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United States Senate

COMMITTEE ON
GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

May 7, 2004

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

I am writing to express my deep concern about the Department of Health and Human Services's ("the Department") implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002[1] ("the Bioterrorism Act") and its bioterrorism preparedness programs, which has clearly not satisfied the letter or the spirit of the law as written by Congress, and left America still too vulnerable to a possible bioterror attack.

As you know, the very first charge from Congress almost two years ago in adopting the Bioterrorism Act was for you to develop a coordinated bioterrorism preparedness and response strategy in collaboration with the states, and the preparation of a "National Preparedness Plan."[2] While your Department has released a document it describes as a "strategic" bioterrorism plan, that document fails to meet either the requirements of the statute or the most basic elements of a comprehensive planning document. You also failed to appoint a permanent Assistant Secretary for Public Health Emergency Preparedness – a position established by the Bioterrorism Act to oversee the Department's preparedness efforts – until April 8, 2004; almost two years after enactment.[3] This is simply unacceptable given what is potentially at risk – the lives of millions of Americans.

I am also troubled by the fact that the Department's FY05 budget request not only fails to address the numerous preparedness needs identified by independent outside experts, such as the General Accounting Office (GAO), the Institute of Medicine (IOM), and the Gilmore

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[1] P.L. 107-188.

[2] *Id.* § 101.

[3] HHS News Release, *"Statement by Tommy G. Thompson, Secretary of Health and Human Services, Regarding the Appointment of Stewart Simonson To Be Assistant Secretary for Public Health Emergency Preparedness,"* April 8, 2004.

Commission,[4] the Federal Government's own review of the Nation's response to the 2001 anthrax attacks ("the CSIS/DTRA report"),[5] and even by the Department's own bioterrorism strategic plan[6] and reports by its Inspector General.[7] In fact, your budget actually makes cuts in core bioterrorism preparedness programs. Without these core programs, key elements of the Administration's biodefense program, such as the expansion of biosurveillance systems, will not function effectively because they depend upon federal, state, and local public health systems and laboratories to carry them out.[8]

Last week, you and other Administration officials announced the signing of a new biodefense directive enumerating the roles that federal agencies will have in protecting the nation from a biological attack.[9] The directive is classified, but as explained by Administration officials, it is a blueprint for coordination among federal agencies. It is not a national preparedness plan, which is what the law requires.

The problem of federal agency coordination is but one aspect of bioterror preparedness. The nation's biodefense responsibilities also rest on an extensive system of state and local public health agencies and laboratories and on our public and private health care delivery systems. In the event of a bioterrorism attack or the natural outbreak of a deadly disease, these are our "first responders." Without a robust public health system, and the preparation and integration of our

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[4] The Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction (commonly known as the "Gilmore Commission").

[5] *"Lessons from the Anthrax Attacks: Implications for U.S. Bioterrorism Preparednes, A Report on a National Forum on Biodefense,"* Center for Strategic and International Studies and the Defense Threat Reduction Agency, April 2002 (redacted). In addition to recommendations contained in the written report, which was available to the Department, several senior HHS officials with responsibility for formulation of the Department's bioterrorism policies and programs participated in the forum itself.

[6]*"Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies,"* US Department of Health and Human Services, October 2003.

[7]*"State and Local Bioterrorism Preparedness,"* OEI-02-01-00550, Office of the Inspector General, HHS, December 2002.

[8] As recently as March 10, 2004, the Association of Public Health Laboratories (APHL) wrote to your Department as well as the Department of Homeland Security and the White House warning that key public health laboratories within the Laboratory Response Network lacked the capability to meet the expanding surveillance requirements.

[9] White House Press Release, *"Fact Sheet: President Bush Signs Biodefense for the 21st Century,"* April 28, 2004.

nation's doctors, clinics, and hospitals in our response planning, we will not achieve the level of protection against these threats that we require. Yet, the preparedness programs and planning efforts centered in your Department and intended to address these very needs are not receiving the priority they demand.

Taken together, this disturbing record demands an explanation – starting with why the Department has essentially ignored the preparedness planning requirements of the Bioterrorism Act. In the absence of the required comprehensive preparedness plan, I would like to know to how and why the Department decided to make significant reductions in core bioterrorism preparedness programs in its FY05 budget.

The Need for a National Preparedness Plan

I do not ask these questions casually. The Committee's Minority Staff has carefully and thoroughly reviewed the legislative history and Department's implementation actions over the last two years, including the Department's "Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies" ("the Bioterrorism Strategic Plan," or "the Plan").[10] What we learned is that the Plan not only falls well short of the goals set out in the legislation, but it is so limited in scope and content that it is hard to see how it could fulfill even the limited purposes the Department has ascribed to it: to "facilitate communications regarding HHS efforts toward ensuring public health emergency preparedness,"[11] to "facilitate the preparation of progress reports required by the Executive Office of the President or the Congress,"[12] and "be an instrument for promoting results-oriented management and for appraising contributions toward public health emergency preparedness."[13]

A Tool to Improve Coordination Among Federal, State and Local Governments

One of the central purposes of the National Preparedness Plan envisioned by Congress was "(e)nsuring coordination and minimizing duplication of Federal, State, and local planning, preparedness, and response activities, including during the investigation of a suspicious disease

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[10] "*Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies,*" US Department of Health and Human Services, October 2003.

[11] *Id.* at 4-5.

[12] *Id.* at 5.

[13] *Id.* at 5.

outbreak or other potential public health emergency."[14] As such, it was intended to map out procedures and jurisdictional responsibilities to respond to bioterrorism events, including responses and responsibilities during such events, and to coordinate efforts at all levels of government. The need for such a plan is self-evident and both the House and the Senate included this requirement in their respective versions of this legislation.[15]

As shown by the response to the 2001 anthrax attacks and the 2003 ricin mailings to a postal facility in South Carolina and to the White House, there has been confusion over which government agencies are responsible for responding to bioterrorism incidents. In both instances, conflicts occurred among the various federal and state public health and law enforcement agencies over who was responsible for the response and which objectives – law enforcement or public health – were to take precedence. Last year's TOPOFF2 exercise[16] also showed that there continues to be confusion about roles and responsibilities of government agencies in responding to a bioterror attack, even during a carefully designed and scripted exercise. The need for interagency and intergovernmental coordination both for preparedness planning and during a response was discussed extensively in the CSIS/DTRA anthrax report.

As the law sets forth, the National Preparedness Plan was intended, in part, to ensure that roles and responsibilities for response were resolved in advance of such outbreaks. The Plan released by your Department, however, contains no clarification of roles and responsibilities among federal, state, and local governments, nor does it propose a mechanism for addressing this issue even though experience shows this is needed. This void is both glaring and inexcusable.

Setting Preparedness Goals and Benchmarks

The National Preparedness Plan was also intended to include "specific benchmarks and outcome measures for evaluating the progress of the Secretary and the States, including local governments" in preparing for bioterrorism, as well as a series of specific national bioterrorism preparedness goals.[17] As such, it was intended to help all levels of government, in a collaborative

[14] P.L. 107-188§ 101.

[15] H.R Conf. Rep. No. 107-481, at 108 (2002).

[16] TOPOFF2 was the second in a series of major terrorism response drills organized by federal emergency response officials, in this case the Department of Homeland Security, to test the readiness of federal, state, and local capabilities in different, pre-determined, terrorist attack scenarios. The two scenarios in the TOPOFF2 exercise in 2003 were the explosion of a "dirty" radiological bomb in Seattle, and a bioterrorism attack of plague in Chicago (TOPOFF stands for "Top Officials").

[17] P.L. 107-188 § 101.

effort, assess preparedness needs, resource and funding requirements to meet those needs, the effectiveness of federal, state, and local preparedness efforts, and ultimately our progress toward ensuring the safety of the American people from this threat.

The need for this kind of measurement has been underscored by a number of independent experts. For example, the Gilmore Commission in its Fourth Annual Report issued in December 2002 observed that, "(t)here are not yet widely agreed upon metrics by which to assess levels of preparedness among the medical and public health workforce. Without baseline data, it is impossible to quantify the gap between the current workforce and a workforce prepared to address these issues." The Commission also recommended "(t)hat DHSS, in consultation with State, local, and private sector stakeholders, establish and implement a formal process for evaluating the effectiveness of investment in State, local, and private preparedness for responses to terrorist attacks, especially bioterrorism."[18] Similarly, one of the two formal recommendations made to you by the GAO in its April 2003 report on bioterrorism preparedness of state and local governments was for the Secretary of HHS to "develop specific benchmarks that define adequate preparedness for a bioterrorist attack and can be used by state and local jurisdictions to assess and guide their preparedness efforts."[19]

The Plan released by your Department contains no such measurement benchmarks or other measures to ascertain preparedness needs, define preparedness goals, or assess progress towards achieving those goals. In fact, the Plan contains no quantitative <u>or</u> qualitative goals, such as time frames, schedules, or levels of health care that need to be provided to guide implementation of preparedness efforts at the federal, state, or local level.

While it could be argued that the Department has other internal measurement mechanisms to evaluate its own efforts, such as its Government Performance and Results Act (GPRA) measures, or quantitative criteria associated with its grants programs, GPRA measures do not establish benchmarks to assist state and local governments in establishing their own preparedness goals or in measuring their progress towards meeting those goals. Similarly, reliance on GPRA measures is clearly not consistent with the intent of the Bioterrorism Act, which was to initiate a national <u>collaborative</u> effort to set goals for bioterrorism preparedness at all levels of government – federal, state, and local – with the mutual participation of all levels of government.

Quantitative grant criteria, in those few instances where they exist at all (such as those

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[18] *"Fourth Annual Report to the President and the Congress of the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction,"* December 15, 2002, at 54.

[19] *"Bioterrorism: Preparedness Varied across State and Local Jurisdiction,"* GAO-03-373, U.S. General Accounting Office, April 7, 2003, at 34.

included in the Health Resources and Services Administration (HRSA) bioterrorism grants), are steps in the right direction. But they too are not the result of the sort of deliberative, collaborative effort involving state, local, and health care officials called for in the Bioterrorism Act. In fact, these grant criteria may be setting entirely arbitrary or inadequate goals. For example, HRSA has a benchmark that public health officials establish a system that "allows the triage, treatment, and disposition of 500 adult and pediatric patients per 1,000,000 population."[20] Recent analyses, available at the time those criteria were established, suggest that this number could be many times too low.[21]

HHS Bioterrorism Priorities Fail to Address Identified Needs

The importance of clear preparedness goals and measurements cannot be overstated. In the Department's recent budget request for FY05, the Administration has decided that HHS funding for key state and local preparedness activities can be reduced. For example, funding for the Centers for Disease Control and Prevention (CDC) cooperative grants to state and local health departments would be cut by $105 million to $829 million, or 11 percent.[22] You are also proposing to reduce HRSA grants to states and local governments for development of hospital surge capacity by $39 million (to $476 million), or 7.5 percent.[23] Your budget also completely eliminates HRSA funding for Public Health Traineeships and Public Health Training Centers – training for the public health workforce we will rely upon to respond to disease outbreaks caused

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[20] *"National Bioterrorism Hospital Preparedness Program: Cooperative Agreement Guidance,"* HRSA, May 2, 2003, at 17.

[21] On March 9, 2004, the Director of Central Intelligence testified that "(a)lthough gaps in our understanding remain, we see al-Qa'ida's program to produce anthrax as one of the most immediate terrorist CBRN [chemical, biological, radiological, and nuclear] threats we are likely to face." Testimony of George Tenet, Director of Central Intelligence, Senate Committee on Armed Services, March 9, 2004, at 1.

A paper by Lawrence M. Wein, *et. al.* estimates that an anthrax attack on a large urban area, such as New York City, would result in almost 1.5 million people being infected and over 120,000 deaths despite medical intervention; many times more than the 5,000 patients postulated by the HRSA benchmark. The authors illustrate that survival rates are directly related to the degree of medical intervention and acute hospital care available. See Wein, L.M., Craft, D.L., & Kaplan, E.H. "*Emergency response to an anthrax attack*," Proceedings of the National Academy of Sciences, 100 (7), April 1, 2003, at 4346-4351 and Webb, G.F, "*A silent bomb: The risk of anthrax as a weapon of mass destruction*," Proceedings of the National Academy of Sciences, Vol. 100 (8), April 15, 2003, at 4355-4356.

[22] *"Budget in Brief FY 2005,"* HHS, February 2, 2004, at 26.

[23] *Id.* at 16.

by a bioterrorist attack.[24] Yet, the evidence is that state and local public health and health care systems are not adequately prepared. Reports available to the Department and the Administration during your budget preparation clearly indicate that preparedness is far from achieved.

State and Local Public Health Capabilities

Specifically, contemporaneous reports by CSIS/DTRA, GAO, the Trust for America's Health (TFAH), and surveys conducted by public health organizations, all indicate that state and local health departments were not, and are not, fully prepared. To cite one example, a report released last December by TFAH concluded that state and local needs were so great, and cut-backs in state and local funding due to state economic and budget problems had been so substantial, that the states were only "modestly more prepared" as a result of increased federal funding.[25] In fact, because nearly two-thirds of the states actually cut funds for public health programs from 2002 to 2003 due to state economic and budget problems, the study concluded that despite the large federal investment, public health budgets and the level of preparedness were actually declining in many states. The need for HHS to ensure that states could continue to support new, federally-funded bioterrorism capability was one of four major recommendations made by the Department's Inspector General in a December 2002 report on the status of state and local bioterrorism preparedness.[26]

Another 2003 TFAH study of public health laboratories found that "despite efforts to improve the country's public health labs after 9/11, overall, the labs had inadequate staffing and

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[24] The Association of Schools of Public Health estimates that 80% of the public health workforce lacks formal public health training, and that HRSA has been spending more than the $5.5 million annually on its Public Health Traineeship Program and Public Health Training Centers. *See* Document entitled *"Public Health Training at CDC and HRSA,"* provided to the Committee by the Association of Schools of Public Health. *Also see* Document entitled *"Key Public Health Facts,"* taken from the HRSA website (http://bhpr.hrsa.gov/publichealth/index.htm). The Traineeship Program alone supports more than 1000 public health students per year. *"Justification of Estimates for Appropriations Committee,"* Department of Health and Human Services, Health Resources and Services Administration, Fiscal Year 2005, at 143 and 145.

[25] *"Ready or Not?: Protecting the Public's Health in the Age of Bioterrorism,"* Trust for America's Health, December 2003, at 6.

[26] The report recommended that "(t)he Assistant Secretary for Public Health Emergency Preparedness should work with States to develop strategies that sustain the public health infrastructure subsequent to the current influx of Federal funding." *"State and Local Bioterrorism Preparedness,"* OEI-02-01-00550, Office of the Inspector General, HHS, December 2002, at iii. The report's principal finding was that "(t)he State and local public health infrastructure is under-prepared to detect and respond to bioterrorism." *Id.* at i.

training, obsolete facilities and equipment, and antiquated communications systems."[27]

These shortcomings in public health capability were also documented by surveys and analyses conducted by other public health organizations. For example, in August 2003, the Association of Public Health Laboratories (APHL) released the results of a survey of state public health bioterrorism capacity conducted in early 2003 and analyzing progress made since its baseline, post 9/11 survey conducted the previous year. This follow-up survey found that state funding had been reduced for the majority of public health labs and that despite improvements resulting from CDC funding, state public health labs continued to lack adequate personnel, equipment, and training.[28]

GAO has also issued a series of reports indicating that despite additional efforts since 9/11 to improve our bioterror response system, state and local health departments continue to fall short in their preparedness capabilities. In April 2003, GAO reported on its survey of seven cities and their corresponding state and local health departments. GAO reported there were "gaps and weaknesses in capacity elements essential to preparedness and response, such as workforce shortages and inadequate laboratory facilities." [29]

Just last month, GAO published an analysis of the initial results of both the CDC and the HRSA grants program on improving bioterrorism preparedness. While all states reported some progress as a result of these grant programs, none reported having met all of the initial benchmarks. In fact, GAO reported that state officials believed that:

> HRSA funding was insufficient for states to meet the requirements of the 2002 program. Similarly, hospital representatives reported that redirection of resources to the National Smallpox Vaccination Program and delays caused by lengthy contracting processes for distributing funds from the state to hospitals hindered efforts to implement the program.

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[27] *"Ready or Not?: Protecting the Public's Health in the Age of Bioterrorism,"* Trust for America's Health, December 2003, at 20.

[28] *"State Public Health Laboratory Bioterrorism Capacity,"* Public Health Laboratory Issues in Brief, Association of Public Health Laboratories, August 2003. In July 2003, APHL also released a study of the lack of capability of public health laboratories to respond to chemical attacks. They reported that only eight state public health labs had a chemical terrorism response plan, only five were being funded by CDC to develop the surge capacity necessary to analyze the large number of clinical samples expected in the event of a chemical attack, and few can test for military chemical weapons agents such as nerve agents. *"Ready or Not...Findings and Recommendations of the APHL Chemical Terrorism Project,"* Association of Public Health Laboratories, July 2003, at 3.

[29] "*Bioterrorism: Preparedness Varied across State and Local Jurisdictions*," GAO-03-373, U.S. General Accounting Office, April 7, 2003, at 4.

Although CDC and HRSA funding had helped, states' progress fell short of even the limited goals of the 2002 program and reportedly did so, in part, because of competing demands placed on them by the Federal Government's smallpox vaccination initiative.

Concern about continuing inadequacies in state public health departments' (SHDs) capabilities, despite the influx of federal bioterrorism funding, was even reported by the Department's own CDC. The October 31, 2003 edition of CDC's *Morbidity and Mortality Weekly Report* (MMWR) noted that additional federal funding had improved state public health preparedness, but preparedness problems remained.[30] It reported that despite a significant increase in epidemiological workers resulting from increased federal funding:

> the surveys identified multiple challenges, including problems: 1) allocating time for planning (66% of responding SHDs), 2) establishing disease surveillance systems (55%), and 3) hiring qualified ID [infectious disease] epidemiologists (57%). Other challenges to preparedness included the complexity of food-security issues, state hiring freezes and budget deficits, political and public policy considerations, and difficulty allocating the necessary time and resources for the pre-event smallpox vaccination program. [31]

Healthcare Surge Capacity

GAO also examined the preparedness of hospitals to respond to bioterrorism events. In August 2003, GAO reported on the results of its survey of over 2,000 urban hospitals and concluded that "bioterrorism preparedness is expensive and hospitals are reluctant to create capacity that is not needed on a routine basis and may never be used."[32] In addition, GAO found that despite some improvement in preparedness since 9/11, hospitals continued to lack "the medical equipment to handle the large increase in the number of patients that would be likely to

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[30] *"Terrorism Preparedness in State Health Departments – United States, 2001-2003,"* MMWR, October 31, 2003, 52(43); 1051-1053.

[31] *Id.*

While a positive sign, the increase in epidemiology workers may mask continued shortcomings in the epidemiologic capabilities of state and local health departments. A second article in the October 31, 2003 MMWR reported that almost half (42.4%) of persons then employed by SHD's "had no formal training in epidemiology." *"Assessment of the Epidemiologic Capacity in State and Territorial Health Departments – United States, 2001,"* MMWR, October 31, 2001, 52(43); 1049-1051. Also see *"National Assessment of Epidemiologic Capacity in Public Health: Findings and Recommendations,"* Council of State and Territorial Epidemiologists, March 2003.

[32] *"Hospital Preparedness: Most Urban Hospitals Have Emergency Plans but Lack Certain Capacities for Bioterrorism Response,"* GAO-03-924, U.S. General Accounting Office, August 6, 2003, at 16.

result from a bioterrorist incident."[33]

In fact, the GAO findings may significantly understate the gravity of the situation. After September 11th, the American Hospital Association (AHA) developed a needs assessment which estimated that the nation's hospitals needed roughly $11.3 billion in additional pharmaceutical inventories, protective clothing and equipment for personnel, decontamination facilities, and other resources simply to provide basic response capability in the first 24 to 48 hours following a bioterrorism attack.[34] At the current HRSA funding levels, levels which the Administration has now proposed to reduce by $39 million in FY05[35] (or 7.5 percent), it would take another 20 years to close this gap.

Corollary evidence of the current lack of adequate preparedness by hospitals to respond to bioterrorism events can be found in the experience of Chicago-area hospitals involved in the TOPOFF2 exercise. Even when these hospitals knew in advance that they would responding to a bioterrorism event and when confronted by "much less than half of the infected population"[36] planned by the exercise designers, the exercise summary reported they experienced "the lack of a robust and efficient emergency communications infrastructure"[37] and "(r)esource demands challenged hospitals throughout the exercise. These included short supplies of isolation and negative pressure rooms, as well as staff shortages."[38] Even though the exercise revealed significant problems, the TOPOFF2 summary report concluded that the exercise "did not last long enough to fully explore the impacts of mass casualties on the medical system." In other words, the TOPOFF2 results, alarming as they may be, appear to significantly understate the shortcomings in the ability of hospitals to respond to a significant bioterrorism event.

Hospitals are not the only primary healthcare delivery facilities that are unprepared to respond to a major bioterrorism event. Their level of preparedness has improved since 9/11, but a recent survey by the National Association of Community Health Centers found that only 49 percent of surveyed community health centers (CHCs) had a disaster preparedness plan that

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[33] *Id.* at 2.

[34] *"Hospital Resources for Disaster Readiness,"* American Hospital Association, November 1, 2001.

[35] *"Budget in Brief FY 2005,"* HHS, February 2, 2004, at 16.

[36] *"Top Officials (TOPOFF) Exercise Series: TOPOFF2 – After Action Summary Report for Public Release,"* Department of Homeland Security, December 19, 2003, at 9.

[37] *Id.* at 6.

[38] *Id.* at 7.

addressed a bioterrorism attack[39] and only 44 percent of the urban community health centers had such a plan.[40] Only 13 percent of CHCs responding to the survey had received any of the HRSA or CDC preparedness funding[41] and only 9 percent felt they were adequately prepared for a disaster.[42]

While CDC and HRSA grants may have begun to increase preparedness, it is clear that much more needs to be done. Cutting these programs – in the absence of clear evidence that bioterrorism preparedness has been achieved at the state and local level and can be sustained, evidence that would need to be based on carefully developed benchmarks and performance measures and verification – is a recipe for disaster. Such a disaster is precisely what Congress sought to avoid when it directed the Department to develop the National Preparedness Plan.

Mental Health Response

Beyond the CDC and HRSA grants, it also appears that the Administration is not requesting adequate funding for other bioterrorism-related health programs, including health programs identified in the Department's own Bioterrorism Strategic Plan. For example, at least seven of the activities identified in the Plan relate to providing mental health care through the Department's Substance Abuse and Mental Health Service (SAMHSA).[43] The need to more fully

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[39] *"Special Topics Issue Brief #4: Ready or Not? Two Years After September 11th Health Centers Work Steadily to Prepare for Future Disasters,"* National Association of Community Health Centers, Inc, March 2004, at 5.

[40] *Id.* at 6.

[41] *Id.* at 8.

[42] *Id.* at 7.

[43] See Activity IIA3, "Assist toward ensuring that the CDC-sponsored cooperative agreements result in State and local health departments prepared to respond effectively to the mental health impacts of bioterrorism and other public health threats," *"Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies,"* US Department of Health and Human Services, October 2003, at 11.

Activity IIA4, "Continue funding State Capacity grants for the development of State mental health and substance abuse plans to address disaster preparedness and response, and expand the program to cover States not already funded," *Id.*

Activity IIB2, "Assist toward ensuring that the HRSA-sponsored cooperative agreements result in hospitals and other health care entities prepared to respond effectively to the mental health impacts of bioterrorism and other public health threats and emergencies," *Id.* at 13.

address mental health needs of both victims and responders was recognized after 9/11. For example, as the AHA needs assessment observed "(s)urvivors of mass casualty events and responders to such incidents (fire, police, rescue workers, health care professionals, etc.) will suffer not only physical injury requiring medical care, but will also undoubtedly undergo extreme psychological trauma." These AHA recommendations for mental health care were based, in part, on the first hand experience of a member hospital in New York City following the 9/11 attacks. The April 2002 CSIS/DTRA report on the 2001 anthrax events specifically called for efforts to address mental health needs of such attacks.

More recently, the IOM and the Gilmore Commission highlighted the need to address the psychological consequences of terrorist attacks. An IOM committee – the Committee on Responding to the Psychological Consequences of Terrorism – examined the need for psychological care in response to terrorism and recommended a series of actions for your Department to take in order to develop training and education in psychological first aid and mental health surveillance methods to be used in the event of an attack. These recommendations specifically include actions within the responsibility of SAMHSA.[44] The Gilmore Commission in its most recent December 2003 report endorsed the IOM recommendations and called on Congress to provide increased funding to your Department and to the Department of Homeland

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Activity IIB3, "Provide technical assistance and guidance to foster the development of emergency all-hazard preparedness and response plans that fully integrate mental health and substance abuse," *Id.*

Activity IVB7, "Develop and assess approaches to ensuring mental health surge capacity for mass casualty events – including needs for psychological first aid, acute hospitalization, long term care, pediatric mental health, and other mental health services," *Id.*

Activity IVC4, "Through contractual agreements with technical assistance centers, continue to develop a database of best practices for anticipating and addressing the psychosocial needs of individuals and communities; continue to collaborate with other HHS agencies to examine the need for psychological triage instruments and other concerns." *Id.* at 20.

SAMHSA has informed my staff that one additional activity, Activity IIIC9, "Following declaration of a national disaster through the SAMHSA/FEMA Crisis Counseling and Training Assistance Program, provide crisis-counseling services to victims and others impacted by the events, as well as providing training to providers" is funded by FEMA, now part of the Department of Homeland Security. *Id.* at 16.

[44] *"Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy,"* National Academy of Sciences, Institute of Medicine, Board on Neuroscience and Behavioral Health, Committee on Responding to the Psychological Consequences of Terrorism, June 3, 2003, at 18.

Security to carry out these recommendations.[45]

Yet despite these expert recommendations, and the inclusion of seven specific activities assigned to SAMHSA in the Department's Bioterrorism Strategic Plan, it appears that no dedicated funding is being requested to carry out these activities in the FY05 budget request. Virtually no funds for any of these "strategic" activities are identified in SAMHSA's FY05 budget justification. For example, in describing its role with regard to the Department's 11 agency-wide research priorities, including Priority VIII ("Ensuring Our Homeland is Prepared to Respond to Health Emergencies"),[46] SAMHSA's budget justification identifies no funding or activities whatsoever for this HHS-wide priority. Similarly, there are no program descriptions or GPRA performance measures that correspond to any of the seven SAMHSA activities identified in the Bioterrorism Strategic Plan. There are no funds identified in the Department's budget justification for the Public Health and Social Services Emergency Fund (a primary source of funds used for many of the Department's bioterrorism programs including the CDC and HRSA grant programs) for use by SAMHSA for any purpose.

The Committee's Minority Staff has been told that for FY05, SAMHSA intends to fund only two programs that are even related to terrorism. In the Disaster and Response Program, the entire $389,000 budget will be used to continue an ongoing research project with the National Institute of Mental Health.[47] This represents a $3.2 million reduction in funding for the SAMHSA Disaster and Response Program from FY04 (or a cut of 89 percent) and an $8.7 million reduction (or a cut of 96 percent) from FY03.[48] The other related SAMHSA program is the Post-Traumatic Stress Disorder program funded at $30 million.[49] While potentially relevant to dealing with the long-term, future consequences of a terrorist attack, this program responds to only one aspect of an overall mental health response. SAMSHA's FY05 budget is simply not responsive to the numerous mental health goals and needs identified by outside experts or to the activities identified in Department's own Bioterrorism Strategic Plan, such as capacity to

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[45] *"V. Forging America's New Normalcy: Securing Our Homeland, Preserving Our Liberty,"* The Fifth Annual Report to the President and the Congress of the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, December 15, 2003, at 36-37.

[46] *"Justification of Estimates for Appropriations Committee,"* Department of Health and Human Services, Substance Abuse and Metal Health Services Administration, Fiscal Year 2005, at 32.

[47] E-mail from Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, to Minority Staff, Committee on Governmental Affairs, U.S. Senate, March 9, 2004.

[48] *Id.,* Center for Mental Health Care Services, at 4.

[49] *Id.* at 14.

provide "psychological first aid" in the event of a major terrorist attack.

Healthcare System Improvements

The Department's apparent failure to directly request funds for the SAMHSA terrorism activities, even those identified in the Department's Bioterrorism Strategic Plan, does not appear to be an isolated occurrence. The Bioterrorism Strategic Plan also identifies a series of four activities assigned to the Agency for Healthcare Research and Quality (AHRQ).[50] However, it does not appear that any funds are being requested to support the four AHRQ bioterrorism activities in the FY05 budget.

In terms of direct request dollars, the AHRQ budget justification contains a description of AHRQ's "Bioterrorism Portfolio," including a description of activities undertaken in FY02 and FY03 and it implies that research activities in four areas are continuing.[51] However, the budget table contained in the AHRQ FY05 justification includes a budget line for bioterrorism but, indicates that no funds are being requested for this purpose in FY05.[52] Neither are any funds identified in the justification's "portfolio" description, as they are for other AHRQ portfolios. And, as in the case of SAMHSA, no FY05 funds are identified in the Public Health and Social Services Emergency Fund for transfer to AHRQ to fund the bioterrorism activities identified in

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[50] See Activity IVB1, "Develop and assess alternative approaches to ensuring health care surge capacity for mass casualty events – including needs of ambulatory care, long term care, pediatric care, and other health services," "*Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies,*" US Department of Health and Human Services, October 2003, at 19.

Activity IVB2, "Develop and assess alternative uses of information technology and electronic communication networks in enhancing the preparedness of the health care systems to deal with public health threats and emergencies," *Id.*

Activity IVB3, "Develop and assess protocols and technologies to enhance interoperability among the health care system, the public health system, and the other organizational participants that constitute the emergency response network," *Id.*

Activity IVB4, "Develop and assess models that address the training and information needs of health care providers related to enhanced emergency preparedness." *Id.*

[51] "*Justification of Estimates for Appropriations Committee,*" Department of Health and Human Services, Agency for Healthcare Research and Quality, Fiscal Year 2005, at 44.

[52] *Id.* at 2.

the Bioterrorism Strategic Plan or any other AHRQ activities.[53]

Oversight and Enforcement Not Addressed

Another important Department player with responsibility for bioterrorism preparedness and response – the Office of the Inspector General (OIG) – has been left out of the Bioterrorism Strategic Plan altogether. As described in the HHS "Budget in Brief" for FY05, "OIG has an important role in furthering the Department's bioterrorism efforts and ensuring the security of HHS programs, staff, facilities, and equipment."[54] For example, under the Bioterrorism Act and regulations issued by HHS implementing the Select Agent Program, OIG was delegated "authority to conduct investigation and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violation of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188)."[55] As discussed in my previous correspondence with you, full compliance with the Select Agent Program was required by regulation to begin November 12, 2003.[56] Yet, no role whatsoever is provided in the Plan for OIG.

Notwithstanding the acknowledgment of OIG's bioterrorism responsibilities in the HHS budget summary, it does not appear that the Office is being given any additional resources to carry out those responsibilities. Discretionary funding for OIG in FY05 is essentially unchanged from FY04.[57]

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[53] On January 27, 2004, you and Secretary Ridge held a joint news conference to announce the Administration's new initiative to expand biosurveillance efforts, including $100 million for CDC's "BioSense" program. This program "unlike traditional approaches, does not rely upon mandatory or voluntary case reports from healthcare providers to public health officials, but uses automated analysis techniques on electronically available health data" according to the Department's budget summary. *"Budget in Brief FY 2005,"* HHS, February 2, 2004, at 30. Despite the institutional role within HHS of AHRQ in managing, accessing, and improving utilization of such electronic databases, no funding appears to have been requested to enable AHRQ to support this initiative.

[54] *"Budget in Brief FY 2005,"* HHS, February 2, 2004, at 109.

[55] 42 CFR § 73.19(2002). "Civil Money penalties" promulgated on December 12, 2002. 67 Federal Register 76886–76905 (December 13, 2002). Statutory authority for this role by the OIG was explicitly conveyed in P.L. 107-188 § 201.

[56] Letter to The Honorable Tommy G. Thompson, The Honorable Ann M. Veneman, The Honorable John Ashcroft from Sen. Joseph I. Lieberman, November 12, 2003.

[57] FY05 discretionary funding increases are only adequate to cover CY 2004 pay raises and increases in agency personnel and administrative costs. Discretionary personnel is actually budgeted to decline by one Full Time Equivalent–or FTE. *"Justification of Estimates for Appropriations Committee,"* Department of Health and Human

Legislative Requirements for Bioterrorism Preparedness Remain Unmet

While the Bioterrorism Act did not establish a deadline for the initial preparation of the National Preparedness Plan, it did contemplate periodic revisions and required the Secretary to submit progress reports both with respect to the status of the plan and with achievement of the preparedness goals it established. The first such report was to have been submitted to Congress not later than June 12, 2003 and biennially thereafter. No such report has ever been submitted to Congress. (Other related reports on preparedness issues required by the Bioterrorism Act, including the unique problems of rural areas, have also not been forthcoming.)[58]

As mentioned earlier, the Bioterrorism Act directed that the National Preparedness Plan be produced in consultation with the states. As described in the plan document, the Department's Bioterrorism Strategic Plan was not produced in consultation the States, but rather was prepared by HHS's internal Bioterrorism Council. Updates of the Plan will similarly be produced by the Council "in concert with the pertinent HHS Operating and Staff Divisions."[59]

All of these facts show that the Department has not come close to complying with the basic requirements and goals of the Bioterrorism Act with regard to preparation of a National Preparedness Plan for bioterrorism. To the extent that it has prepared a plan, the Bioterrorism Strategic Plan appears inadequate to accomplish even the Department's three stated goals: to facilitate HHS communications and public affairs activities concerning its bioterrorism preparedness efforts; to facilitate preparation of progress reports required by the President or Congress; and to promote results-oriented management and measure progress toward preparedness.[60] For example, the document produced by the Department does not describe the context, content, or objective of a single one of the strategic goals contained in the Plan. Section 3, which ostensibly contains the operational details of the Plan, is merely a listing of

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Services, Office of Inspector General, Fiscal Year 2005, at 17-18.

[58] Sec. 101(b) of P.L. 107-188 directed the Secretary of HHS to produce a report to Congress within one year of enactment (June 12, 2003) addressing a series of six separate preparedness issues – the recommendations and findings of the National Advisory Committee on Children and Terrorism, the recommendations and findings of the EPIC Advisory Committee, the unique characteristics of rural areas, the unique characteristics of medically underserved populations, recommendations for additional legislative authority to address the needs of rural and medically underserved communities, and the benefits of creating a National Disaster Response Medical Volunteer Service. This report was never prepared.

[59] "*Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies,*" US Department of Health and Human Services, October 2003, at 5.

[60] *Id.* at 4-5.

bioterrorism-related activities in which agencies within the Department are engaged.[61] These activities, in turn, are described in the most limited way without any discussion of what the activities actually entail, how they relate to the strategic goal, what level of funding they will receive, what they are expected to accomplish, when they are to be completed, or how they are to be measured.

It is clear that the Department's bioterrorism funding and program priorities are not being directed by the Bioterrorism Strategic Plan, to the extent that it even is a plan. It is also clear that neither the Plan nor the Department's bioterrorism budget priorities are responsive to the recommendations of outside experts for this critical homeland security obligation or practical needs of the public health and health care systems. What is not clear is why the Department has ignored Congress's direction to prepare a National Preparedness Plan for bioterrorism or on what basis the Department and the Administration are actually deciding what bioterrorism activities to fund.

Finally, the Bioterrorism Act established a new position, at the assistant secretarial level, within HHS to coordinate the Department's preparedness efforts with respect to "bioterrorism and other public health emergencies."[62] This position – the Assistant Secretary for Public Health Emergency Preparedness – was assigned specific statutory duties including to "(c)oordinate the efforts of the Department to bolster State and local emergency preparedness for a bioterrorist attack or other public health emergency, and evaluate the progress of such entities in meeting the benchmarks and other outcome measures contained in the national plan..."[63] [Emphasis added]

Although on June 28, 2002, you announced the appointment of Jerome M. Hauer as acting Assistant Secretary for Public Health Preparedness,[64] this appointment was never made permanent. Mr. Hauer left your Department last fall and a new acting Assistant Secretary was put in place. It was not until April 8, 2004 that you named a permanent Assistant Secretary.[65] I am questioning why a critical, statutorily-created position remained without a permanent appointment for some twenty-two months. This position was intended by Congress to be the

[61] *Id.* at 8.

[62] P.L. 107-188 § 102.

[63] *Id.*

[64] HHS Press Release "*Thompson Names Hauer To New Assistant Secretary Post,*" June 28, 2002.

[65] HHS News Release, *"Statement by Tommy G. Thompson, Secretary of Health and Human Services, Regarding the Appointment of Stewart Simonson To Be Assistant Secretary for Public Health Emergency Preparedness,"* April 8, 2004.

focal point of the Department's bioterrorism preparedness efforts in dealing with other cabinet agencies, internal coordination within HHS, in interactions with state and local government, and in measuring progress towards the preparedness goals articulated in the National Preparedness Plan. Yet, no permanent appointment has been forthcoming until now.

Questions

In sum, given the clear charge the Department was given from Congress and the enormous stakes involved, the facts cited above warrant a serious accounting. Specifically, I am asking for answers to the following questions at your earliest convenience:

National Preparedness Plan

1a) Why has the Department failed to prepare the National Preparedness Plan, in collaboration with the States, as directed by the Bioterrorism Act?[66]

1b) Why has the Department failed to comply with the congressional reporting requirements on the status of its preparation of the National Preparedness Plan and progress toward achieving its goals?[67]

State and Local Public Health Priorities

2a) What specific quantitative and qualitative state and local public health capabilities are the CDC cooperative grants intended to achieve and in what time frame?

2b) How did the Department establish these goals and to what extent and through what mechanisms did the Department collaborate with state and local health officials in establishing these goals?

2c) What percent of state and local public health departments have achieved these capabilities?

2d) What performance measures and benchmarks were used and what data were collected, and by whom, to justify the proposed FY05 funding reduction in the CDC cooperative

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[66] P.L. 107-188 § 101.

[67] *Id.*

grant program?[68]

2e) How was the Bioterrorism Strategic Plan used to determine that the funding for the CDC cooperative grant program should be reduced in FY05?

Healthcare Surge Capacity Funding

3a) What specific quantitative and qualitative health care capabilities are the HRSA grants intended to achieve and in what time frame?

3b) How did the Department establish these goals and to what extent and through what mechanisms did the Department collaborate with state and local health officials, hospitals, and other primary health care delivery institutions in establishing these goals?

3c) What percent of hospitals and primary health care delivery facilities have achieved these goals?

3d) What performance measures and benchmarks were used and what data were collected, and by whom, to justify the proposed FY05 funding reduction in the HRSA grant program?[69]

3e) How was the Bioterrorism Strategic Plan used to determine that the funding for the HRSA bioterrorism grant program should be reduced in FY05?

3f) A portion of both the CDC and HRSA grants issued to date were used to fund state and local smallpox vaccination implementation activities. What percent of CDC and HRSA funds were used for this purpose?

3g) Why were funds for the HRSA Public Health Traineeship and Public Health Training Centers programs eliminated in the FY05 budget?

Mental Health Funding

4a) Given the recommendations of the Institute of Medicine, the Gilmore Commission, and other experts concerning the need to ensure that preparations are made to provide mental

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[68] *"Budget in Brief FY 2005,"* HHS, February 2, 2004, at 26.

[69] *Id.* at 16.

health services in the event of bioterrorist and other terrorist attacks and public health emergencies, what was the basis for the Administration's decision to significantly reduce funding for the SAMHSA "Disaster and Response" program for FY05?[70]

4b) Given these recommendations and the SAMHSA activities enumerated in the Bioterrorism Strategic Plan, why doesn't the FY05 budget contain specific requests to support these SAMHSA activities identified in the Plan?

Healthcare System Improvements

5) Given the goals outlined by the Department in its FY05 budget for programs like BioSense,[71] and the AHRQ activities enumerated in the Bioterrorism Strategic Plan,[72] why doesn't the FY05 budget contain specific requests to support a role for AHRQ in BioSense and the AHRQ activities identified in the Plan?

Oversight and Enforcement

6a) Why wasn't the Office of Inspector General included in the Bioterrorism Strategic Plan?

6b) What additional resources are being provided to the Office of Inspector General to ensure that it can carry out its responsibilities for bioterrorism?

Assistant Secretary Appointment

7) Why wasn't a permanent Assistant Secretary for Public Health Emergency Preparedness appointed until April 8, 2004?

Conclusion

Preparing the nation for bioterrorism is an extremely complex, costly, and urgent task. Efforts must be simultaneously undertaken on many fronts involving all levels of government

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[70] *"Justification of Estimates for Appropriations Committee,"* Department of Health and Human Services, Substance Abuse and Metal Health Services Administration, Fiscal Year 2005, Center for Mental Health Services, at 4.

[71] *"Budget in Brief FY 2005,"* HHS, February 2, 2004, at 30.

[72] *"Strategic Plan to Combat Bioterrorism and Other Public Health Threats and Emergencies,"* US Department of Health and Human Services, October 2003, at 19.

and the private sector – from upgrading federal, state, and local public health departments to developing countermeasures to establishing surge capacity for treatment. As we have seen with the outbreaks of SARS and influenza in 2003, improvements in bioterrorism preparedness also aid our ability to respond to naturally-occurring outbreaks of disease or mass casualty events.

In 2002, Congress directed your Department to proceed in a collaborative process with the states to achieve these difficult goals, and to document this effort and our progress in a National Preparedness Plan. Regrettably, it appears that this direction has been ignored and, in the absence of a concrete plan of action, funding is being cut from core bioterrorism preparedness programs and priorities, and preparedness is not being achieved.

I look forward to your prompt explanation of these events. If you have any questions regarding this matter, please have your staff contact David Berick of the Committee on Governmental Affairs Minority Staff at 202-224-2627.

Sincerely,

Joseph I. Lieberman
Ranking Member
Committee on Governmental Affairs

cc: The Honorable Susan Collins
Chair, Committee on Governmental Affairs