



ASPR

EVOLUTION OF U.S. BIODEFENSE POLICY

*Dr. Robert Kadlec, ASPR
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George Mason University*

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WHAT IS BIODEFENSE ?

Actions to counter biological threats, reduce risks, and prepare for, respond to, and recover from bioincidents.

U.S. National Biodefense Strategy

September 18, 2018

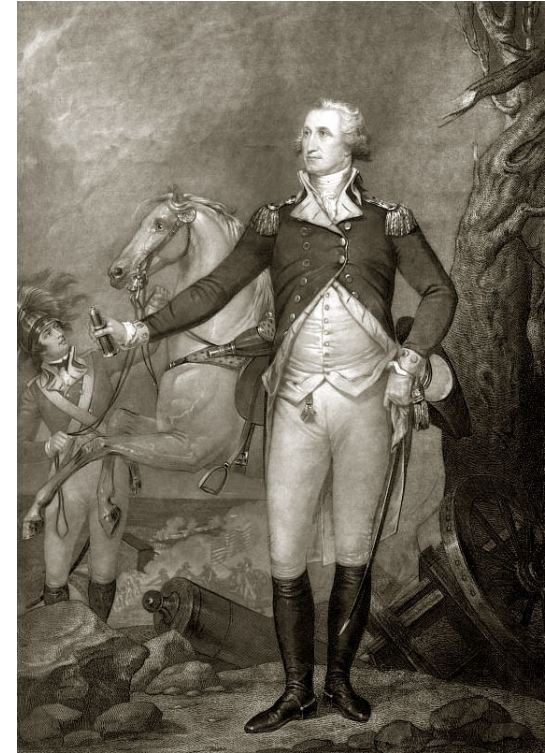
What are “Bioincidents”?

1. Any act of biological warfare or terrorism
2. A crime involving a biohazard
3. Any natural or accidental occurrence in which a biohazard harms humans, animals, plants or the environment.

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1st President to Institute a Biodefense Policy

- 90–95% of New World native population died from Old World diseases (smallpox #1)
- 1763: French Indian Wars
 - British military tried spreading smallpox
- 1777-78: American Revolutionary War
 - Smallpox killed at least 130,000 North Americans
 - General George Washington ordered “variolation” of the Continental Army



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1943: FDR Established U.S. Offensive & Defensive BW Effort



FDR Started It All With a Bluff
*U.S. Response to Axis use of poisonous
gases*

“to any perpetrators full and
swift retaliation in kind”

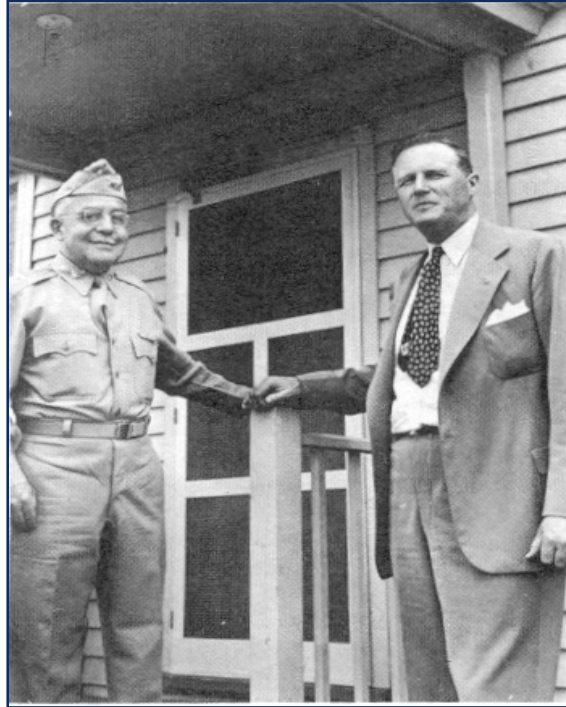
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The Father of U.S. WMD—Nuclear



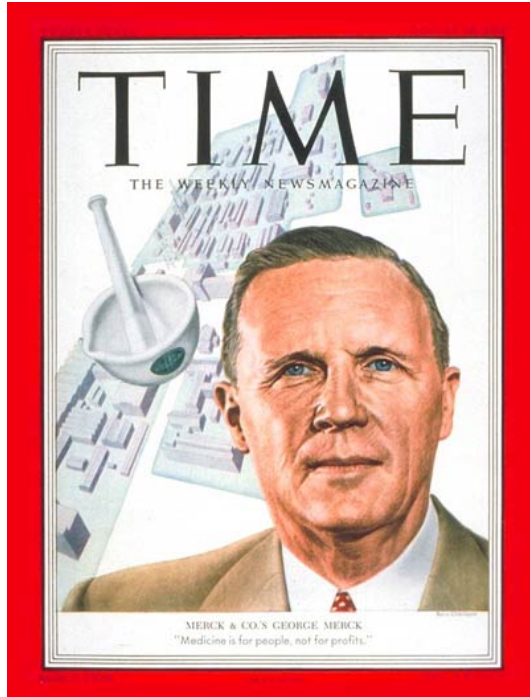
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The Father of U.S.WMD—Biological



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George Merck's Unfulfilled Mission



"The value of biological warfare will be a debatable question until it has been clearly proven or disproven by experience"

"While it is true that BW is still in the realm of theory rather than fact...this type of warfare cannot be discounted by those who are concerned with the national security"

*Report to the Secretary of War
January 3, 1946*

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1950's: Ike Moves the Ball....Forward



Feb 18 1960: Eisenhower NSC meeting
“Advances in chemistry & biology may permit “controlled temporary incapacitation” that “might open a new dimension of warfare” in situations “short of all-out war” and “where nuclear weapons was not possible or feasible”.

“The President said one great difficulty occurred to him in connection with the use of incapacitating agents. While the use was a splendid idea, if we tried to use them in a humane manner,... our enemy would proceed in retaliation with lethal CW and BW weapons.”

- **1950:** U.S. policy undertakes gas warfare only in retaliation
- **1954:** Dugway Field Trial demonstrating the ability to infect troops in simulated combat environment
- **1956:** Soviet Field Marshall Zhukov states CW & BW would be used in future wars
- **1956:** U.S. policy revised prepared to use CW & BW to the extent that such use will enhance the military effectiveness of the armed forces, the decision for use will be made by the President
- **1957:** RAND/DSB Study on BW
- **1958** (Jun-Jul) PSAC recommends expanding BW program

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1959: Demonstration of Large Area Coverage (LAC): Delivering Primary Aerosols Against Military & Civilian Populations

1959 Summary of Major Events & Problems US Army Chemical Corps

(C) The contract proved that airborne BW attacks could be carried out at low levels, and that a properly designed spray system could contaminate 50,000 square miles with BW aerosol in a single sortie. The significance of this lies in the remarkable efficiency of this means of attack. For example, on a night when the wind was blowing ten miles per hour, three large aircraft, each carrying 4,000 gallons of liquid BW agent, and flying at a speed of 500 knots, could spray an area of 150,000 square miles, causing more than half the people in the area to become ill.¹⁷²

*The effectiveness & coverage increased dramatically with dry agents
Focus on using cruise missiles, drones/UAV for BW LAC &
Role for Special Forces*

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How Good was the Science?



“Played an extremely important role in the establishment of Ft Detrick, not through the formal organization always, but through its members”

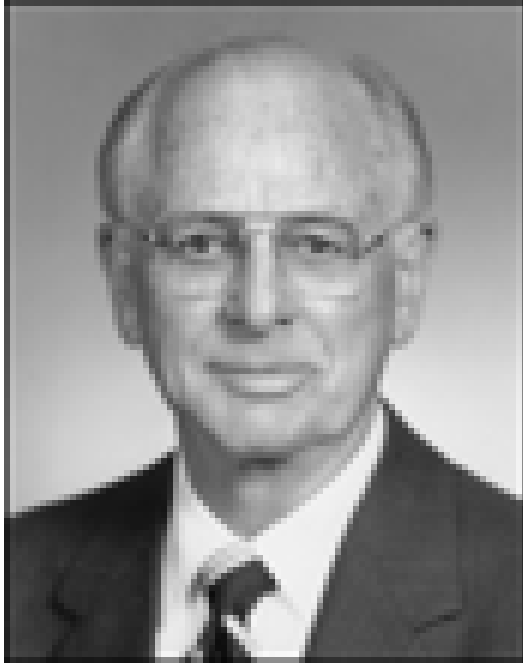
- 10 ASM(SAB) Presidents served at Ft Detrick, 10 others served as consultants or contractors.
 - Dr Ira Baldwin notable bio-fermentation expert 1st technical director of the WWII BW program
- 1942: Society of American Bacteriology “War Committee on Bacteriology”
- 1951: Ad Hoc Committee on Biological Warfare (Civil Defense) formed
- 1955: Advisory Committee to the Chemical Corps (Ft Detrick) established to provide “scientific & professional advice”
 - Addressed “problems” has no responsibilities regarding the “moral, political, or military aspects of BW”
 - Providing the Technical Director an evaluation of planning, execution, analysis & interpretation of scientific projects.”
- 1968: Advisory Committee dissolved

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Dr. Riley Housewright

President, American Society of Microbiology 1965-1966

Fort Detrick Technical Director 1956-1970



From Interview Dec 12-14 1995

“Our job was to translate it [policy] into reality.”

Ft Detrick developed offensive & defensive BW from “scratch” & none of it *“had ever been done on the scale we’re talking about.”*

Main mission: *“develop BW defensive methods and devise means for offensive retaliation in case of BW attack on U.S.”*

Retaliation in kind meant *“why we had to go to large scale production.”*

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Strategic Policy Objectives

More Than “*Nuclear Equivalence*”

Strategic Deterrence

Lethal agents:

- Tularemia: multi-antibiotic resistant & vaccine resistant
- Anthrax: multi-antibiotic resistant
- Plague: multi-antibiotic resistant

Enhanced War-fighting

Rapid acting incapacitating agents:

- Staphylococcal enterotoxins
- Venezuelan equine encephalitis
- Q Fever
- Brucellosis
- Tularemia—non-lethal strain



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Incapacitants preferred in Low Intensity Conflict when friendlies & hostiles are

mixed together & against those who could not retaliate in kind or escalate.

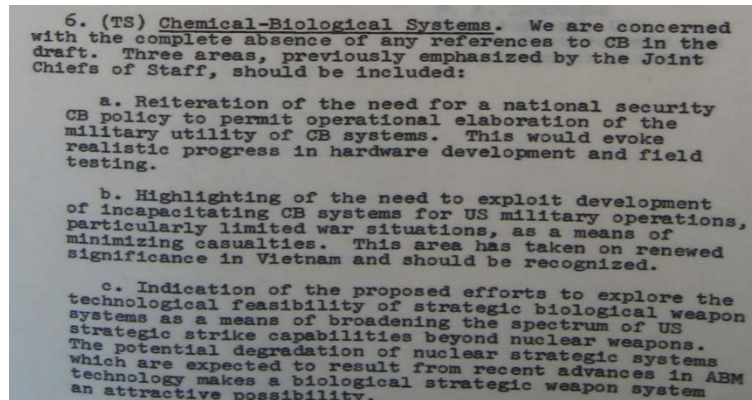
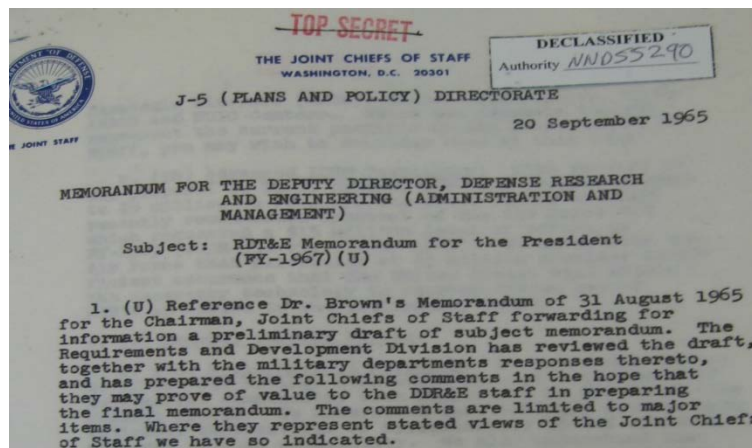
Saving Lives. Protecting Americans.

Operational Objective:

“Confound Diagnosis & Frustrate Treatment”

- **Highly virulent organisms**
 - Non-endemic diseases
- **Non-natural routes of exposure**
 - “Primary aerosols” 1-5 micron particles
- **Overwhelming doses**
 - Shorten incubation period
 - Overwhelm immunity
- **Resistance to conventional treatments** Multiple antibiotic resistance
- **Coagents & Combination of agents**

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1965: JCS Strategic Calculus

“The potential degradation of nuclear strategic systems which are expected to result from recent advances in ABM (Anti-Ballistic Missile) technology makes a biological strategic weapons system an attractive possibility.”

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LBJ: The Beginning of the End



- 1963-1968: 7 Large Area Coverage (LAC) Atmospheric tests
 - 1963 Nuclear Test Ban Treaty
 - 1965: *Shady Grove*: liquid tularemia
 - 1966: *Red Cloud*: Dry powdered tularemia
 - 1968: *Speckled Start*: Dry SEB
- 1960's Covert Vulnerability BW tests
- 1968: Signs Defense Planning Memorandum terminating lethal BW program

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Which President Issued Executive Order 11490?

Richard M. Nixon October 1969

WHEREAS our national security is dependent upon our ability to assure continuity of government, at every level, in any national emergency type situation that might conceivably confront the nation; and

WHEREAS effective national preparedness planning to meet such an emergency, including a massive nuclear attack, is essential to our national survival; and

WHEREAS effective national preparedness planning requires the identification of functions that would have to be performed during such an emergency, the assignment of responsibility for developing plans for performing these functions, and the assignment of responsibility for developing the capability to implement those plans; and

SEC. 1103 Health Functions.

The Secretary of Health, Education, and Welfare shall:

Biological and chemical warfare. Develop and coordinate programs for the prevention, detection, and identification of human exposure to chemical and biological warfare agents as may be necessary to carry out the responsibilities involved in the provision of emergency health services, including the provision of guidance and consultation to Federal, State, and local authorities on measures for minimizing the effects of biological or chemical warfare.

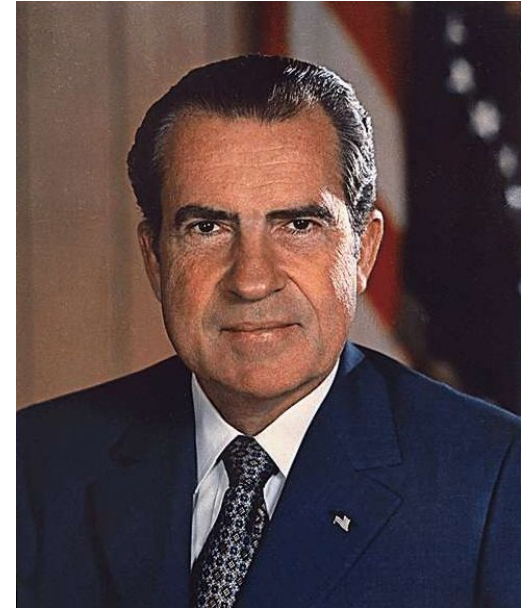
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President Nixon's Imprint: 1969 & 1970

National Security Decision Memorandums 35 & 44 Executive Order 11490

- Nixon opened the NSC debate with *“This is a difficult and unpleasant subject about which we have real little knowledge.”*
- Renounced lethal & incapacitating use bacteriological/biological & toxin agents.
- Recognized that some offensive work was needed “to give meaning to the defense aspect”
- Defensive research on develop immunizations and act as a hedge against technological surprise.

NSC Meeting November 1969



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Dr. Housewright's Summary of the U.S. Experience

NSSM-59: Technical Conclusions 21 May 1969

- BW is primarily **strategic** weapon: civilians & economic targets
 - It has “no quick kill effect”
 - Possibility of covering “very extensive target areas with agent”
- *It (BW) worked...too well*
 - “Results from field trials and the extrapolation of laboratory data provide credible indications that large areas can be covered effectively”
 - Limitation of BW is the “inability to confine the target effects with selected boundaries”
- *BW/BT are not natural diseases or events*
 - “BW is not natural but artificial. Large Area Coverage (LAC) will create new, different and unique epidemiological situation, one that is entirely different from normal or natural epidemic behavior....sudden exposure of all of the multitudinous fauna ..to an infectious aerosol would be new and unprecedented phenomenon.. (**Total ecologic threat**)”
- *Relying entirely on intelligence is the recipe for failure*
 - Effective defense cannot be built without an understanding of the weapons against which they are meant to protect...It is essential...to measure the offensive potential of [BW] agents” to develop effective defenses.

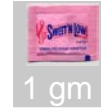
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The Challenge of Catastrophic Bioterrorism

Past Experience: 2001 Anthrax Attacks Current Concern: Aerosol Release



via letters



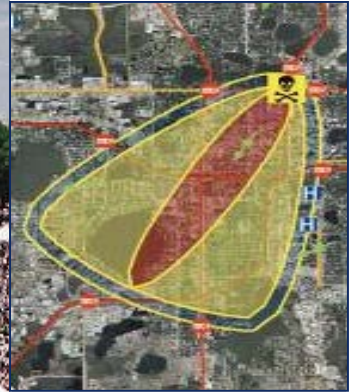
1 gm



Number that received antibiotic treatment	30,000
Number of illnesses	22
Number of deaths	5
Decontamination	3 Buildings
Direct Economic Cost	>\$1 B



1-2 kg



via cropduster

Number that will need antibiotic treatment	1.9-3.4 M
Number of illnesses	~450,000
Number of deaths	~380,000
Decontamination	City wide
Projected Economic Cost	>\$1.8 T

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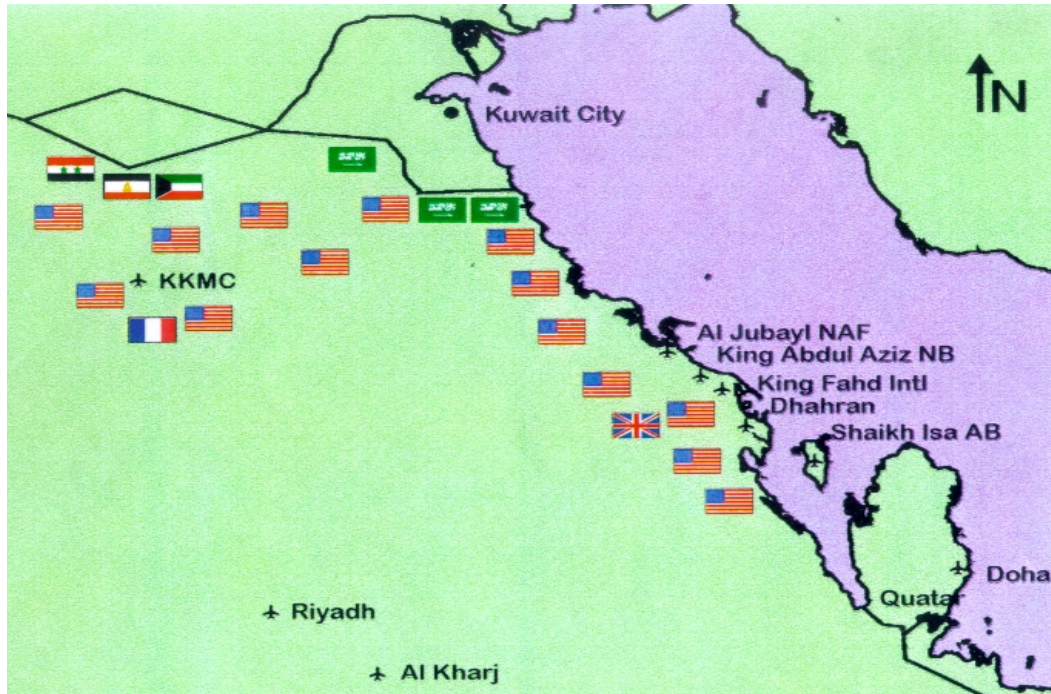
1990: Bush 41 & Near Miss



- Iraq “surged” BW production in March 1990
- Saddam gave release authority for BW use in Dec 1990
- BW weapons dispersed to auxiliary airfields
- U.S. military actions pre-empted their use

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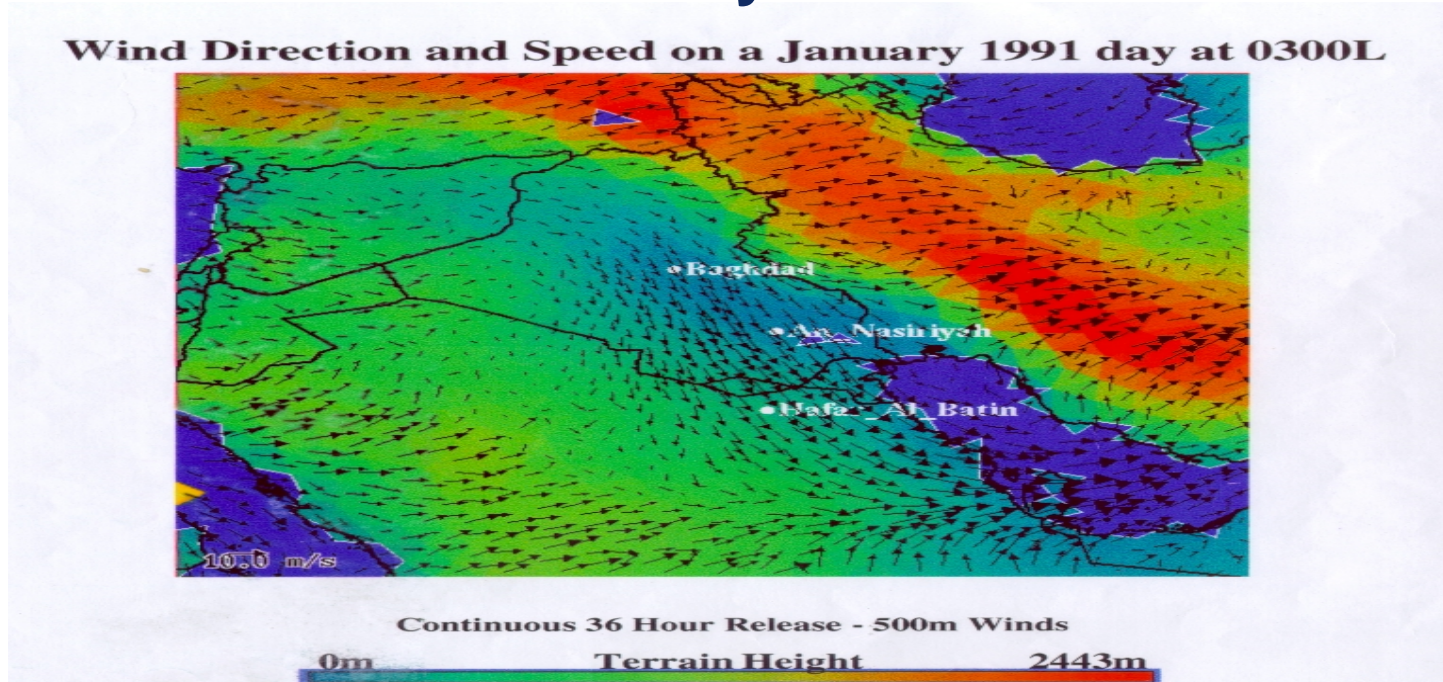
December 1990: Near Miss in the Middle East



Coalition Force Disposition: January 1991

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Prevailing Seasonal Atmospheric Conditions January 1991



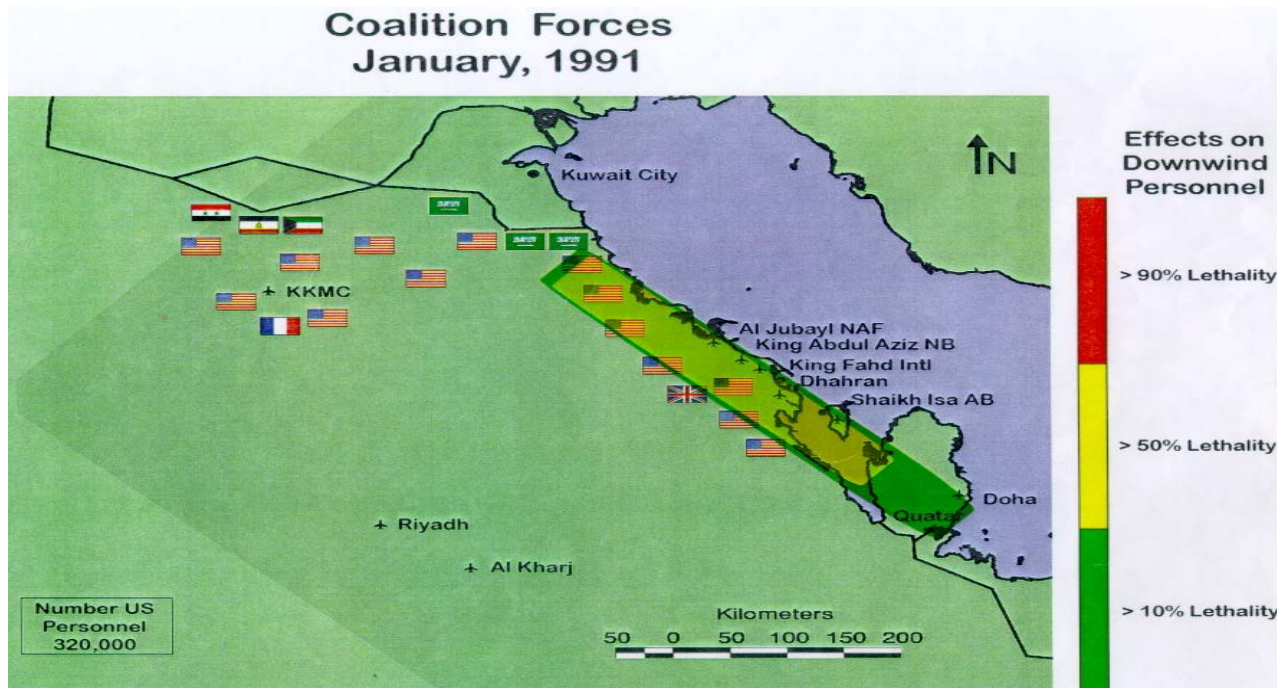
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Jan 1991 Gulf War Threat: Iraqi Aerial Dispersion of Anthrax Simulant



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Downwind Hazard Secondary to Line Source Release



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In 1993, Which President Said This?

“Terrorism is coming.....that in the future there will be terrorism with weapons of mass destruction. What prevents this technology from developing and people from smuggling it? All of this, before the stories of smuggling, before that, in 1989. I told... “in the future, what would prevent that we see a booby trapped car causing a nuclear explosion in Washington or a germ or a chemical one?”

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President Saddam Hussein's 1993 Prophecy

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1998: President Clinton: Rekindled U.S. BioDefense Efforts

- FSU “fallout,” impact of the Lederberg Letter & “Cobra Event”
- Increased diplomatic and military means abroad....increased preparedness at home
- Signed 3 Presidential Decision Directives (PDD): prevent, deter, or combat WMD
- Launched effort to train & equip 1st responders in 120 cities
- Directed \$300 M for preparedness
 - Improve biosurveillance
 - Create national stockpile of countermeasures



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Prior to 9-11, Which President Wrote This? Published 2000

I want to pass along a few more ideas about responding to bioterrorism that I've come across in my reading:

- We need to stockpile antibiotics in major population areas and train emergency workers to respond quickly to biological attack. Perhaps some of those people in the criminal justice system who are doing community service could learn emergency response.
- We need to develop and deploy sensors in major cities that will give us early warning that biological devices have been detonated. Remember, these microbes can take a while to spread, so any warning we have will help to save lives—perhaps tens of thousands of them.

- We need to keep a very close eye on former Soviet biotechnicians, offering them jobs where we can and steering them clear of terrorist regimes. Call your congressman. When private citizens start asking about the Joint Statement on Biological Weapons, politicians will know this is an issue they'd better start taking seriously.
- Prepare for the possibility of attack, to avoid total panic in case an attack does occur. Our adversaries understand that if they are able to blindside us they will be much more likely to succeed in blackmailing us.

★ ★ ★

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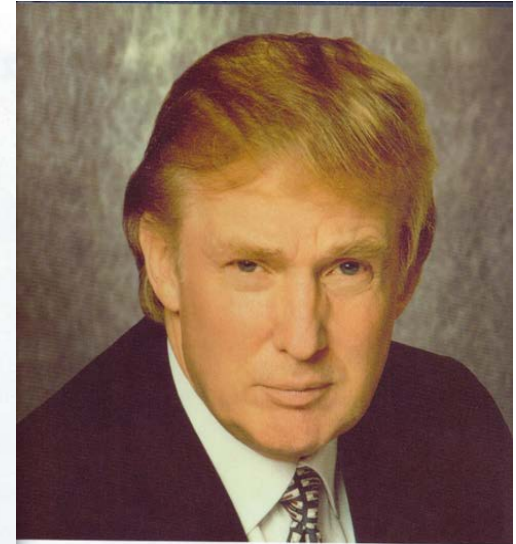
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FREEDOM FROM TERRORISM

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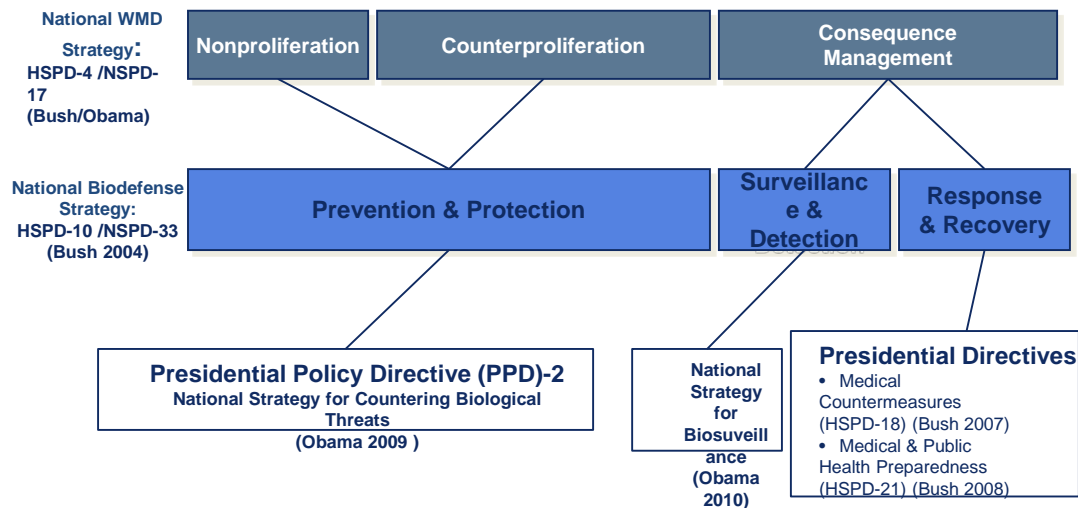
TRUMP
THE AMERICA WE DESERVE
WITH DAVE SHIFLETT

US Government Response: “Imperfect Incrementalism”

- Public Health Security and Bioterrorism Preparedness and Response Act Jan 2002
- White House (WH) National Smallpox Immunization Policy-Dec 2002
- Smallpox Emergency Personnel Protection Act-Jan 2003
- White House Homeland Security & National Security Presidential Directive 10/33 (HSPD-10 NSPD-33)-Apr 2004
- Project BioShield-Jul 2004
- White House National Strategy for Pandemic Influenza-Nov 2005
- Public Readiness and Emergency Preparedness Act-Dec 2005
- White House Pandemic Influenza Implementation Plan-May 2006
- Pandemic All Hazards Preparedness Act-December 2006
- White House HSPD-18 Medical Countermeasures Against Weapons of Mass Destruction 31 Jan 2007
- HHS Office of Public Health Emergency Medical Countermeasures (OPHEMC) Strategy 20 Mar 2007 and HHS OPHEMC Implementation Plan 20 Apr 2007
- White House HSPD-21 Public Health & Medical Preparedness Oct 2007
- White House Presidential Policy Directive (PPD) 2 Countering Biological Threats
- *Reauthorization of the Pandemic & All Hazards Preparedness Act 2013*
- National Biodefense Strategy 2018
- Reauthorization of the Pandemic and & All Hazards Preparedness Act 2018?

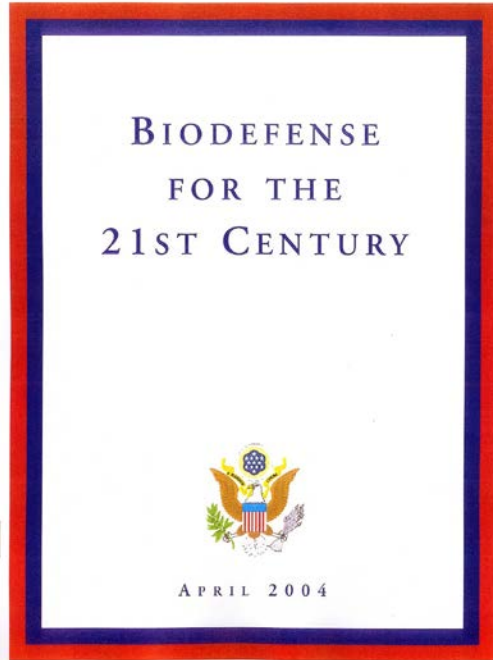
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WMD/Biodefense Strategy Mapping



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Homeland Security Presidential Directive-10



“Biological weapons in the possession of hostile states or terrorists pose unique and grave threats to the safety and security of the United States and our allies.”

- Could cause catastrophic numbers of acute casualties, long-term disease and disability, psychological trauma, and mass panic
- Disrupt critical sectors of our economy and the day-to-day lives of Americans
- Create cascading international effects by disrupting and damaging international trade relationships
- Advances in biotechnology and life sciences -- including the spread of expertise to create modified or novel organisms-- present the prospect of new toxins, live agents, and bioregulators

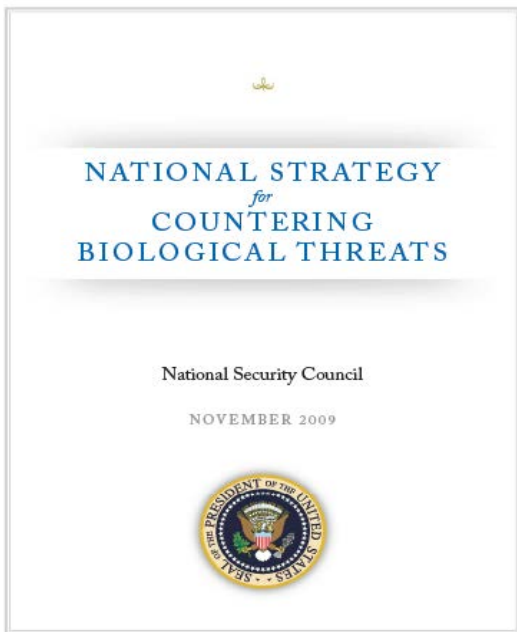
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HSPD-10 BioDefense Strategic Framework



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Presidential Policy Directive Two (PPD-2)



- Promote Global Health Security
- Reinforce Norms of Safe & Responsible Conduct
- Obtain Timely & Accurate Insight on Current & Emerging Risks
- Take Reasonable Steps to Reduce Potential for Exploitation
- Expand our Capability to Prevent, Attribute, & Apprehend
- Communicate Effectively with All Stakeholders
- Transform International Dialogue on Biological Threats.

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National Biodefense Strategy

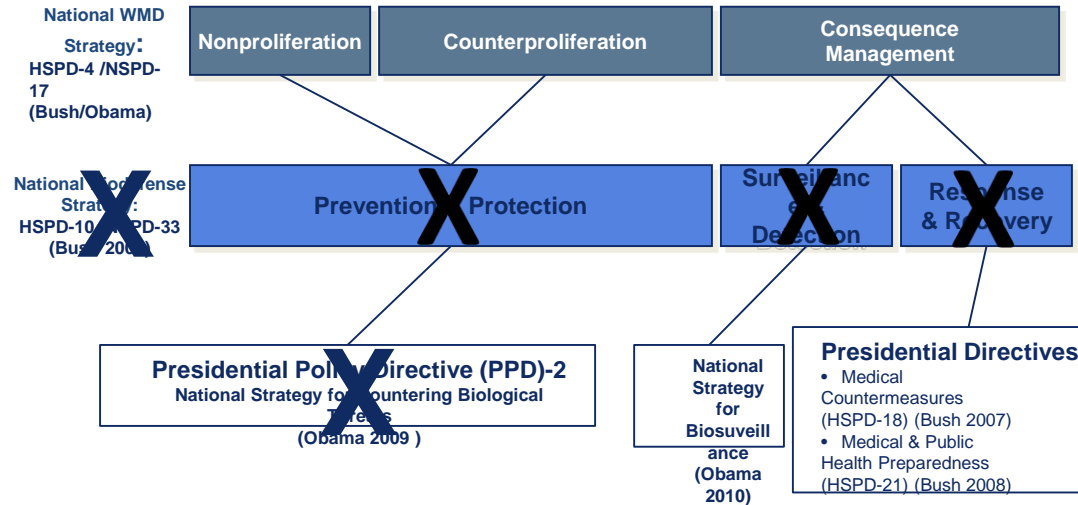
September 18, 2018

“It is a vital interest of the United States to manage the risk of biological incidents”



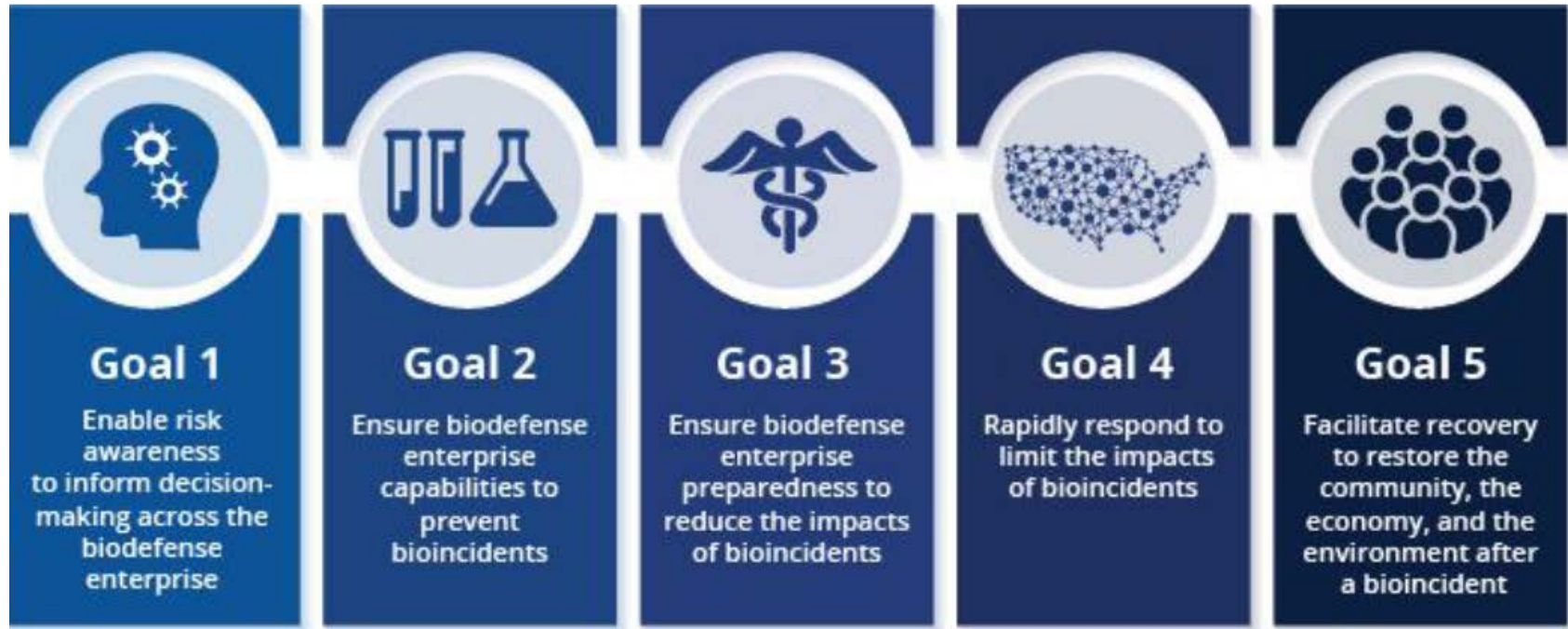
WMD/Biodefense Strategy Mapping: 2018 National Biodefense Strategy

*Replaces 2004 HSPD-10/NSPD-33 National Biodefense Policy (President George W. Bush)
2009 PPD-2 Countering Biological Threats (President Barack Obama)*



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National Biodefense Strategy Goals 2018



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Biodefense Enterprise Structure

