

**PROJECT BIOSHIELD: LINKING BIOTERRORISM
THREATS AND COUNTERMEASURE PROCUREMENT
TO ENHANCE TERRORISM PREPAREDNESS**

HEARING
BEFORE THE
SUBCOMMITTEE ON EMERGENCY
PREPAREDNESS, SCIENCE,
AND TECHNOLOGY
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CONTENTS

	Page
STATEMENTS	
The Honorable Peter T. King, a Representative in Congress From the State of New York, and Chairman Subcommittee on Emergency Preparedness, Science, and Technology	1
The Honorable Bill Pascrell, Jr., a Representative in Congress From the State of New Jersey, and Ranking Member, Subcommittee on Emergency Preparedness, Science and Technology	3
The Honorable Christopher Cox, a Representative in Congress From the State of California, and Chairman, Committee on Homeland Security: Prepared Opening Statement	24
The Honorable Bennie G. Thompson, a Representative in Congress From the State of Mississippi, and Ranking Member, Committee on Homeland Security	4
The Honorable Donna M. Christensen, a Delegate From the U.S. Virgin Islands	29
The Honorable Charlie Dent, a Representative in Congress From the State of Pennsylvania	31
The Honorable Norman D. Dicks, a Representative in Congress From the State of Washington	42
The Honorable Bob Etheridge, a Representative in Congress From the State of North Carolina	26
The Honorable Jane Harman, a Representative in Congress From the State of California	32
The Honorable Nita M. Lowey, a Representative in Congress From the State of New York	38
The Honorable Michael McCaul, a Representative in Congress From the State of Texas	37
The Honorable Stevan Pearce, a Representative in Congress from the State of New Mexico	34
The Honorable Dave G. Reichert, a Representative in Congress From the State of Washington	41
The Honorable Rob Simmons, a Representative in Congress From the State of Connecticut	35
The Honorable Curt Weldon, a Representative in Congress From the State of Pennsylvania	27
WITNESSES	
PANEL I	
Ms. Karen T. Morr, Acting Assistant Secretary, Office of Information Analysis, Information Analysis and Infrastructure Protection, Directorate, Department of Homeland Security: Oral Statement	5
Prepared Statement	7
The Honorable Stewart Simonson, Assistant Secretary, Office of Public Health Emergency Preparedness, Department of Health and Human Services: Oral Statement	15
Prepared Statement	17

IV

	Page
Dr. John Vitko, Jr., Director, Biological Countermeasures Portfolio, Directorate of Science and Technology, Department of Homeland Security:	
Oral Statement	10
Prepared Statement	12

PANEL II

Dr. Marcus Eugene Carr, Jr., Executive Director, Clinical Research- Hemostasis, Novo Nordisk, Inc.:	
Oral Statement	44
Prepared Statement	45
Mr. Michael Greenberger, Director, Center for Health and Homeland Security, University of Maryland School of Law:	
Oral Statement	49
Prepared Statement	51
Mr. Richard Hollis, Chief Executive Officer, Hollis-Eden Pharmaceuticals, Inc.:	
Oral Statement	54
Prepared Statement	56
Mr. James A. Joyce, Chairman and Chief Executive Officer, Aethlon Medical, Inc.:	
Oral Statement	64
Prepared Statement	66
Mr. David P. Wright, President & Chief Executive Officer, PharmAthene, Inc.:	
Oral Statement	72
Prepared Statement	73
Ms. Nancy Wysenski, President, EMD Pharmaceuticals:	
Oral Statement	67
Prepared Statement	69

FOR THE RECORD

Mr. John Vitko Responses to Questions From the Honorable Mike Rogers	86
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~~ster the SNS. First, the procurement of countermeasures is limited by the current implementation scheme because there must be a call for material threat assessments against a specific agent, followed by a call for a countermeasure against that threat. Unfortunately, this process is not well suited to countermeasures such as NovoSeven that are effective for treatment of multiple threats.~~

~~Further, the current procurement process precludes products with a significant commercial market. This provision of the legislation serves as a disincentive to companies with marketable products with potential broad applications in the CBRN arena (e.g., broad spectrum antibiotics) and deters their participation in CBRN medical countermeasure research and development. While many of the specifically targeted countermeasures are in such early stages of development that it will be years before they can be stockpiled under IND status and then subsequently licensed, it is likely that mature technologies exist that are approved for other uses that could also provide *near-term* solutions to the country's CBRN defense needs if given the opportunity to compete for Project BioShield contracts. Pursuing FDA approved drugs for other CBRN related indications could significantly expedite the regulatory and development process since these products have already been used in humans.~~

~~With the two changes identified above, BioShield is more likely to meet its goal of establishing a stockpile of vaccines and therapeutics to counter various CBRN agents. Our nation should acquire effective countermeasures **now**, while still promoting an innovative pipeline of countermeasures, thereby stockpiling a broad range of products that defend against immediate and future threats.~~

~~In closing, let me say that I hoped I have provided you with valuable information about the use of NovoSeven as a broadly applicable countermeasure and also about changes to the legislation that represent good, sound public policy that will enhance US security. I look forward to hearing the committee's thoughts and answering any questions the members may have.~~

~~Thank you again for this opportunity to testify today.~~

Mr. KING. Mr. Michael Greenberger.

STATEMENT OF MICHAEL GREENBERGER

Mr. GREENBERGER. Thank you, Mr. Chairman. My name is Michael Greenberger. I am director of the University of Maryland Center for Health and Homeland Security. I am not a scientist or involved with any corporation; I am a lawyer by training and a professor of law. But I do work extensively with researchers who have been given substantial grants by the National Institute of Allergy and Infectious Diseases to develop countermeasures for Class A, B, and C agents on the CDC's lists.

My focal point of what I would like to say to you in this brief time is I think emblematic of the difficulties with Project BioShield is that nothing, none of that \$5.6 billion, can be released until the Department of Homeland Security makes a material threat assessment. You heard time and time again worries about pandemic flu and the avian flu, and the answers that we do not have an industrial base. The \$5.6 billion was intended to create an industrial base. After 1 year after BioShield has been passed, almost 4 years after 9/11, 5 years after the Defense Science Board has made findings in this regard, the Department of Homeland Security, its one responsibility that it is the leader of under BioShield, has made four material threat assessments for anthrax, smallpox, botulism toxin, and radiological and nuclear devices.

Dr. Carr is talking about something that his company has that is principally designed to deal with hemorrhagic fevers. You, Mr. Chairman, opened the meeting up by talking about Marburg and ebola hemorrhagic fevers. After 1 year, the hemorrhagic fever is not on the material threat assessment list; therefore, the entire country who is worried about this is being told do not invest your time,

your research time, your development time, your manufacturing time in hemorrhagic fevers.

Dr. Vitko says—first in prior testimony he said by the end of fiscal year they will—which I take it to mean before October 1st, hemorrhagic fevers will be on the list of—material threat assessment list. Today we learned it will be at the end of the fiscal year. These—nothing can be done until these items are listed. They have talked about a 3—or 4-month assessment to get a draft up with regard to meetings. Dr. Morr says in Afghanistan they found in the tents of al-Qa’ida documented information that they intend to use tularemia and plague. Tularemia and plague are not yet material threat assessments.

When the BioShield statute was set up, this wasn’t supposed to be some complicated hearing endorsed by substantial evidence and reviewed by courts of appeals. My reading of the statute is this was a very preliminary assessment that was supposed to be made, the Defense Science Board, the Center for Disease Control. Congressman Weldon talked about Jessica Stern, who has one of the leading scholarships in this area. Her book was published in 1999. She lists 60 agents that need to be considered.

Now, Dr. Vitko said the CDC’s work is a good starting point. They are going to add to it. Well, the CDC, by however you count, is at least 33 agents, and they are going to add to it? How long is that going to take? And if there are surprises, he said, some of the CDC’s agents aren’t going to be listed. That is going to be a very big surprise.

I can tell you that the scientists I work with are in the elementary stages of developing vaccines for tularemia, plague, smallpox, anthrax, avian flu, and many other threats to this country. It goes—even if they are successful, it is a long step between the research and going through all the clinical trials and then getting the stuff manufactured. And if we can’t do this fundamental work, which is the one responsibility the Department of Homeland Security has, in all this time, that is worrisome. And I think this committee should grab the Department of Homeland Security by the scruff of its neck and get these assessments made.

The final point I would make in this regard is that there are—if we want to create an industrial base, we must move more quickly. I know there is worry about coordination between Department of Homeland Security and HHS. To my mind, there is too much coordination. There are a lot of committee meetings, and we have to wait until everybody is available for the meeting.

I am reading a biography now of Winston Churchill. He would have not taken 3 to 4 months to figure out material threat assessments when the blitz was happening in London.

We are essentially—speaking of London, we are in our own kind of blitz. We must move more quickly. There are many problems with BioShield. I would be happy to answer other questions, but I think this is emblematic of the maladministration of a wise program proposed by the President and passed bipartisan by this Congress.

Mr. KING. Thank you for your understated testimony. Thank you, Mr. Greenberger.

[The statement of Mr. Greenberger follows:]

PREPARED STATEMENT OF MICHAEL GREENBERGER

My name is Michael Greenberger.

I want to thank the subcommittee for inviting me to testify on the important issue that is the subject of today's hearings.

From 1999 to 2001, I served as Justice Department's Principal Deputy Associate Attorney General. Included within my portfolio of responsibilities were several counterterrorism projects concerning both law enforcement and public health policy, including organizing the first nationwide counter terrorism field exercise, "TOPOFF I."

I now serve as a Law School Professor at the University of Maryland School of Law and, since May 2002, as the Director of the University of Maryland Center for Health and Homeland Security.

At the School of Law, I have designed and teach two courses focused on legal and public policy issues concerning counterterrorism: (1) "Homeland Security and the Law of Counterterrorism," which addresses the legal framework surrounding the response to the terrorist threat facing the United States, including the Project BioShield Act of 2004; (2) "Homeland Security—The Interdisciplinary Study of Crisis and Health Consequence Management Policy in the Era of Counterterrorism" which is open to students from all of the University of Maryland professional schools and explores public health policy implications of counterterrorism strategy, including the development of a stable biodefense vaccine industry.

The University of Maryland Center for Health and Homeland Security (CHHS) serves as an advisor on public health emergency planning to various state and local agencies. CHHS also works closely with: (1) the Center for Vaccine Development (CVD) at the University of Maryland School of Medicine, which is the only university vaccine center in the world engaged in the full range of vaccinology: from basic science through vaccine development, clinical evaluation and field studies, including groundbreaking work on biodefense vaccines; and (2) the Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases (MARCE), one of eight Regional Centers of Excellence (RCE) funded by the National Institute of Allergy and Infectious Diseases (NIAID). MARCE is headed by Dr Myron Levine, the director of CVD. MARCE is now in the process of researching and developing new biodefense vaccine products to be used as prophylaxis against a broad array of biological agents.

Through CHHS's work with CVD and MARCE, CHHS has organized symposia¹ and I have written several articles² addressing the substantial economic, regulatory, and legal roadblocks to creating biodefense vaccines.

One of the bright milestones toward the development of a vibrant biodefense vaccine industry was the passage of the Project BioShield Act of 2004. That statute was designed "to provide protections and countermeasures against chemical, radiological, or nuclear [CBRN] agents that may be used in a terrorist attack against the United States."³ The most prominent parts of that legislation were its procurement provisions designed to address the key significant impediment to biodefense vaccine production, lack of a significant market.⁴ These provisions encourage the development of effective vaccine countermeasures by establishing a Special Reserve Fund of \$5.6 billion to be spent over the next ten years to purchase for the Nation's Strategic National Stockpile (SNS) the "next generation of countermeasures against" a broad array of chemical, biological, radiological, and nuclear agents, all of which were seen by Congress as weapons that could be deployed against the United States in the War on Terror.⁵ Due to the substantial expense and risk of bringing a vaccine to market, along with the infrequency with which these diseases occur naturally, phar-

¹ Symposium, *Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development*, at the University of Maryland School of Law, June 9, 2004.

² Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7 (2005) (hereinafter Greenberger, *800 Pound Gorilla*); Michael Greenberger, et al., *The Threat of Smallpox: Eradicated but not Erased*, J. HOMELAND SEC., Feb. 2004, <http://www.homelandsecurity.org/journal/Articles/displayarticle.asp?article=103>; ELIN GURSKY & MICHAEL GREENBERGER, ANSER INSTITUTE FOR HOMELAND SECURITY, INSTITUTE COMMENTARY: SUPPOSE THEY GAVE A CIVILIAN SMALLPOX VACCINATION PROGRAM—AND (ALMOST) NOBODY CAME? (Feb. 20, 2004), http://www.homelandsecurity.org/Hls/commentary/gursky_smallpox_commentary_20feb04.html.

³ Project BioShield Act, Pub. L. 108-276, 118 Stat 835 (2004).

⁴ Frank Gottron, *Project BioShield*, CRS REP. NO. RS21507 (Updated December 27, 2004), at 1.

⁵ United States Department of Health and Human Services, HHS Fact Sheet—Project BioShield, July 21, 2004, <http://www.hhs.gov/news/press/2004pres/20040721b.html>

maceutical manufacturers have little to no incentive to invest without BioShield funds.⁶

In order for the BioShield Special Reserve Funds to be released for the purchase of a countermeasure for SNS, a series of actions must occur.⁷ However, the first action (and the one on which all later actions are based) is that “the Homeland Security [DHS] Secretary, in consultation with the [HHS] Secretary and the heads of other agencies as appropriate,” must make a “determination” of “current and emerging threats of CBRN agents” that “present a material threat against the United States. . . .”⁸ Once that “material threat assessment” is made various government agencies, up to and including, the President, through a series of decisions then determine whether promising countermeasures may be purchased with the special reserve funds to address those identified threats.⁹

The BioShield Act established no procedure for DHS to employ in supervising the making of the material threat determinations. Despite what was an obvious Congressional invitation to summarily determine what are the widely recognized CBRN threats to the United States, DHS has employed an opaque, highly bureaucratized, relatively lengthy process for determining material threats. Over the course of the past year, this cumbersome and poorly delineated administrative process has led to only four material threat determinations. Findings have been made that Anthrax, Smallpox, Botulinum toxin and radiological/nuclear devices pose a material threat to the United States. DHS officials have promised that by the close of this fiscal year material threat determinations will be made concerning plague, tularemia, and viral hemorrhagic fevers.¹⁰

Because there have only been material threat determinations pertaining to four CBRN agents, BioShield’s Special Reserve funds can only be used for countermeasures directed to those agents. Accordingly, three contracts have been let over this last year, two directed to the purchase of anthrax vaccines¹¹ and one for the delivery of pediatric doses of liquid potassium iodide.¹² Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would not be eligible for procurement if there were no corresponding finding that the agent to which it was directed was a “material threat.”

DHS’s lassitude in supervising the making of material threat findings is mystifying. The legislative history of the statute is replete with references to a myriad of agents, beyond the four agents identified, posing a substantial threat to the United States.

Moreover, the Center for Disease Control (CDC) has a long established and widely recognized hierarchy of highly damaging biological agents that are likely to be deployed by terrorists against the United States. CDC’s Category A agents, ranked as the most dangerous to the United States, include Anthrax, Botulism, Plague, Smallpox, Tularemia, and Viral hemorrhagic fevers. Only three of those agents have as yet been identified under the BioShield bureaucracy as posing a material threat. DHS has assured committees of Congress that it will by the end of this fiscal year make findings on the remaining three Class A agents identified by CDC.

When you look at the Category B and C agents identified by CDC, there are total of more than 33 agents which ultimately will need to be addressed with medical

⁶*BioShield: Countering the Bioterrorist Threat: Hearing Before the House Select Committee on Homeland Security*, 108th Cong. (May 15, 2003) (statement of Alan Pemberton, Pharmaceutical Research and Manufacturers of America), available at http://www.globalsecurity.org/security/library/congress/2003_h/5-15-03_pharmaceutical.pdf; Frank Gotron, *Project BioShield*, CRS REP. NO. RS21507 (Updated December 27, 2004), at 1–2.

⁷Project BioShield Act of 2004, Pub. L. 108–276, § 3(a)(2), 118 Stat. 835,843–52 (2004); United States Department of Health and Human Services, Procurement Items—BioShield Funds, March 23, 2005, <http://www.hhs.gov/ophep/bioshield/bioshieldfunds.html>.

⁸Project BioShield Act of 2004, Pub. L. 108–276, § 3(a)(2), 118 Stat. 835, 844 (2004).

⁹Project BioShield Act of 2004, Pub. L. 108–276, § 3(a)(2), 118 Stat. 835, 843–48 (2004); United States Department of Health and Human Services, Procurement Items—BioShield Funds, March 23, 2005, <http://www.hhs.gov/ophep/bioshield/bioshieldfunds.html>.

¹⁰*Combating Weapons of Mass Destruction: Hearing Before the Subcommittee on National Security, Emerging Threats, and International Relations of the H. Comm. Of Government Reform*, 109th Cong. (June 15, 2005) (testimony of Dr. John Vitko, Jr., Director, Biological Countermeasures Portfolio, Science and Technology Directorate, Department of Homeland Security), available at <http://reform.house.gov/UploadedFiles/ST.Govt%20Ref.Vitko.06-14-05.pdf>.

¹¹ Press Release, United States Department of Health and Human Services, HHS Buys New Anthrax Vaccine for Stockpile (Nov. 4, 2004), <http://www.hhs.gov/news/press/2004pres/20041104a.html>; Press Release, United States Department of Health and Human Services, HHS Awards BioShield Contract for AVA Anthrax Vaccine (May 6, 2005), http://communitydispatch.com/artman/publish/article_961.shtml.

¹² Press Release, United States Department of Health and Human Services, HHS Awards BioShield Contract for Liquid Potassium Iodide (March 18, 2005), <http://www.hhs.gov/news/press/2005pres/20050318.html>.

countermeasures.¹³ At the rate the “material threat” findings have been made to date, it could be years before BioShield procurement funds can be used to purchase products designed to counter the as yet undesignated agents.

Leaving CDC’s findings to the side, scholarship on terrorist threats abound with long standing and well recognized findings about a significant number of CBRN agents likely to be deployed against the United States. For example, Jessica Stern in her 1999 classic, *The Ultimate Terrorists*, lists two dozen chemical agents that have been historically deployed by terrorists going all the back to World War I.¹⁴ Not one of these chemical agents has been certified under DHS’ leadership. Nor has DHS even committed to making such designations in the future.

Quite ironically, under other provisions of the BioShield statute concerning HHS funding for research (which does not require a “material threat” finding), grants have been made for the development of countermeasures relating to tularemia, Ebola, and plague.¹⁵ Yet, none of these agents has yet been designated as a material threat. If HHS has already commenced funding for research in this area, one would assume that there is substantial evidence available to DHS demonstrating that these agents should be so designated.

From CHHS own experience, substantial NIH funding outside of the BioShield appropriations is being committed to the development of medical countermeasures not yet declared to be “material threats”. For example, MARCE is researching countermeasures for tularemia as part of a five-year, grant from NIAID, which is supported by funding wholly apart from monies appropriated under the BioShield statute.¹⁶ Simultaneously, plague vaccine research is being performed in the laboratories of James Nataro, M.D. at the CVD that is funded by funded by a National Institutes of Health U19 grant,¹⁷ again a project being done wholly apart from the BioShield Act.

The BioShield Act is an impressive starting point for the creation of a vibrant bio-defense vaccine industry. It has many problems that must be corrected both administratively and legislatively.¹⁸ I would be happy to address each of those issues with you today. However, only one of those problems deals directly with DHS, the agency over which you have direct oversight responsibilities. DHS bureaucratic quagmire in identifying CBRN agents posing a material threat to the United States (thereby delaying the use of procurement efforts for well recognized CBRN dangers to this country) is a matter that deserves your full attention.

This problem does not require a legislative fix. What it requires is prodding the agency to abandon an administrative morass. It requires directing the agency to follow the well worn path already trodden through scholarship and the work of the CDC to quickly list the full panoply of CBRN agents. Such an expedited effort would be an encouragement to both researchers and the vaccine industry that a broad array of efforts might be funded over the next decade by the BioShield Special Reserve Fund.

Finally, this subcommittee should be aware that the legislation recently introduced as a corrective to the Bioshield Act (S. 975, or the Project Bioshield II Act of 2005) places the major procurement responsibility principally in the hands of DHS, reducing substantially the role of HHS.¹⁹ This displacement of HHS is supposedly called for because industry supporters of Bioshield II view “HHS as having a contentious relationship with the biopharma industry.”²⁰ However, given the dif-

¹³ CDC, Bioterrorism Agents/Diseases (Nov. 19, 2004), <http://www.bt.cdc.gov/agent/agentlist-category.asp>.

¹⁴ JESSICA STERN, *THE ULTIMATE TERRORISTS* 24–25 (1999).

¹⁵ Press Release, United States Department of Health and Human Services, NIH News, NIAID Awards First \$27 Million Using New Bioshield Authorities (May 9, 2005), <http://www.nih.gov/news/pr/may2005/niad-09.htm>.

¹⁶ Virginia Bioinformatics Institute, Mid-Atlantic Regional Center of Excellence, <https://www.vbi.vt.edu/article/view/426>.

¹⁷ Center for Vaccine Development, University of Maryland School of Medicine, Nataro Lab, <http://medschool.umaryland.edu/cvd/natarolab/natarolab.html>

¹⁸ For a complete description of the problems with implementing the BioShield statute, see *Crossing the Valley of Death: Bringing Promising Medical Countermeasures to BioShield: Hearing Before the Senate Health, Education, Labor and Pensions Subcommittee on Public Health*, 109th Cong. (June 9, 2005) (statement of Dr. Phillip Russell, Major General, Retired, U.S. Army), http://help.senate.gov/testimony/t319_tes.html. I agree with almost all of Dr. Russell’s assessments. For a proposal to resolve indemnification problems identified by Dr. Russell and others, see Greenberger, *800 Pound Gorilla*, *supra* note 2.

¹⁹ ARNOLD & PORTER, LLP., CLIENT ADVISORY: “BIOSHIELD II” BILL WOULD EXPAND INCENTIVES TO DEVELOP BIODEFENSE COUNTERMEASURES 1 (May 2005), [http://www.arnoldporter.com/pubs/files/A&PAdvisory-BioshieldII\(0505\).pdf](http://www.arnoldporter.com/pubs/files/A&PAdvisory-BioshieldII(0505).pdf).

²⁰ *Id.* at 2.

faculties DHS has had with effectively carrying out its single major mission under the existing legislation, Congress should think long and hard before it puts the entire biodefense vaccine apparatus under DHS.

TESTIMONY SUMMARY

The Department of Homeland Security has employed an opaque, highly bureaucratized, and lengthy process under the Project Bioshield statute for determining those chemical, biological, radiological and nuclear (CBRN) agents which pose “material threats” to the United States. BioShield’s Special Reserve funds can only be used for countermeasures directed to those agents designated by DHS as material threats. DHS’s decision-making apparatus has to date only made material threat determinations pertaining to four CBRN agents. It is well understood both within the Center for Disease Control and in the scientific research community that there are as many a 60 agents that now pose a “material threat.” Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would not be eligible for procurement because of a lack of a material threat finding. At the rate the “material threat” findings have been made to date, it could be years before funds will be eligible to purchase products designed to counter those as yet undesignated agents. Moreover, the delay in recognizing agents as a material threat amounts to a disincentive to both researchers and the vaccine industry to devote resources to CBRN agents that are not as yet designated as material threats.

~~Mr. KING. The Chair now recognizes Dr. Richard Hollis, the chief executive officer of Hollis Eden Pharmaceuticals.~~

STATEMENT OF RICHARD B. HOLLIS

~~Mr. HOLLIS. Thank you, Mr. Chairman, members of the committee. My name is Richard Hollis. I am chairman of Hollis Eden Pharmaceuticals, the manufacturer of a product called NEUMUNE. It is the first drug that is specifically being developed as a medical countermeasure to acute radiation syndrome, commonly referred to as radiation sickness, as a result of nuclear terrorism.~~

~~And I also ask that I please have my entire statement entered into the record.~~

~~Mr. KING. Without objection.~~

~~Mr. HOLLIS. All of our Nation’s leaders from the President on down have concluded that the greatest threat to our Nation is nuclear proliferation and nuclear materials in the hands of a terrorist. The head of the Domestic Nuclear Detection Office recently said there is a 100 percent chance someone will try to attack the U.S. with a nuclear weapon in the next 5 to 10 years. Also, in a recent televised interview the Chairman and Vice Chairman of the 9/11 Commission both stated that not only is a nuclear detonation in one or more of our inner major cities possible, but it is also probable.~~

~~Imagine what would happen if a small nuclear bomb went off in Washington, New York, or Los Angeles, a bomb similar to the mockup that Congressman Weldon uses to demonstrate how small these devices actually are. The death toll from the detonation of a relatively small nuclear device in one or more of our major cities would be devastating. Medical reports indicate the vast majority of those who are killed, hundreds of thousands would die from acute radiation syndrome, also known as ARS.~~

~~When humans are exposed to radiation injury, the bone marrow is incapacitated, and it doesn’t have the ability to produce red blood cells that carry oxygen, platelets that help fight blood clots, and~~