sentiment is based on the widespread expert and industry conclusion that: 1) the Bioshield Program is not living up to its promise; and, 2) federal efforts are not creating a biodefense market worth investing in or pursuing.

State efforts to leapfrog the federal government and forward deploy medical counter-measures make sound policy sense. First, one of the inherent values of a federal system is the ability of the states to serve as distinct, and to a degree independent, test beds for examining new and innovative policy approaches. Scores of programs get tested at the state level, are found to work, and then get adopted and expanded at the federal level.

Second, the reality is the federal Bioshield procurement effort has not yet addressed a range of serious threats. We have no stockpiled counter-measures for a host of already recognized chemical and biological threats. In fact, faced with scores of serious nuclear, biological, chemical and radiological threats, the Department of Health and Human Services' (HHS) Bioshield Program has awarded just two contracts for anthrax vaccines, one contract for liquid potassium iodine, and one contract for a combination of chelating

agents. All other threats go unaddressed. For example, almost five years after 9-11, the federal government still has not procured and deployed a medical counter-measure for acute radiation sickness—the condition that will cause hundreds of thousands of deaths in the wake of a nuclear attack. Similarly, despite serious concerns about the threat of a smallpox outbreak or attack, the federal government has not sought to procure a next generation, general population smallpox vaccine. At the same time, the health risks associated with the current smallpox vaccine have greatly undermined our preparedness for a smallpox epidemic. As a result, states are right to want to protect their citizens in what they see as the absence of federal action—after all, as we saw in Katrina, much of the blame will fall on the state officials if we cannot effectively respond to such an attack.

Third, medical counter-measures offer the promise of significantly shifting the strategic balance between the United States and the terrorists. Every WMD medical counter-measure that we develop and effectively deploy removes a weapon from the terrorists' arsenal. Additionally, the ability to treat or prevent an attack with a certain WMD deters the terrorists from using that weapon—or seeking to obtain that weapon. Moreover, being able to treat or prevent a WMD attack dramatically diminishes the terror of such an attack. A WMD attack is an inherently frightening thing. However, if we can treat the harm behind the fear with little or no consequences, that fear factor drops sharply and the predominant concern becomes mere logistics.

Fourth, deploying field-ready medical counter-measures can significantly diminish the burdens on public health surge capacity. Exercise after exercise has demonstrated that a mass casualty attack will swiftly overwhelm the clinical care resources of any state or region. For example, the Department of Homeland Security's (DHS) TOPOFF 2 exercise tested the ability of 64 hospitals in Illinois to respond to a biological weapon attack. A recent GAO report summarized the results of the exercise:

[On the second and third days of the exercise] the situation worsened and medical care in the city was described as beginning to shut down, with insufficient hospital staff, beds, ventilators, and drugs. At the conclusion of the exercise, 1 week after the attack, an estimated 3,700 cases of plague had been reported, with 950 to 2,000 deaths, including cases in other cities and abroad. In the early stages of the epidemic, hospitals were seeing 2 to 3 times their normal volume of patients and later in the exercise up to 10 times normal volumes were arriving at hospitals. Hospitals were not able to effectively isolate patients to prevent the spread of the disease to hospital staff.

In essence, surge capacity can be increased either by adding capacity, or by shrinking the surge (through other forms of treatment or care)—or some combination of the two. Medical counter-measures capable of treating victims outside of hospital settings can significantly diminish the surge of victims requiring hospitalization or clinical care after a

mass casualty WMD event. In this way, such counter-measures can play a major role in addressing the serious surge capacity challenges the nation faces.

Fifth, such countermeasures can also sharply reduce the costs of preparedness and response. Consider the example of nuclear response. If victims of a nuclear attack are treated for neutropenia (one of the two impacts of radiation on the body) in a clinical setting (using figures for treatment of analogous cancer therapy-induced neutropenia), such care will require average hospital stays of over 11 days and cost just under \$20,000 per victim. And, given the impacts of an actual nuclear attack, such figures are likely vastly understated. For example, few cancer patients suffer from shrapnel wounds or burns.

DHS estimates that a 10 kiloton bomb used against Washington, DC, will result in over 300,000 people requiring care. Assuming we had the capacity to care for all these victims, which we do not, the cost of such a response would exceed \$6,000,000,000. One of the drugs being developed by the Department of Defense to treat radiation sickness requires no hospitalization and, if bought in bulk, could cost as little as \$100 per course of therapy. Assuming the same attack scenario, deploying this drug to care for 300,000 victims would cost just \$30,000,000.

Sixth, given the strategic value of medical counter-measures, the nation needs a biodefense industry and all indications are that the current federal program has not provided the market required for the development of this industry. Congressional members and other experts increasingly conclude that the Bioshield Program has failed to live up to its original promise. This shortcoming is the result of the program's slow, small and often nonexistent procurement efforts. The size of the latest Bioshield RFP would not qualify the drug ultimately procured for orphan status—by legal definition not a market. Because the federal market has not materialized, there are numerous indications that the much needed biodefense industry will not develop absent significant changes that may or may not be in the offing. If enough states can move more quickly, they may be able to create enough of a market to foster the creation of a biodefense industry, albeit a more modest one. In other words, state efforts may actually save the federal program from some of its own missteps.

Seventh, as we saw with Hurricane Katrina, the immediate response to a disaster or attack needs to come at the state and local level. The federal government's own homeland security policies and grant programs rightly focus on the need to build response capabilities at the state and local level. If medical counter-measures are deployed by the states, these counter-measures will be closer at hand and more quickly in the hands of first responders, medical personnel and victims. Such a granular state or local deployment is particularly important in the case of threats like nuclear and chemical, where the window for treatment is so narrow as to necessitate forward deployment at the state and local level—not within the federal stockpile. The Centers for Disease Control's (CDC) "Chempacks" Program already recognizes the importance of state and local authorities in the effective, forward deployment of medical counter-measures to chemical weapons threats.

Eighth, states have a “closer to the ground” understanding of the specific threats that their citizens face. The federal government is charged with looking at threats on a nationwide basis—arguably the 10,000 foot level. States view these threats from a much more intimate distance—ground level. This enables a state to plan on a more individualized basis. It also allows a state to plan for threats that are serious from a state perspective, but may not rise to the level of a national threat. If a state determines that the greatest threat to its citizens is a certain biological attack, and that a specific medical counter-measure is needed to counter that threat, it makes little sense for a state to be unable to move ahead to procure that counter-measure, and address the threat, simply because the federal government has not decided to act on that risk as a national priority. Similarly, if a state’s citizens are worried about an attack on a nearby nuclear plant, that state should be able to respond to these concerns.

As a general rule, we ought to be doing all that we can to encourage the development and deployment of such counter-measures, whether by the federal government, the states, localities, or private interests.

While some states are moving ahead out of a sense of security imperative, urgency and necessity, the responsibility to deploy counter-measures to terrorism Constitutionally—and fiscally—should reside with the federal government. Additionally, given the relatively limited resources of individual states, if states have to buy these counter-measures without any federal support, some states will not be able to afford them. It makes bad security and worse policy for one state to be able to safeguard itself from some form of attack if its equally at-risk neighboring states cannot. Further, if states are forced to buy these drugs on their own dime, state-based forward deployment of vital medical counter-measures to WMD will be severely limited, which would squander a tool for our nation’s security.

The obvious conclusion is that while it makes sense for the states to be able to leapfrog the federal government’s biodefense efforts, such efforts should be funded by federal dollars.

There is precedence for federal funding for the forward deployment at the state level of counter-terrorism drugs. In the wake of the 9-11 attacks, a number of states expressed serious concerns about the security of the nation’s nuclear plants. A series of states demanded and received through the Nuclear Regulatory Commission (NRC) federally funded stockpiles of potassium iodide (KI) to be provided to people in the areas surrounding nuclear plants.¹ The NRC also has made funding available on a going forward basis to provide KI to states that amend their response plans to incorporate the

¹ The KI example not only serves as a precedent for state-based, federally-funded forward deployments, it also underscores the need. KI is used to reduce the rate of thyroid cancer among people exposed to harmful doses of radiation. However, KI does not treat radiation sickness, the actual primary cause of death and injury post a nuclear attack. Ironically, the focus on KI immediately following the 9-11 attacks may have quelled public concerns, which, in turn, has allowed HHS to delay procuring a radiation sickness counter-measure. HHS delays now bring the issue full circle with states once again having to fight to obtain the counter-measures they deem necessary to protect their citizens.

drug. Under this program, the manner of distribution is left up to each individual state and distribution plans vary widely. At least one state has for sound policy reasons elected to forgo the program. South Carolina has determined not to seek and distribute the drug because it provides so little protection that a massive distribution plan is unwarranted. In essence, South Carolina has said that, given our circumstances, we have a better plan—the states as test bed at work.

II. FEDERAL FUNDING FOR STATE-BASED FORWARD DEPLOYMENTS OF MEDICAL COUNTER-MEASURES

To what extent are current federal dollars available to fund state deployments of medical counter-measures to WMD? The following looks at the leading potential sources of federal funds for such efforts.

1. BIOSHIELD

The primary funding source, or procurement vehicle, for medical counter-measures is the Bioshield Program. The program was appropriated \$2.5 billion to procure and deploy medical counter-measures to WMD. However, the program provides no vehicle for these monies to be used by, or granted to, the states for forward deploying counter-measures at the state and/or local levels. Additionally, the program's few procurements to date have focused on deployment of counter-measures not at the state or local level, but into the federal Strategic National Stockpile (SNS). Congress is presently taking a hard look at the program and there are a number of efforts underway to correct the flaws in the program. However, because the program is federally focused, state-based efforts have not played a role in these discussions.

2. CHEMPACKS

CDC's Chempacks Program is currently forward deploying stockpiles of antidotes to chemical weapons in areas around the nation. Each Chempack has enough counter-measures to treat 1,000 victims. Forward deployment here is critical because the window to treat victims of these weapons is far shorter than the 12 hour promised response time for the SNS. Under the Chempacks Program, CDC determines what drugs are deployed within the program, procures these drugs and retains ownership over the stockpiles. However, states are responsible for storing, monitoring, maintaining, dispensing the counter-measures and covering the costs associated with those activities.

There are four main differences between this program and a model that would offer federal funds for state-based stockpiling efforts. First, CDC determines what counter-measures are included in the Chempacks, as opposed to the states. As a result, if HHS and CDC are not supplying a certain type of counter-measure, the states cannot obtain it through the program. Second, Chempacks is limited to just chemical WMD threats. It does not provide states with stockpiles of counter-measures for any kind of biological, nuclear and radiological threats that the states may want to guard against. Third, CDC

owns the stockpiles, as opposed to the states having title. Fourth, because CDC still owns the stockpiles, the federal agency sets the rules for the program. These rules act to limit the types of deployment a state might want to implement. For example, the specific rules on maintaining a Chempack stockpile make it functionally impossible for a state to deploy a counter-measure in a community (e.g., at stadiums, major employers, schools, universities, malls). In essence, the Chempack program remains a top down (federal→state) approach, rather than bottom up (state→federal) approach.

3. HOMELAND SECURITY GRANT PROGRAM

States seeking to offset medical counter-measure costs can look to the Homeland Security Grant Program (HSGP).

The FY 2006 HSGP integrates the State Homeland Security Program, the Urban Areas Security Initiative, the Law Enforcement Terrorism Prevention Program, the Metropolitan Medical Response System, and the Citizen Corps Program. The HSGP seeks to streamline efforts to assist states and urban areas obtain resources to meet the Interim National Preparedness Goal (INPG) and implement State and Urban Area Homeland Security Strategies. In FY2005, the combined program provided states with \$2.5 billion in homeland security assistance.

These programs now exist separately together: grant applications for all of these programs are now combined under one application; individual program funding is leveraged between and among the programs; all of the funding under these programs is now focused on the achievement of the INPG; yet, each program retains its base areas of responsibility and funding levels. This year marks the first time that DHS' core homeland security grants programs are so organized.

The INPG Requirement and Medical Counter-Measures: By definition the INPG, which drives the grant program, encompasses all actions necessary to address the entire range of threats and hazards, including terrorism. State, local and tribal deployment of medical counter-measures to WMD, in general, should qualify as implementing INPG goals and objectives.

The INPG focuses efforts on seven "National Priorities." This list of seven priorities specifically includes two priorities that speak to the deployment of WMD medical counter-measures: "Strengthen Chemical, Biological, Radiological/Nuclear and Explosive (CBRNE) Detection, Response and Decontamination Capabilities";² and, "Strengthen Medical Surge and Mass Prophylaxis Capabilities."³

Under these priority areas the INPG provides 37 target capabilities that federal, state, local and tribal entities are expected to develop and maintain. These 37 capabilities fall within five general missions: prevent, protect, respond, recover and "common capabilities." At least five capabilities in the response area apply to deployment of

² However, the benchmarks listed under this priority do not directly address medical counter-measures.

³ This priority includes a benchmark which further focuses such efforts on oral medications.

medical counter-measures of some form: responder safety and health; environmental health; triage and pre-hospital treatment; medical surge; and mass prophylaxis.

Allowable Costs and Medical Counter-Measures: Allowable costs under the HSGP include equipment and supplies, generally including drugs and other counter-measures. Allowable equipment and supplies for HSGP funded expenditures are listed in the DHS Authorized Equipment List (AEL). The AEL includes a compound-specific listing of authorized pharmaceuticals.

The AEL listing requirement could be an impediment to the use of HSGP funds for state deployments of WMD medical counter-measures. The AEL pharmaceutical component tends not to reflect the most advanced, or latest, medical technologies and the best available medical and science information. For example, the AEL lists Cipro, the antibiotic used in response to the 2001 anthrax attacks. However, it does not list next generation anthrax vaccines, at least one of which has shown the ability in pre-clinical trials to increase the efficacy of antibiotics in responding to anthrax exposure. Similarly, in terms of nuclear attack response, the listing covers Potassium iodide, which will not improve immediate response efforts, but not the DoD drug, which has shown the ability to increase post-attack survival rates in pre-clinical trials. Additionally, the AEL pharmaceutical component tends to be weighted towards only a few select WMD threats—mostly chemical in nature.

The AEL, however, can be adjusted. DHS makes changes and additions to the AEL based upon input from DHS' own Office of Domestic Preparedness and state and local first responders. Counter-measures not yet on the list can work with these entities to seek a listing that allows for their counter-measure to fall within the grant program. It seems likely that if one or more states and/or the first responder community were to press to have a specific drug, or set of drugs, added, DHS would look favorably upon the request.

In addition, states can also seek funding for planning programs (e.g., developing plans for deploying counter-measures), organization and leadership support, training (e.g., training in how to deploy and/or use counter-measures) and exercises (e.g., exercising counter-measure deployment in response to an attack).

Risk and Need and Medical Counter-Measures: The 2006 grant cycle is also the first time that much of the funding provide through the HSGP will be driven by risk and need, instead of block grant formulas. The use of risk and need in funding decisions would seem to favor grant applications for medical counter-measures to WMD.

For 2006, DHS defined risk for HSGP purposes as a product of three variables:

- Consequences of a specific attack on a specific asset.
- Vulnerability of the asset to such an attack.
- Threat to the asset.

These calculations are made on both an asset and geographic basis.

DHS' own National Planning Scenarios provide that with respect to these variables WMD attacks are among the most devastating attacks that could be carried out against the United States. Additionally, risk determinations based on asset and geography would also seem to favor WMD counter-measures in the grant process. For example, radiation counter-measures deployed around nuclear plants respond to an asset-specific threat. Similarly, smallpox vaccines deployed in major cities respond to a geographic specific threat.

With respect to need, DHS' guidance suggests that need is a function of the "Investment Justification" that each state submits as part of its grant application. Here again, WMD counter-measures have a number of advantages. For example, the required Investment Justification stresses initiatives that respond to multiple INPG's and capabilities. As discussed above, WMD counter-measures tend to be justifiable under this standard. Similarly, the required Investment Justification focuses on precisely how an initiative will mitigate or reduce a threat. WMD medical countermeasures, which directly mitigate, treat, cure, or prevent a form of attack, would seem to score well by this standard.

Timing and Medical Counter-Measures: HSPG grant funding is provided on a pre-approval basis: states apply for monies to carry out delineated efforts, grants are made, monies are conveyed, funded work must be performed within 24 months of the grant award.

Such a framework presents no problem for states seeking to offset future medical counter-measure costs. A state can build counter-measures into their planning; seek to have the counter-measures added to the AEL if necessary; apply for funding for the counter-measures in the next available grant cycle; hopefully receive sought after funds; and, then, procure and deploy the countermeasures over the next 24 months.

However, two aspects of timing may present issues under other procurement and deployment scenarios. First, if a state has acted proactively and gone out to procure a medical counter-measure, it cannot then apply after-the-fact for grant monies to offset such costs. Second, if a state seeks to procure a counter-measure that is not yet FDA approved, it faces two hurdles. The unapproved drug is unlikely to be listed as an AEL, even if the drug qualifies for Bioshield deployment (for example, under an Emergency Use Authorization). Additionally, the time to obtain FDA approval may, in some cases, make it impossible for a state to obtain the funds and carry out deployment within 24 months of the award. The alternative—wait for all the bureaucratic pieces to be in place before seeking funding for a medical counter-measure—means that state efforts to deploy advanced medical counter-measures may be substantially delayed. As such, the combination of the 24 month from award implementation requirement and the AEL listing requirement may provide a significant impediment to the state-based deployment of next-generation, most-advanced medical counter-measures.

Congress and/or the Executive should consider correcting this tension between when and what medical counter-measures can be HSGP grant funded and the goals of enhanced

state preparedness, improved surge capacity, and strengthened CBRN response through the deployment of counter-measures. At first glance a number of options exist for bridging this gap. For example, Congress (legislatively) or DHS (administratively) could simply expand the AEL to automatically incorporate any Bioshield eligible counter-measure. Such a correction should not apply solely to Bioshield procured compounds because this would impinge on the ability of states to act as laboratories for cutting-edge homeland security. Additionally, such a limitation would continue to slow the deployment of advanced medical counter-measures. Finally, the reason states are now seeking to deploy medical counter-measures separately from Bioshield efforts, is because the states view the Bioshield Program as acting too slowly and ineffectually; hinging what states can procure to what Bioshield procures would only compound this problem.

4. NATIONAL BIOTERRORISM HOSPITAL PREPAREDNESS PROGRAM

The purpose of the National Bioterrorism Hospital Preparedness Program (NBHPP) is to enhance the ability of hospitals and healthcare systems to prepare for and respond to bioterrorism and other public health emergencies. The program focuses on improving bed and personnel surge capacity, decontamination capabilities, isolation capacity, pharmaceutical supplies, and supporting training, education, and drills and exercises. The NBHPP's main funding component is a cooperative agreement program that funds efforts at the state, territorial and sometimes city level.

NBHPP funding is typically awarded to each state's health department. The states then provide program funds to hospitals, EMS systems, outpatient centers, and other providers.

The NBHPP's FY2005 budget was \$491,410,000, of which \$470,755,000 was given in cooperative agreement funds. All fifty states, all the territories and some cities currently receive funds under the program. Under the program's current guidance, only current grantees (states) are eligible for future funding. Funding for each recipient is determined by a formula. Recipients have significant latitude in how the funds they receive from the program are expended.

Benchmarks and Medical Counter-Measures: In order to receive program funds, states are required to submit a plan for reaching certain objectives, which must be approved by the federal program office. In general, if a state wishes to procure medical counter-measures using NBHPP funds, that intent must be made clear in the federally approved plan.

The NBHPP focuses the state plans, and in turn spending of cooperative agreement dollars, by setting a series of priorities, which are tied to benchmark actions, which are, in turned, tied to specific reporting requirements against set "sentinel" indicators." States are obligated to meet these benchmarks within the five-year authorization of the program and must report out on progress against the indicators.

Among the objectives that states must meet are a series of critical surge capacity goals for the care of victims in the wake of a terrorist attack or public health emergency. Specifically states are required to:

Establish systems that, at a minimum, can provide triage treatment and initial stabilization, above the current daily staffed bed capacity, for the following classes of adult and pediatric patients requiring hospitalization within three hours in the wake of a terrorism incident or other public health emergency:

1. 500 cases per million population for patients with symptoms of acute infectious disease – especially smallpox, anthrax, plague, tularemia and influenza;
2. 50 cases per million population for patients with symptoms of acute botulinum intoxication or other acute chemical poisoning – especially that resulting from nerve agent exposure;
3. 50 cases per million population for patients suffering burn or trauma; and
4. 50 cases per million population for patients manifesting the symptoms of radiation-induced injury – especially bone marrow suppression.

Additionally, in order for a counter-measure procurement to be approved it must comport with the more specific program benchmarks that implement these general goals and objectives.

The NBHPP benchmarks start with a series of “cross-cutting” benchmarks. These benchmarks are supposed to be addressed in all aspects of a state’s program. One of these cross-cutting benchmarks is stockpiling of antiviral drugs. The program guidance provides in pertinent part:

[A]s part of preparedness for an influenza pandemic, States and municipalities should consider amassing appropriate quantities of antiviral drugs as a first line of protection for the staff of hospitals, hospital based EMS providers, their family members and their most critically ill patients.

To that end, please provide the following information as part of the HRSA cooperative agreement application:

- **Do any of the HRSA-funded hospital-based pharmaceutical caches within your jurisdiction maintain a supply of antiviral drugs?**

- **If so, please provide an estimate of the number of 10-day treatment courses on hand, facility-by-facility, as of June 15, 2005.**
- **Also, please indicate the quantity and estimated cost of antiviral drugs that the jurisdiction plans to acquire for these caches during the period September 1, 2005 to August 31, 2006 and how much of that cost is to be charged to the HRSA cooperative agreement.**

In addition to the cross-cutting focus on antivirals as a response to influenza, the NBHPP provides more general direction that allows for state spending on medical counter-measures. Specifically, “Critical Benchmark #2-5 Surge Capacity: Pharmaceutical Caches” provides that NBHPP funded states shall:

Establish a regional system that insures a sufficient supply of pharmaceuticals to provide prophylaxis for 3 days to hospital personnel (medical and ancillary staff), hospital based emergency first responders and their families -- in the wake of a terrorist-induced outbreak of anthrax or other disease for which such countermeasures are appropriate.

Awardees may continue to use HRSA funds to purchase strategically placed pharmaceutical caches for hospitals. HRSA funds may continue to be used to allow participation in the joint CHEMPACK program with CDC. Through multiple mailings to awardees these funds must be approved in advance, may only be used for certain purposes and in FY 2005 will be limited to \$2,500.00 per site.

Minimal Level of Readiness

1. 100% of participating hospitals will have access to pharmaceutical caches sufficient to cover hospital personnel (medical and ancillary), hospital based emergency first responders and family members associated with their facilities for a 72-hour time period.

In order to demonstrate compliance with the minimal level of readiness, awardees will submit the following documentation to HRSA, under separate cover, 90 days after the end of the FY 2005 funding cycle:

1. An inventory, by awardee defined regions, of all participating hospital facilities that have provided assurances that they have access to sufficient pharmaceutical caches for their hospital personnel (medical and ancillary), hospital based emergency first responders and family members.

Sentinel Indicator #2-5

To be reported with the FY 2005 funding application

1. Number of hospital personnel (medical and ancillary), emergency first responders and their family members for whom a 3-day supply of antibiotics is available through state, local and regional caches.

Sentinel Indicator #2-5

To be reported with the mid-year progress report and end-of-the-year report

1. Number of participating hospitals **statewide** that have access to pharmaceutical caches sufficient to cover hospital personnel (medical and ancillary), hospital based emergency first responders and family members associated with their facilities for a 72-hour time period.
2. Number of participating hospitals, **within the 2 most populated awardee defined regions**, that have access to pharmaceutical caches sufficient to cover hospital personnel (medical and ancillary), hospital based emergency first responders and family members associated with their facilities for a 72-hour time period.
3. Number of participating hospitals **in other regions of the state for which predictable high-risk scenarios have been identified through the HVA**, that have access to pharmaceutical caches sufficient to cover hospital personnel (medical and ancillary), hospital based emergency first responders and family members associated with their facilities for a 72-hour time period.

Allowable Costs and Medical Counter-Measures: At first glance it would seem that a state should be able to use NBHPP grant monies to procure a pharmaceutical so long as

the counter-measure procured is part of the state's plan to meet the programs goal and objectives and specific benchmarks; and, the purchase is approved by HHS as part of its general approval of the state's plan.

However, HHS reads one component of the benchmark language set out above as limiting the use of NBHPP funds to only pharmaceuticals for hospital staffs and their families:

Establish a regional system that insures a sufficient supply of pharmaceuticals to provide prophylaxis for 3 days to hospital personnel (medical and ancillary staff), hospital based emergency first responders and their families -- in the wake of a terrorist-induced outbreak of anthrax or other disease for which such countermeasures are appropriate.

This provision could be easily be read as establishing a minimum standard—one thing state plans must do is stockpile prophylaxis counter-measures as set out in the provision for hospital personnel and their families—but not a bar on states procuring counter-measures more broadly. However, rather than reading the provision as a floor, the agency reads it as a ceiling or a limitation: these are the only pharmaceuticals that can be bought with program funding.

This is a curious interpretation for three reasons. First, the language of the provision does not include typically used limiting language (e.g., “only,” “solely”).

Second, a limiting reading results in a number of odd distinctions and bad policy results. This reading greatly narrows the types of counter-measures that can be bought with these funds. For example, NBHPP funds can only be used to buy preventive drugs, not treatments. Similarly, a state cannot use NBHPP funds to pre-vaccinate even covered healthcare workers and their families in advance of an attack. As a result, for example, a state cannot use program funds to buy a smallpox vaccine for its healthcare workers—even though the federal government has an entire program focused on getting the nation's healthcare workers vaccinated for smallpox. Such a reading also significantly winnows down the universe of people who can be protected with counter-measures procured with program funds. NBHPP funds can be used to buy counter-measures for EMS workers, provided that they are hospital-based EMS workers. However, if EMS responders are part of a city-wide fire and rescue agency (as is the case in most jurisdictions), NBHPP funds cannot be used to protect them. Such distinctions and results seem nonsensical.

Third, such a reading seems to undercut the goals of the program more broadly. It is difficult to see how such a limitation fits with the specific overarching goals the program lays out for state grant recipients to have surge capacity for:

1. 500 cases per million population for patients with symptoms of acute infectious disease – especially smallpox, anthrax, plague, tularemia and influenza;
2. 50 cases per million population for patients with symptoms of acute botulinum intoxication or other acute chemical poisoning – especially that resulting from nerve agent exposure;
3. 50 cases per million population for patients suffering burn or trauma; and
4. 50 cases per million population for patients manifesting the symptoms of radiation-induced injury – especially bone marrow suppression.

While it is vital for hospital personnel and the medical system as a whole to be protected, how can a state be capable of treating these numbers of victims without procuring pharmaceuticals? For example, if a state cannot use program funds to procure a drug to treat radiation sickness, how can the state's hospitals care increase surge capacity adequately to care for the required 50 per-million-in-population cases of radiation sickness? If the program funds only beds, training, and other elements of care, but not life-saving drugs, victims may find a bed but not a treatment, and still die nonetheless.

Moreover, if medical countermeasures can help a state meet these care benchmarks in ways that require less in the way of costly and resource intensive hospitalizations, the program should be encouraging such a transformation, not impeding it. For example, if a state forward deploys a cost effective cure for anthrax, the need for vast numbers of beds to respond to a wave of anthrax victims is greatly diminished.

5. Public Health Emergency Preparedness Cooperative Agreement Program

The Centers for Disease Control administers the Public Health Emergency Preparedness Cooperative Agreement Cities Readiness Initiative Pilot Program (CRIPP). The CRIPP currently provides funding to thirty-six cities and metropolitan areas to assist these areas improve state and local response capabilities for bioterrorism response and to integrate these efforts with existing federal programs. Individual area funding ranges from \$5.1 million (New York) down to \$690,000 (Pittsburgh, PA, and St. Louis, MO).

The program provides funding to assist states and localities in logistical planning to deploy medical counter-measures that are provided via the federal SNS.

Critical Capabilities and Medical Counter-Measures: The “Critical Capabilities” CRIPP funding is intended to strengthen within each state are:

- Developing an SNS plan;
- Incident command and control, with a focus on SNS deployment issues;
- Procedures for requesting SNS assets;
- Management of SNS operations;

- Tactical command;
- Public information;
- Security;
- Warehousing, staging and storing of SNS materiel;
- Inventory control;
- SNS distribution;
- Dispensing of oral medications;
- Treatment center coordination; and,
- Training, exercise and evaluation.

Allowable Costs and Medical Counter-Measures: The program provides no direct funding for state efforts to procure and forward deploy medical counter-measures

That said, to the extent that plans to distribute SNS counter-measures also support the forward deployment and distribution of state-stockpiled counter-measures, there is no reason why states should be precluded from using these funds for dual-use benefit. For example, under the program award recipients are required to develop plans for warehousing, inventory control and distribution of SNS materiel. It would seem logical that whatever the plan is for SNS materiel, that plan would simultaneously support any state-funded and forward deployed stockpile—it would make little sense for a state to implement two parallel counter-measure deployment plans.

III. FACILITATING STATE-BASED FORWARD DEPLOYMENTS OF MEDICAL COUNTER-MEASURES

There are a number of actions that could be undertaken at both the state and federal levels to facilitate the wider state-based forward deployment of medical counter-measures to WMD.

1. Federal

At the federal level, the government could facilitate such state efforts by providing funding and technical assistance.

First, as discussed in detail above, while a range of federal programs offer funding for elements of such state programs, none of them are a good or comprehensive fit. As a result, state efforts to fund such programs through federal grants will be piecemeal and produce less than optimal programs from a strategic standpoint. This situation could be corrected through changes to existing programs. For example, the Bioshield Program could be amended to offer a state grant component. However, such a state grant component within the Bioshield program would likely draw down funds from the federal reserve. The most obvious answer to this problem is that if funds are running low, and if the program is showing a strong return on investment, leaders (federal and state) should go to the Congress to seek more funding. If such a program could demonstrate that it had

protected the American people from a list of real and substantial terrorist threats, and that a list of more threats loomed that could be addressed, it seems likely that Congress would readily provide additional funds. Additionally, even if this approach causes a marginal cut in funds for the federal effort, it might not be such a bad thing. Such a result might actually spur the federal program into action. It may provide some measure of urgency (“if we don’t spend it they will”) that currently seems lacking. Here one is reminded of Lincoln’s challenge to General McClellan: “If you are not using the army, I should like to borrow it for a short while.”

Similarly, the NBHPP could be expanded to fund the full cycle of public health emergency response—from the city EMS responders to the hospital administrators. A more expansive change would make the program a comprehensive public health medical response funding stream. Such a program would make funding available not just to protect the medical system, but to safeguard the public at large. In either event, such an expansion of the program would require a corresponding increase of funding.

Beyond these two examples, the Congress could go down the list of current grant programs and build state-based forward deployment capacity into some or all of these programs. The incorporation of state-based forward deployments into these programs would significantly increase the incentive for and capacity of states to undertake these programs—which would greatly increase the nation’s ability to respond to WMD and other threats.

However, such an approach would still not provide a comprehensive solution. If the goal is to truly increase state response capabilities through forward deployment of medical counter-measures, the first best solution is the creation of a new program targeted to funding and facilitating state efforts along these lines. If properly constructed such a program would ensure that state-based deployments are: strategic in nature; comprehensive; effective; supportive of regional preparedness; and, supported by in-state infrastructure to ensure efficacy.

Such a program should also provide states with technical assistance. This technical assistance could come from current federal programs. However, it might be more effective if this technical assistance came from funding for inter-state expertise exchange. In terms of direct federal assistance, many states do not have extensive expertise in drug development and procurement; technical assistance in these areas could help ensure that states have access to the best, most advanced, safe and effective. DHS, DoD, CDC, FDA and other agencies could provide invaluable assistance.

In considering a new federal program, one note of caution should be stressed: In crafting such a program Congress or the Executive should be careful not to saddle it with provisions that would undermine the benefits of state-based efforts. For example, as noted above the states are considering their own forward deployments because of perceived shortcomings in the Bioshield Program. It may be tempting to tie state-based efforts to Bioshield efforts (for example in the name of coordination or technical

capacity). However, to do so would only carry over the problems now driving state-based efforts.

There is one other obvious federal response here. To the extent that the underlying problem here is the flaws in the Bioshield Program, the solution could be to simply fix the Bioshield Program outright—and thereby reduce the need for state-based efforts. However, even an effective Bioshield Program would benefit from state-based supportive efforts. In fact, the better the Bioshield Program gets, the more important state-based efforts become. For example, many of the threats Bioshield counter-measures need to address already require faster deployment than the SNS can provide. State-specific expertise (on issues ranging from transportation logistics to population dynamics to geography) is vital to ensuring that forward deployment plans are capable of most effectively getting counter-measures out to affected, or at-risk populations.

Finally, along this same line of thought, if Congress seeks to address these issues through an improved Bioshield Program (without any specific state component) such “fixes” would be more effective if they provided the states a role in the program’s decision-making. (The rationale for this need is described more fully below.)

2. States

The states can also undertake certain efforts to facilitate state-based forward deployment of medical counter-measures.

First, inter-state cooperation on procurement efforts can greatly increase the ability of states to pursue larger, more effective forward deployments. In theory, the federal Bioshield Program should be purchasing counter-measures on a scale that provides for market leverage and economies of scale. This should enable the federal government to strike cost effective contracts even in dealing with drug companies used to high returns. The typical single state entering this market likely lacks such buying power. However, if multiple states work together to build stockpiles, such buying consortia can achieve adequate market power. Further, the bulk of the cost of a new drug is the sunk cost of development. If the known market for a drug is small, the sunk costs component of the drug price will be substantially larger than if the market is bigger. By coming together to procure a drug, the states can increase the expected size of a market, thereby reducing the per unit sales price by more widely spreading the sunk costs. As a result, states considering such stockpiles should consider building procurement consortia.

Second, states can start reaching out to the federal grant-making agencies now to have these agencies make allowable changes to current programs that would foster state-based deployments. For example, DHS’ AEL covers only a handful of current generation medical counter-measures, and the process for adding new counter-measures does not fit well with drug development and deployment cycles. To correct these issues the states should consider working with DHS to expand the current listing of AEL counter-measures and to modify and expedite how the program handles future listings. Similarly, if HHS abandoned the current restrictive reading of the NBHPP regulations, the program

could fund a much wider range of counter-measure deployments. This would allow deployments that are four-square within the goals of the program but are not allowed under current rules.

Third, the states should consider pressing for fixes to the Bioshield Program to enable the program to better suit their needs. States might also consider working with Congress to ensure that the states have a seat at the Bioshield decision-making table. Such a voice could both assist the states and improve the Bioshield Program. Bioshield is effectively determining what new counter-measures are funded and deployed at the state and local level; it makes good sense that the states should have a voice in determining the program's priorities, policies and procurements.

For example, the Bioshield Program is now looking to procure a radiation counter-measure that requires hospitalization. (This direction was announced as part of a recent Bioshield procurement process.) In order for such a drug to be effectively deployed, states and cities will need vastly more numbers of hospital beds. A terrorist nuclear attack on New York City will result in hundreds of thousands of victims. On a normal day, absent the impact of a nuclear attack, the entire State of New York has just a total of 20,000 open hospital beds, most of which are not critical care beds. To treat victims with a drug requiring hospitalization, New York would need to add hundreds of thousands of hospital beds.⁴ However, there are no federal funds for such an effort. The Bioshield Program may fund procurement, but it does not provide funding for the logistics of deployment. The NBHPP and the CRIPP can fund some logistics, but not in the area of radiological counter-measures.⁵ As a result, it seems that HHS may procure a drug that would require infrastructure that the states simply do not have—and the states lack the budget dollars to develop that infrastructure. States should be telling HHS that it needs to alter course—and some states are now doing this, in directly, through their own procurement efforts. This example clearly demonstrates why states must have a greater voice in the Bioshield and related counter-measure development and deployment programs.

CONCLUSION

The wider development and forward deployment of medical counter-measures to terrorist WMD threats is an important tool for advancing both preparedness and deterrence. For a variety of reasons described in detail above, the deployment of such counter-measures at the state and local level can serve as an important adjunct to federal efforts under the Bioshield Program.

⁴ Surrounding states, which might also face impacts of such an attack, also lack surge capacity. There are also reports that the federal government's efforts to develop and deploy mobile hospital capacity is seriously behind schedule. As a result, to deploy a hospital-based treatment, New York's only present day option is to add beds.

⁵ The program guidance for both the NBHPP and CRIPP provide that funding is limited to bioterrorism.

As a general rule, we ought to be doing all that we can to encourage the development and deployment of such counter-measures, whether by the federal government, the states, localities, or private interests.

As a result of the lack of progress in the federal program, some states are now beginning to consider procuring and deploying medical counter-measures on their own, with their own resources. However, if states are forced to buy these drugs on their own dime, state-based forward deployment of vital medical counter-measures to WMD will be severely limited, which would squander an important tool for national and homeland security.

Some federal funding is available for such state-based counter-measure forward deployments. However, the federal funding that exists for these purposes is: extremely limited in amount; lacking in a comprehensive focus and strategy; and, constrained in the purposes for which it can be used. In many instances, the constraints on the use of federal dollars for these purposes are simply counterproductive and illogical in nature.

Policy-makers should seriously consider changes in approach to facilitate, encourage and more fully and comprehensively fund state-based forward deployments of medical counter-measures. Such changes could be made within existing programs. Alternatively, and preferably, policy-makers could consider implementing an entirely new programmatic framework that is designed specifically to assist states in forward deploying medical counter-measures to WMD. Such a program should also provide states with technical assistance to aid them in developing effective deployments.

Finally, apart from the lack of federal funding, the most serious impediments to greater state counter-measure deployment efforts are economies of scale and pricing. Assuming the federal government purchased large quantities of counter-measures, it can negotiate better deals with counter-measure manufacturers than a single state. The typical state acting alone lacks such market leverage. States looking to deploy such counter-measures should consider acting in concert to increase the size of their combined procurements, and as a result increase their market power.

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