Testimony of

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October 6, 2004

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WASHINGTON, D.C.
TESTIFYING BEFORE THE UNITED STATES SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
AND
COMMITTEE ON THE JUDICIARY
REGARDING THE
BIOSHIELD II: RESPONDING TO AN EVER-CHANGING THREAT
October 6, 2004
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Chairman Gregg, Chairman Hatch, Senator Kennedy, Senator Leahy, and Members of the Committees, it is an honor for me to testify before you today regarding liability and antitrust issues surrounding the creation of an effective biodefense industry in the United States. I would like to recognize the commitment and leadership on the issue of bio-defense displayed by each of you in the drafting and passage of the Project Bioshield Act of 2004. Specifically, the foresight of Chairman Hatch and Senator Lieberman in introducing similar legislation soon after the attacks of 2001 and the leadership of Chairman Gregg and Senator Kennedy in introducing S. 15 and seeing it through to passage are to be commended. America is safer thanks to your leadership and actions.

My testimony today is based on direct experience advising government contractors, pharmaceutical, and bio-tech companies throughout America and throughout the world on how to bring the best possible homeland security and antiterrorism solutions to both the government and private markets. My work over the last three years has centered on addressing liability issues surrounding anti-terror goods and services, including, specifically, bio-defense countermeasures. My firm and I played a key role in the drafting and passage of the SAFETY Act, including representing all four entities that received the first certifications under the Act on June 18, 2004. There is no greater concern - particularly, for public corporations in the post- Sarbanes/Oxley environment - than ensuring a balance between responding to the nation's need for high-quality anti-terror technology and protecting corporate assets from unnecessary, expensive litigation that threatens

the very existence of these companies and prevents effective countermeasures from being deployed.

In the area of bio-defense, we have worked closely with a number of pharmaceutical and bio-tech companies to ensure that the Project Bioshield Act of 2004 addressed what they perceived as obstacles to entering the bio-defense market. I am happy to testify that through the leadership of the Bush Administration and Congress, this landmark legislation has achieved a great deal. It provides the Federal government the ability to ensure industry a market for biodefense products. It streamlines the contracting process to attract great interest from non-traditional government contractors. It provides funding to allow the Federal government to purchase and stockpile critical countermeasures. And it allows the President to act during an emergency to get the best countermeasures available into the hands of our public health officials, regardless of whether every regulatory step required in peacetime has been completed. In short, Project Bioshield is a positive step in protecting the nation.

Congress now has the opportunity to build upon this success by enacting Bioshield II. There are two issues that I would like to discuss today that merit consideration as part of Bioshield II. First, Congress should act to remove obstacles caused by liability concerns that prevent bio-defense countermeasures from coming to market. Second, Congress should encourage the use of existing antitrust authorities to stimulate and streamline industry participation in this critical market.

Liability Must be Addresses to Have a Successful Bio-Defense Industry

Make no mistake - liability concerns are preventing critical bio-defense measures from being developed and coming to market. There is a clear difference between the liability concerns of a company engaged in day to day drug development and sales and the concerns of a bio-defense provider. First and foremost, these countermeasures are, by their very nature, meant to prevent or mitigate the impact of a criminal, terrorist act. Such acts are unpredictable and the means to address their impact must rely only upon available intelligence, predictive models, and, to a large degree, luck. This is not an environment that any responsible company can enter lightly. And without an effort to address the issue of liability, it is a market I regret to say many of the best and brightest will simply avoid.

Nature of the Liability Threat

Manufacturers of countermeasures produced under Project Bioshield risk exposure to devastating product liability lawsuits to a far greater degree than typical drug companies. Project Bioshield specifically contemplates that such countermeasures may be made available without the usual battery of clinical trials required for other FDA-approved products. Safety and efficacy data must be derived, for the most part, from animal trials since healthy humans cannot be exposed toxic agents during testing for obvious reasons. Thus, these critical

countermeasures must be developed and are likely be deployed without the full

battery of testing typical of other drugs.
Moreover, the distribution and administration of countermeasures in response to a bioterrorist attack will most certainly require the government's enhanced role in recommending, distributing and administering countermeasures during a crisis. The very nature of deploying countermeasures in the fog of a crisis will clearly expose manufacturers to unknown and unquantifiable liability that cannot be addressed simply by good laboratory and manufacturing practices and insurance.
Additionally, the government may rightly decide to purchase and stockpile countermeasures with undetermined side effects until a better countermeasure is developed. These stockpiles could remain in place for years, only to be deployed in an emergency. Further, the government has the ability now to administer countermeasures developed under Bioshield, even without full regulatory approval.
Finally, the market for bio-defense countermeasures is limited primarily to government stockpiles. Thus, unlike with drugs produced to treat illness or even infectious disease, there is no predictable, reoccurring market that would allow a company to spread the liability risk across a large volume of drugs for a period of years.
Even as the government has begun to purchase Bioshield countermeasures, it has no current way to resolve issues of liability - an issue of grave concern to

industry - with any degree of certainty as part of the procurement process. The net impact of this atmosphere results in needed countermeasures not being developed and deployed, thereby exposing the economy, and the nation as a whole, to far greater potential liability due to the lack of available effective countermeasures in the event of attack. Either way, the Federal government is likely to the bear both the human and financial cost of such an attack as it did on September 11th. But by failing to account for these costs before an attack, countermeasures will not be developed and the nation will be more exposed to attack.
Available Liability Mitigation Tools are Inadequate
Congress should act to address liability in, at a minimum, three ways: by encouraging expanded use of existing indemnification authorities; by expanding the SAFETY Act to cover vaccines and other countermeasures deployed prior to a terrorist attack; and, by expanding the compensation scheme provided for smallpox countermeasures to cover all countermeasures produced under Project Bioshield.
Currently, there exists only two ways the Federal government can mitigate the liability concerns for providers of countermeasures other than smallpox vaccine - through Federal indemnification under Public Law 85-804 and through designation/certification under the SAFETY Act.
Public Law 85-804

As you are aware, Public Law (P.L.) 85-804 (August 28, 1958, codified at 50 U.S.C. § § 1431 - 1435) grants the President extremely broad authority that allows a Federal government contractor to obtain financial or other forms of relief under certain circumstances, even when the government may have no express legal obligation to grant such relief, or when there are express prohibitions against such

relief contained in other statutes, regulations, or common law. Under this authority, the heads of designated departments or agencies have the discretionary power to provide contractors with government indemnity when they are engaged in unusually hazardous or nuclear activities and when it is in the interest of the national defense to provide such indemnity. Of course, the liability protections offered by P.L. 85-804 still requires years of litigation until victims are ultimately compensated.

In essence, indemnification under P.L. 85-804 relies upon the usual tort system and simply places the Federal government in the position of an insurer where payments are made only after all claims have been adjudicated in the court system and judgments have bee rendered. This rather lengthy process does not result in compensation to victims being paid in a timely manor nor does it place any effective limits on the Federal government's contingent liabilities when it acts in this capacity. However, given the types of risk it is meant to address, P.L. 85-804 has proven to be an effective means of addressing liability concerns for the deployment of unusually hazardous technologies to the Federal government.

This authority has been invoked by the Department of Health and Human Services (which was first granted the authority in October 2001 following the anthrax attacks) in agreements involving the donation of smallpox vaccine by Wyeth and Aventis Pasteur to the Federal government in 2001. However, HHS will not, as a matter of HHS policy, address the issue of indemnification prior to award of a contract for a countermeasure. This policy leaves potential providers of biodefense countermeasures in the position of having to expend scarce resources to prepare and submit a proposal that may result in a contract that cannot be accepted due to the lack of liability protections should HHS ultimately refuse to provide indemnification. More often, companies simply refuse to bid at all due to the lack of certainty on the issue of liability. This has resulted in the largest, and far more experienced, drug companies with the necessary expertise to address this threat being left on the sidelines of the war on terror - a result that does not serve the nation well.

In addition, on February 28, 2003, President Bush significantly modified E.O. 10789 implementing P.L 85-804 by adding additional requirements for heads of agencies and departments considering requests from contractors seeking Federal indemnification for certain products and services. Under the Executive Order, as revised, the head of a Federal agency or department, other than the Secretary of Defense, considering a contractor's request for Federal indemnification for products or services that have been or could be designated as "qualified antiterrorism technologies" under the SAFETY Act must now consult with the Secretary of

Homeland Security and receive the approval of the Director of the Office of Management and Budget (OMB) before granting such a request. During this consultation, the Secretary of Homeland Security must advise the head of the agency or department whether use of the authorities provided to the Secretary of Homeland Security under the SAFETY Act would be more appropriate than Federal indemnification. If the head of the non-Defense agency or department determines

that Federal indemnification is appropriate after such consultation, he must also receive approval from the Director of OMB before granting the contractor's request for Federal indemnification under P.L. 85-804. The revised Executive Order further states that the Secretary of Defense must only consider whether use of the SAFETY Act is appropriate before granting Federal indemnity for indemnification for products or services that have been or could be designated as "qualified antiterrorism technologies" under the SAFETY Act. Coordination with the Secretary of Homeland Security and approval by the Director of OMB is not required.

SAFETY Act Does Not Provide Protection from Pre-Terrorist Liability

The SAFETY Act does, in fact, provide significant protections to providers of countermeasures that receive certification under the Act. I must note, however, that to date, no such certifications have been granted for bio-defense countermeasures.

Significantly, Section 865(1) of the SAFETY Act notes that qualified antiterrorism technologies may include technologies deployed for the purpose of

"limiting the harm such acts [of terrorism] might otherwise cause." The "harm" that may be caused by an act of terrorism clearly goes beyond the immediate effects of the act itself. An act of terrorism such as the attacks of September 11th or the October 2001 anthrax attacks trigger a number of immediate remedial and emergency responses to limit the resulting harm and deter follow-on attacks. For example, immediately following the detection of anthrax in the offices of Senator Tom Daschle and Senator Patrick Leahy, Members of Congress and their staffs were treated with antibiotics and other prophylactic measures with the goal of limiting the harm that this act of terrorism could cause. Clearly, any injuries that might have been caused by the administration of these treatments, even though direct results of the act of terrorism itself could be directly traced to the act and the objective of limiting the resulting harm. Moreover, any claims brought as a result of such injuries would clearly be "arising out of, relating to, or resulting from an act of terrorism."

Limitations of the SAFETY Act for Bio-Defense Countermeasures

While the SAFETY Act can provide signification protections to a company, it has limitations in the context of countermeasures. Most significantly, the SAFETY Act does not provide compensation for those injured by qualified technology. Rather, the liability is removed as matter of law. That said, if the SAFETY Act were to be coupled with a limited compensation scheme bio-defense coutermeasures, liability would be addressed and victims could be made whole.

Moreover, the potential liability of a provider of anti-terrorist technologies that may allegedly cause injury PRIOR to a terrorist attack, such as a vaccine, are not currently addressed by the SAFETY Act.

In the legislative history of the Project BioShield Act of 2002, Congress stated that the Secretary of Homeland Security is "encouraged to designate [biodefense] countermeasures as 'qualified anti-terrorism technologies' as defined in section 862 of the Homeland Security Act." In the context of Project BioShield, there is great concern

by makers of bio-terrorism countermeasures, diagnostics, and therapeutics that SAFETY Act protections do provide protection since liability frequently exists PRIOR to, in addition to following an act of terrorism.

For example, in the context of a diagnostic, a test kit for Anthrax exposure that may, perhaps, provide false positives would expose the manufacturer to tremendous - and likely insurable liability - thereby preventing widespread deployment, even if the diagnostic is the current state of the art.

Also, recognize that the research and development into these bio-defense measures as well as production, itself, may expose a company to potential liability given that both R&D and production may involve toxic materials, even if those toxic materials cannot possibly harm the public. For example, BIOPORT, the manufacturer of the Anthrax vaccine provided to the Department of Defense long before 9/11, was sued in Florida in the Fall 2003 for allegedly not preventing the Anthrax strain that killed the gentlemen in Florida in October 2001 from being stolen by terrorists. However, BIOPORT does not possess - nor has it ever

possessed - live strains of Anthrax. Moreover, the R&D companies that support the bio-defense industry that do routinely use these toxins, and yet, very rarely receive indemnification. This is just one example among many.

SAFETY Act Protections Should be Extended

Through minor changes to existing language, SAFETY Act protections should apply to technologies that mitigate against terrorist incidents, and such protections should attach if there is the POTENTIAL for a terrorist attack - not just after an act of terrorism occurs. Minor changes to the SAFETY Act, such as those proposed by Congressman Curt Weldon (R-PA) would easily address this issue and would be a significant step in providing the certainty necessary to stimulate the bio-defense market. (See attached).

Protections for Smallpox Vaccine Should be Expanded to All Biodefense Countermeasures

The liability protections provided under the Homeland Security Act of 2002 (P.L. 107-296), and further expanded by the Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20) for the administration of smallpox vaccines are, indeed, quite powerful. Though currently limited only to smallpox vaccine, the Congress should strongly considered extending this legislation to apply to providers of any countermeasure developed under Project Bioshield. Such a change would provide additional certainty on the issue of liability and would positively impact the creation of bio-defense countermeasures. I note that this provision is somewhat limited in that it is only triggered by declaration of the Secretary of Health and Human Services such that has been made regarding smallpox. Moreover, there are

significant questions regarding the precise scope of the protections afforded by this measure regarding the types of claims covered and the specific entities that are protected. Still, expansion of this measure to protect manufactures of countermeasures produced under Project Bioshield would be a significant improvement to the status quo.

Any legislation expanding the coverage of the liability protections afforded

smallpox vaccines under the Homeland Security Act of 2002 must also expand the statutory language provided by the Smallpox Emergency Personnel Protection Act of 2003 to ensure identical treatment of all countermeasures with smallpox vaccine. It must also squarely provide liability protections for injuries alleged to be caused by non-negligent administration of the countermeasure (e.g., claims for breach of warranty and/or strict liability). Such legislation, coupled with expansion of the SAFETY Act, will provide the certainty necessary to develop a fully responsive biodefense industry as quickly as possible and will provide a means for unintended victims to be compensated.

Existing Antitrust Measures Should Be Used to Address Bio-Defense Market Concerns

Turning to antitrust concerns surrounding Project Bioshield, the government's current homeland security efforts require various agencies, including the Department of Defense, to purchase a number of vaccines and other drugs to address multiple bio-terror threats. There are a limited number of companies capable of supplying such products to meet the government's growing needs. Further, no single company has the resources necessary to respond effectively to

multiple solicitations for such products. Moreover, the government market for these products is rather limited and uncertain, even with the passage of Project Bioshield. The limitations and uncertainties inhibit research, development and production of these products to satisfy the government's national defense needs that would normally be spurred through competitive market forces.

Defense Production Act Provides the Authority to Convene an Industry-wide Meeting

To address these challenges, the government has the express authority under the Defense Production Act (DPA) of 1950, as amended, 50 USC App. § 2361 et seq., to convene a meeting of all relevant companies competing for government contracts that call for the development and production of certain vaccines for national defense purposes. Under such authority, the government may provide immunity from potential antitrust liability to a company that participates in a process with its competition, including meetings, the objective of which is to address issues of common concern to industry and the government. The government may, in exercising this authority, require competitors to act in collaboration or share information that otherwise could not be shared due to antitrust laws and regulations. The objective of this process would be to reduce or eliminate barriers that prevent companies from satisfying the government's national defense needs. The DPA provides the government with the authority to permit companies to enter into certain agreements that could include potential competitors and would have the effect of altering competitive behavior for the development of bio-defense countermeasures -- activities which would otherwise violate the antitrust laws.

Under the DPA, the government may convene a meeting with all or some of the nation's bio-defense manufacturers to discuss the government's bio-defense procurement requirements. Topics at such a meeting may include issues of common concern such as market allocation, agreements that certain companies respond to

specific solicitations, and/or required contract terms such as indemnification. If the DPA's statutory prescriptions are satisfied, the government's valid exercise of its DPA authority would provide complete protection against the operation of certain antitrust laws for the private-entity participants in this process.

The government has the authority to convene meetings and execute agreements creating what could be described as a "managed market" that fall under the DPA's exemption from the antitrust laws. Under this authority, parties could meet to discuss a proposed division of the total market for vaccines, countermeasures, and other drugs necessary to support homeland security, including possibly allocating drug research development and production contracts among potential competitors to avoid inefficient procedures associated with full and open competition in this context. Such a meeting might also address the need for certain contract provisions. The conduct of such meetings undoubtedly would require the sharing of information that could otherwise not be shared due to the operation of antitrust laws and regulations.

The DPA, and specifically 50 USC App. § 2158, expressly enable the creation of agreements among potential competitors, with the participation of the United States, the purpose of which is to manage the development and production of

defense-related goods and services and which agreements, but for this provision, might violate certain antitrust laws. Thus, the DPA will provide immunity1 from any public or private antitrust action brought against a company that participates in such a meeting, provided that all of the technical elements outlined in the DPA have been met.

Essential to the operation of this exemption from the antitrust laws and regulations is the active participation of the United States which participation is described in considerable detail in the DPA itself. When conditions exist that directly threaten the national defense or its preparedness programs, the DPA authorizes the President to give antitrust immunity to rival contractors for the purposes of forming agreements to develop preparedness programs and to expand production capacity and supply beyond levels needed to meet essential civilian demand. William E. Kovacic, Antitrust Analysis of Joint Ventures and Teaming Arrangements Involving Government Contractors, 58 Antitrust L.J. 1059 (1989).

Immunity against any civil or criminal action brought under federal antitrust laws or any similar law of any state may be conferred on any person that:

· Takes any action in the course of developing a voluntary agreement initiated by the President or a plan of action adopted under such agreement; or

1 While the statute itself refers to an "immunity" that is being conferred, we do not believe that the exemption amounts, literally, to an "immunity." Our reason for differing on the effect of the law is that a company would not be "immune" from an action brought by a private party or government, but rather could prevail in an antitrust action brought against it by showing that it had complied with a government supervised voluntary agreement or plan of action. See, 50 USC App. §

2158(j).
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· Takes any action to carry out an approved voluntary agreement or plan of action initiated by the President; and
· Complies with the requirements of the DPA; and
· Acts in accordance with the terms of voluntary agreement or plan of action.
50 USC App. § 2158(j)(1).2
"Antitrust laws" for purposes of the DPA, have "the meaning given to such term in subsection (a) of the first section of the Clayton Act, except that such term includes Section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition." 50 USC App. § 2158(b). That definition includes (by referencing the Clayton Act) the Sherman Act, 15 U.S.C. § 1, et seq., which contains the antitrust prohibitions potentially applicable to the actions contemplated in this memorandum. The person seeking the immunity has the burden of persuasion to establish that each of the elements for receiving immunity under the DPA have been met. 50 USC App. § 2158(j)(3).
While immunity is not available if "the action was taken for the purpose of violating the antitrust laws," this provision does not present a problem for the government to achieve the overall objectives of the DPA. This language was
2 If a voluntary agreement or plan of action is accompanied by contracts with the United States that call for the conduct of the necessary research, development, and production, additional statutes exist which would protect against antitrust laws. See 10 USC § 2304(c) and 41 USC § 303©.
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inserted during reauthorization of the DPA in 1991 as a "face-saving" measure for those legislators hesitant to reenact the antitrust immunity provisions of the DPA for fear of eviscerating existing antitrust law. Assuming that a company act in accordance with provisions of the DPA, and follows the government's directions in that regard, by definition, they are not acting for the "purpose" of violating antitrust laws.
Separately, the DPA provides immunity from liability, damages or penalties based upon acts or omissions "...resulting directly or indirectly from compliance with a rule, regulation or order issued pursuant to this act" even if such rule, regulation or order is thereafter held to have been invalid. This additional protection is operative here because the supervised agreements contemplated by the DPA would generally be effectuated by agency "rule" and "order" under the terms of the Act. This provision of the DPA is indeed written as a true immunity provision and, in our view, would bar a private antitrust action.
The Homeland Security Act of 2002 contains a provision that expressly references the antitrust exemptions of the DPA. The provision recites that the DPA confers antitrust immunity to participants in a "critical infrastructure protection program" established in accordance with the Homeland Security Act of 2002. This language was inserted in lieu of a stand-alone antitrust exemption which was ultimately considered unnecessary.

Moreover, the Federal Maritime Administration used the DPA for these purposes as recently as 1996. Under that voluntary agreement, the Department of Transportation convened a meeting with eligible U.S.-flag vessel operators to enter into a "Voluntary Intermodal Sealift Agreement" (VISA) to address the total sealift needs of the United States in the event of a national emergency. Specifically, the action was undertaken with the intention that "the participants that are party to a VISA will provide capacity to support a significant portion of surge and sustainment requirements in the deployment of U.S. military forces." 60 FR 54144 (October 19, 1995). While the DPA was used to allocate market-share on at least fifty occasions during the Korean War,3 the VISA program is the most recent example of the governments use of the DPA for these purposes. The VISA program remains in effect today. These examples demonstrate that the DPA is available to protect participants from antitrust liability for government-sponsored agreements to divide market share among competitors.

As a prerequisite to establishing a voluntary agreement under the DPA, the President (or his approved designee) must find that "conditions exist which may pose a direct threat to the national defense or its preparedness programs." 50 USC App. § 2158(c)(1). By Executive Order 12919, dated June 3, 1994, the President has delegated this authority to the heads of each federal department or agency. E.O. 12919, Part V, Sec. 501. Once appointed, the President's designee (defined as the

3 See generally, Harold L. Schilz, Voluntary Industry Agreements and Their Exemptions from the
Antitrust Laws, 40 Va. L. Rev. 1 (1954).

"sponsor" by the governing regulations) must consult with the Attorney General and the FTC not less than 10 days before attending a meeting discussing any proposal to develop a voluntary agreement. In addition, the sponsor must have received prior approval from the Attorney General to have such a meeting. 50 USC App. § 2158(c)(2).

Regulations providing the standards and procedures by which voluntary agreements may be developed are found at 44 CFR 331.1-4. In accordance with these regulations, any sponsor that wishes to develop a voluntary agreement shall submit to the Attorney General and the Director the Federal Emergency Management Agency (FEMA) a proposal that includes statements regarding:

· The purpose of the agreement;
· The factual basis for making the finding that "conditions exist which may pose a direct threat to the national defense or its preparedness programs;"
· The proposed participants in the agreement; and
· Any coordination with other federal agencies accomplished in connection with the proposal.

Upon a finding that the prerequisites for initiating a meeting to discuss a voluntary agreement under the DPA have been met, "the President [or the approved sponsor] may consult with representatives of industry, business, financing,

agriculture, labor, and other interests...[to facilitate the creation of]...voluntary agreements and plans of action to help provide for the defense of the United States through the development of preparedness programs and the expansion of productive capacity and supply beyond levels needed to meet essential civilian demand in the United States." 50 USC App. § 2158(c)(1).

Voluntary agreements may only be developed with the direct involvement of the Attorney General, the Chairman of the FTC, and the Director of FEMA, or their designees. The sponsor of the agreement must serve as the chairman of any meeting discussing proposed voluntary agreements. The sponsor must ensure that notice of the time, location, and nature of any meeting discussing a proposed voluntary agreement is published at least seven day in advance. All interested persons must be invited to submit written data and views concerning the proposed voluntary agreement, with or without the opportunity for oral presentation. In addition, all interested persons must be invited to attend any meeting discussing the proposed agreement, unless the chairman finds the subject of the meeting is protected under the Freedom of Information Act (FOIA). Finally, a full and verbatim transcript must be prepared for any meeting discussing the proposed agreement. This transcript must be provided to the Attorney General, the FTC, and Congress, and be made available for public inspection and copying, subject to FOIA. 50 USC App. § 2158(d); 44 CFR 332.2.

Voluntary agreements are executed through a "plan of action," which may include the conduct of research and development contracts. Such a plan may also

include contracts for the production of goods and services or other actions as agreed to by the parties to the voluntary agreement and the government.4

Voluntary agreements, and any plans of action contemplated by such agreements, become effective when the sponsor certifies, in writing, that the agreement or plan is necessary and the sponsor submits the agreement or plan to Congress. In addition, the Attorney General (with consultation from the FTC Chairman and the FEMA Director) must find, in writing, that the purpose of the action "may not reasonably be achieved through a voluntary agreement or plan of action having less anticompetitive effects or without any voluntary agreement or plan of action and publishes such finding in the Federal Register." 50 USC App. § 2158(f)(1); 44 CFR 332.1(b)(2); E.O. 10480, §§ 101 & 501(a).

Voluntary agreements and plans of action contemplated by such agreements expire two years from the effective date and may be extended upon certification or finding by the sponsor and the FEMA Director that such extension is appropriate. 50 USC App. § 2158(f)(2). The Attorney General may terminate or modify a voluntary agreement, in writing, after consultation with the FTC Chairman. The sponsor of the agreement, with the concurrence of the FEMA Director, may terminate or modify a voluntary agreement, in writing, after consultation with the Attorney General and the FTC Chairman. Any person who is a party to a voluntary

4 The term "plan of action," as defined by the DPA, means "any of 1 or more documented methods adopted by participants in an existing voluntary agreement to implement that agreement." 50 USC

App. § 2158(b)(2). A plan of action is issued by the government with the express agreement and cooperation of all of the parties to the voluntary agreement.

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agreement may terminate his participation in the agreement upon written notice to the sponsor. No antitrust immunity shall apply to any act or omission occurring after the termination of the voluntary agreement or any act or omission that is beyond the scope of the agreement. 44 CFR 332.5.

If the technical elements of the DPA have been satisfied, competitors may meet to discuss with government the formation of voluntary agreements with its potential competitors that could have the effect of dividing the markets or developing common contract terms for the countermeasures to be developed. Such voluntary agreements may include a plan of action to be issued by the sponsoring agency that permits, among other things, division of market share and/or assignment of certain contracts among participants to the agreements. Again, all such meetings, voluntary agreements, and plans of action must comply with all of the requirements of the DPA to be afforded protection from antitrust laws and regulations.

I note that this authority exists today - and has since 1950. Congress should consider whether use of this authority would enable HHS to address many of the issues facing companies that are resistant to otherwise participate in this market. Clearly, simply convening a meeting under the authorities of the DPA to discuss this issue would most certainly stimulate interest and facilitate discussion with a far broader number of entities than are expressed interest in the bio-defense interest today.

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Thank you again to Chairman Gregg, Chairman Hatch, Senator Kennedy and Senator Leahy and members of the Committees for your attention to this critical issue. I welcome your questions.