



# Medical Countermeasures and Public Health Emergencies

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**April 5, 2024**

# Disclosures

**Dale W. Bratzler, DO, MPH**

- I have no financial disclosures for this presentation.

# What do I want you to get from this talk?

- Recall the definition of medical countermeasures.
- Discuss the types of public health emergencies that are addressed through medical countermeasures.
- Describe the strategic national stockpile.
- Discuss ways the FDA accelerated development of medical countermeasures for the COVID pandemic.
- Describe the public-private partnership to accelerate the development of medical countermeasures.

- The magnitude-9.0 earthquake struck at 2:46 PM lasting approximately 6 minutes.
- It was the most powerful earthquake ever recorded in Japan, and the fourth most powerful earthquake recorded in the world since modern seismography began in 1900.
- The earthquake triggered powerful tsunami waves that may have reached heights of up to 133 ft in traveling at ~500 mph and up to 6 miles inland.
- It generated waves 11 to 12 feet high along the coasts of Hawaii. Several hours later 9-foot tsunami waves struck the coasts of California and Oregon in North America.
- The final death toll was approximately 20,000 with the great majority of deaths due to drowning from tsunami waves.



<https://www.youtube.com/watch?v=f9AcMn6ygq8>



**Fukushima Daiichi Nuclear Power Plant in 2007**

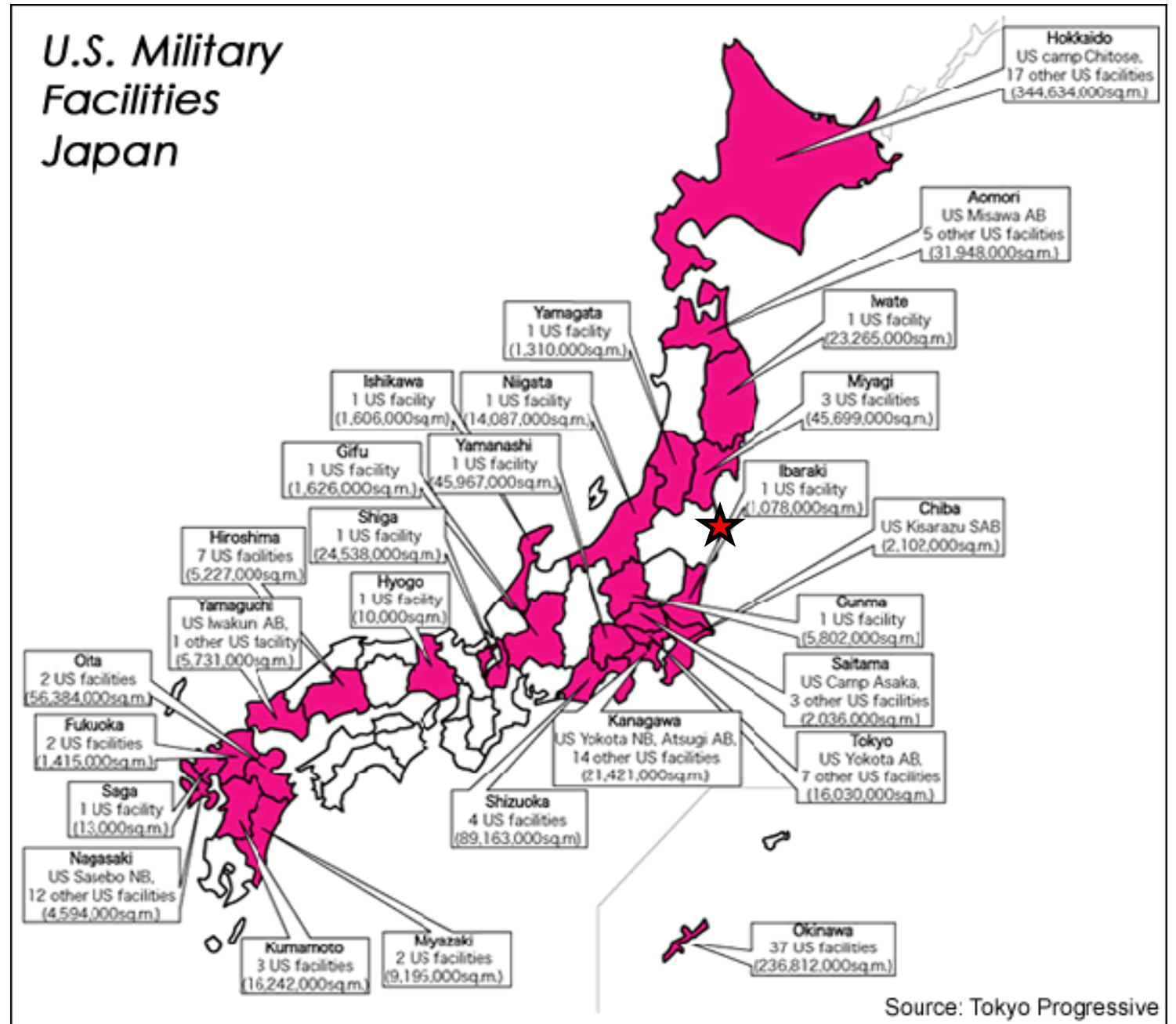
## **Fukushima Daiichi Nuclear Power Plant March 11, 2011**





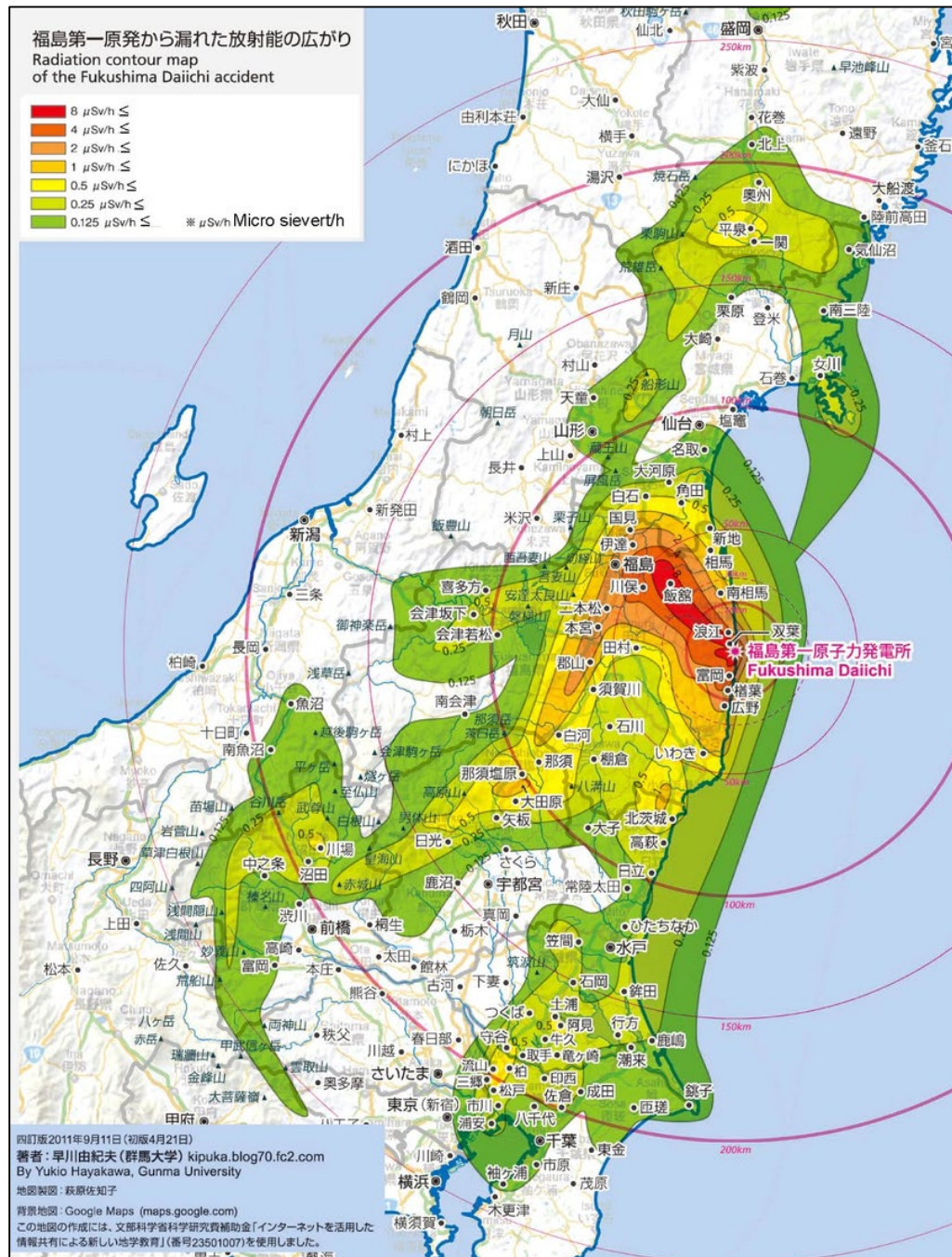
**Three of the reactors at Fukushima Daiichi overheated causing meltdowns that eventually led to explosions, which released large amounts of radioactive material into the air.**

***What were the implications for the US military of this disaster and what were the public health consequences?***



Source: Tokyo Progressive





***US military had to consider personnel evacuations at many US facilities.***

***Apparently did order the evacuation of all pregnant women in contamination zones.***

***Was more going to be necessary?***

# What are Medical Countermeasures?

# PUBLIC HEALTH EMERGENCY PREPAREDNESS (PHEP) PROGRAM

## WHAT ARE MEDICAL COUNTERMEASURES?

Medical countermeasures (MCMs) are medicines and medical supplies that can be used to diagnose, prevent, or treat diseases related to chemical, biological, radiological, or nuclear (CBRN) threats.

## MCMS CAN INCLUDE:



### **Biologic products:**

vaccines, blood products, and antibodies



### **Drugs:**

antimicrobial or antiviral drugs



### **Devices:**

diagnostic tests to identify threat agents and personal protective equipment (PPE)

Learn more: [www.cdc.gov/phpr/readiness](http://www.cdc.gov/phpr/readiness)



# Medical Countermeasures (MCMs)

- During a public health emergency, MCMs may be provided by the Strategic National Stockpile (SNS), which is overseen by the Administration for Strategic Preparedness and Response (ASPR), or through state and local stockpiles or other pharmaceutical caches.
- MCMs are usually dispensed or administered by health care workers and public health responders under official federal, state, and/or local emergency response plans.
- FDA may need to use special authorities to allow the use of such MCMs in impacted populations during or in anticipation of emergencies. (e.g., Emergency Use Authorization)

# Strategic National Stockpile (SNS)



- The SNS is the nation's largest supply of life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause state and local supplies to run out.
- Strategically stored in a network of warehouses across the country, stockpiled products are ready for rapid deployment to protect the U.S. population against 21st century health security threats, such as anthrax, botulism, smallpox, plague, tularemia and viral hemorrhagic fevers, as well as emerging infectious diseases, pandemic influenza, natural disasters, and other chemical, biological, radiological, and nuclear incidents.

## Public Health Emergency Medical Countermeasures Enterprise

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) contributes to the nation's preparedness for chemical, biological, radiological, and nuclear threats, as well as emerging infectious disease threats. It does so by enhancing timely availability and equitable use of effective medical countermeasures (e.g., vaccines, treatments, devices, personal protective equipment) to protect Americans from those threats.

The PHEMCE partners work to holistically inform the plans and actions that ensure the right balance of medical countermeasures and improve availability and use of those medical countermeasures during disasters and emergencies. Improving the capabilities also enhances the nation's ability to nimbly respond to unknown and unforeseen threats.



Functions, Goals, and Objectives



Strategy and Implementation Plan



Multiyear Budget 2023 - 2027



Capabilities, Threats, and Solutions

## Mission Statement

ASPR's mission is to assist the country in preparing for, responding to, and recovering from public health emergencies and disasters.



# What are the risks from a nuclear plant meltdown?

- The radioactive isotopes released in nuclear power plant accidents include iodine-131 (I-131), cesium-134 (Cs-134), and Cs-137. In the most severe kinds of accidents, such as the Chernobyl accident in 1986, other dangerous radioactive isotopes, such as strontium-90 (Sr-90) and plutonium-239, may also be released.
  - Possible external and internal contamination

# What does CDC advise us to do?

## In a radiation emergency:



Get Inside

Get inside a building and take shelter for at least 24 hours.



Stay Inside

Stay inside to reduce your exposure to radiation.



Stay Tuned

Stay tuned for important information about how to keep you and your family safe.

## Protect Yourself and Your Loved Ones



How to Self-Decontaminate



When to Evacuate



Radiation Injuries & Illness



Food and Drinking Water  
Safety in a Radiation  
Emergency



Radiation Contamination vs.  
Exposure

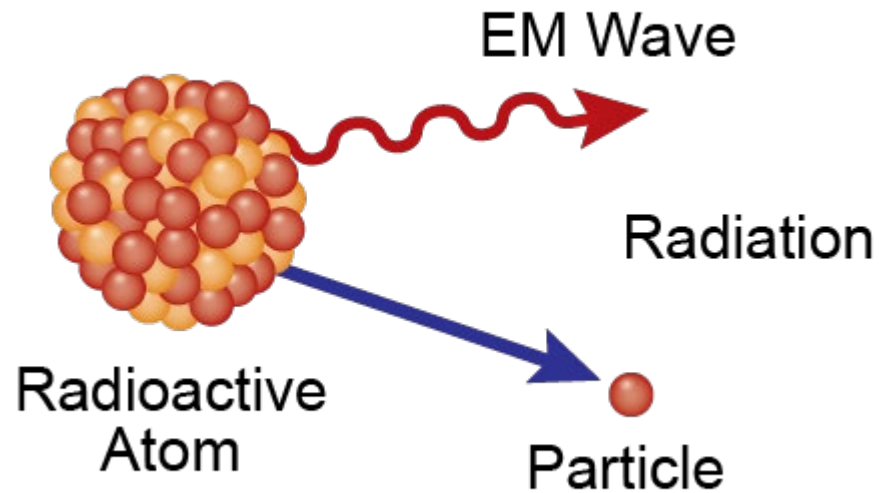


Infant Feeding and  
Pregnancy



# Exposure from nuclear accidents.

## Radioactive Decay of an Atom



*Source: Nuclear Regulatory Commission*

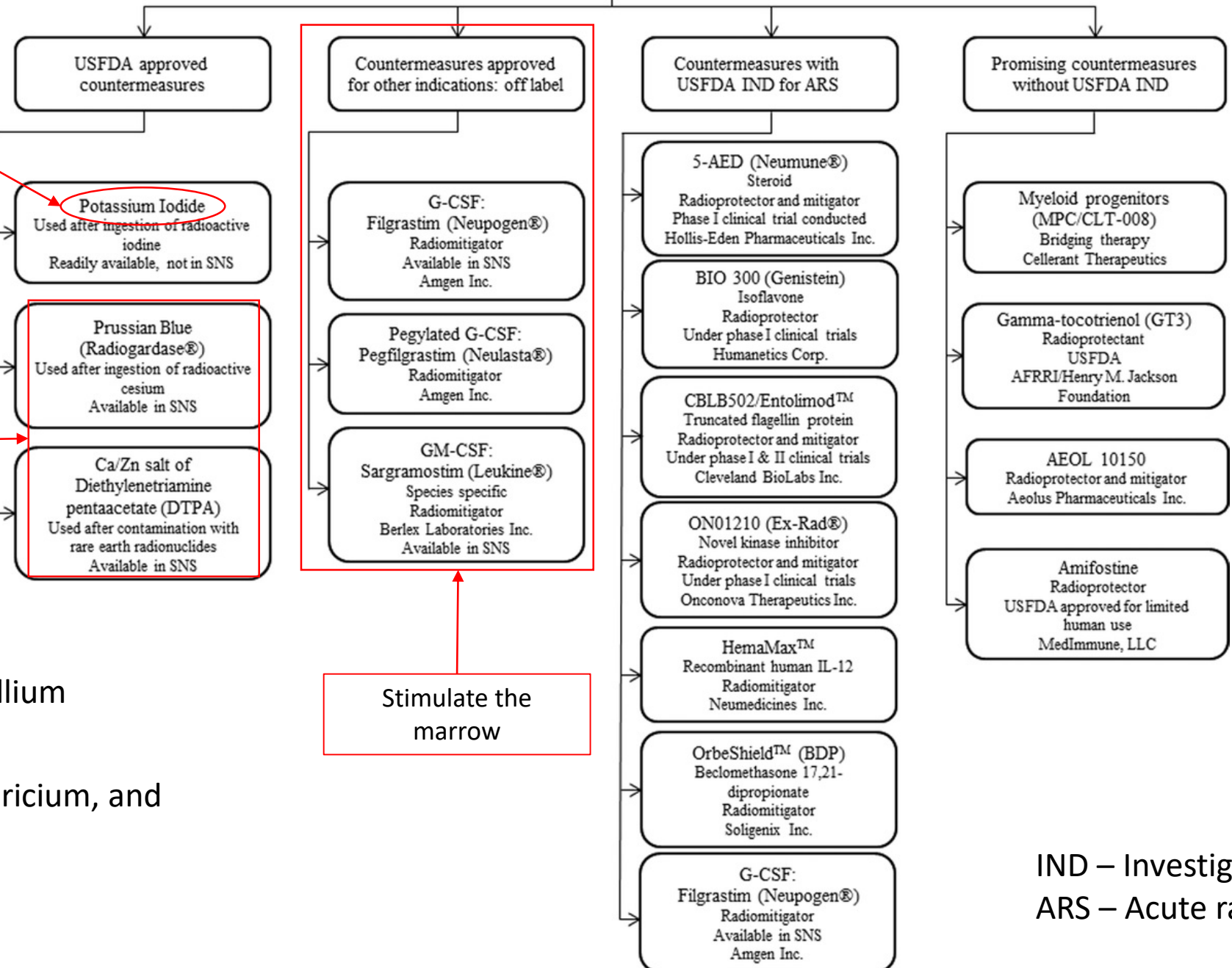
## Ionizing Radiation:

- Alpha particles
- Beta particles
- Neutrons
- X-rays
- Gamma rays

# Drug Countermeasures for Radiation Exposure

- Potassium iodide
- Drugs to enhance excretion of radioactive particles
- Drugs to stimulate bone marrow recovery
- New agents that may have radioprotective properties

**Current Radiation Countermeasures:  
USFDA Approved and Under Development**



Protect the thyroid

Enhance excretion

Stimulate the marrow

**Prussian Blue**  
- Cesium and thallium

**DTPA**  
- Plutonium, americium, and curium

IND – Investigational New Drug  
ARS – Acute radiation sickness

## Other sources of radiation accidents.



## Radiation Overdoses At Cedars-Sinai Prompt Investigation

OCTOBER 14, 2009 · 1:57 PM ET

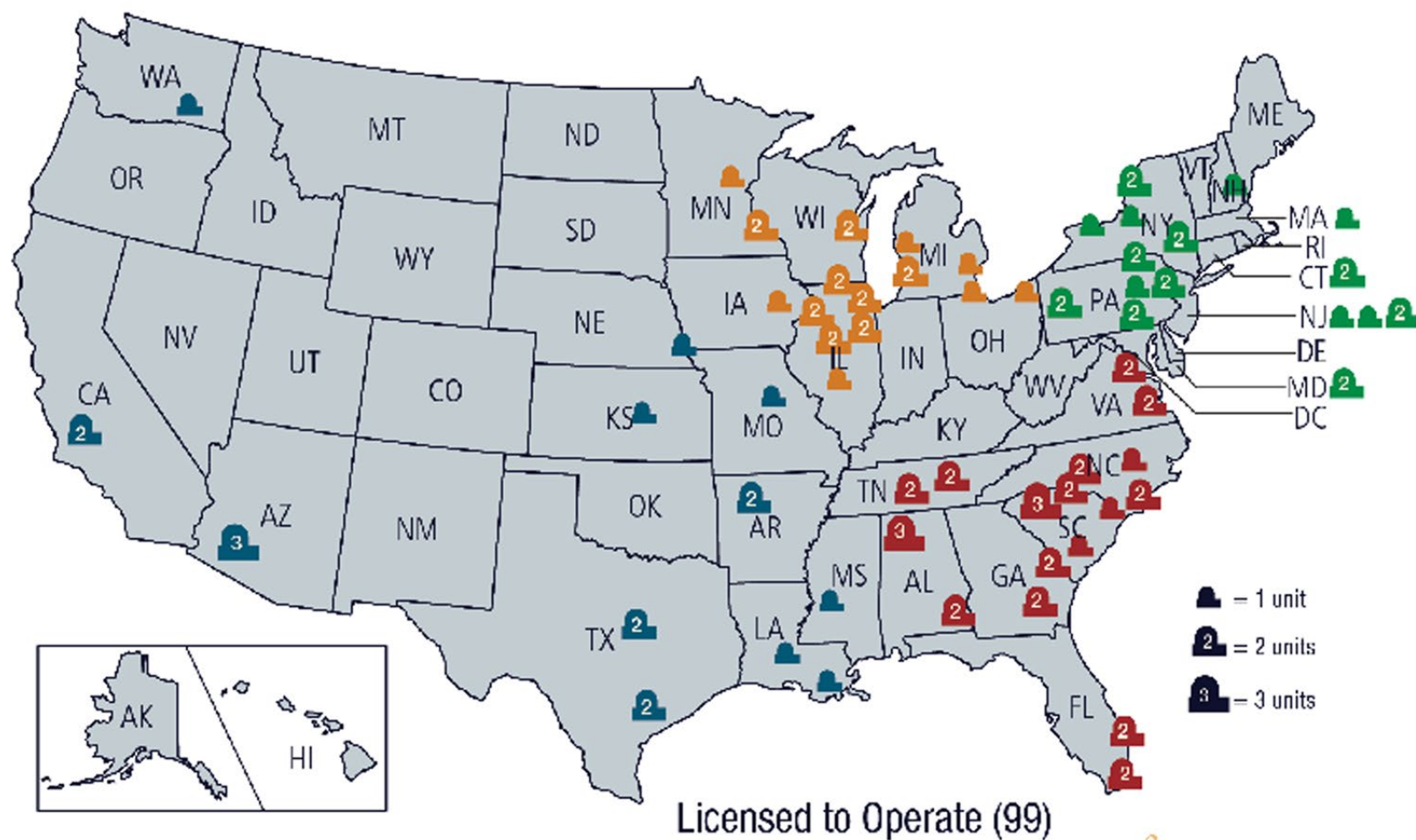
By Maggie Mertens

Only after a patient complained in August about losing some hair following a CT scan did Cedars-Sinai Medical Center realize more than 200 people had been exposed to excessive radiation from diagnostic tests performed there in the last year and a half.



Cedars-Sinai Medical Center in Los Angeles, where more than 200 patients were exposed patients to excess radiation during CT scans.

# U.S. Operating Commercial Nuclear Power Reactors



As of May 2017



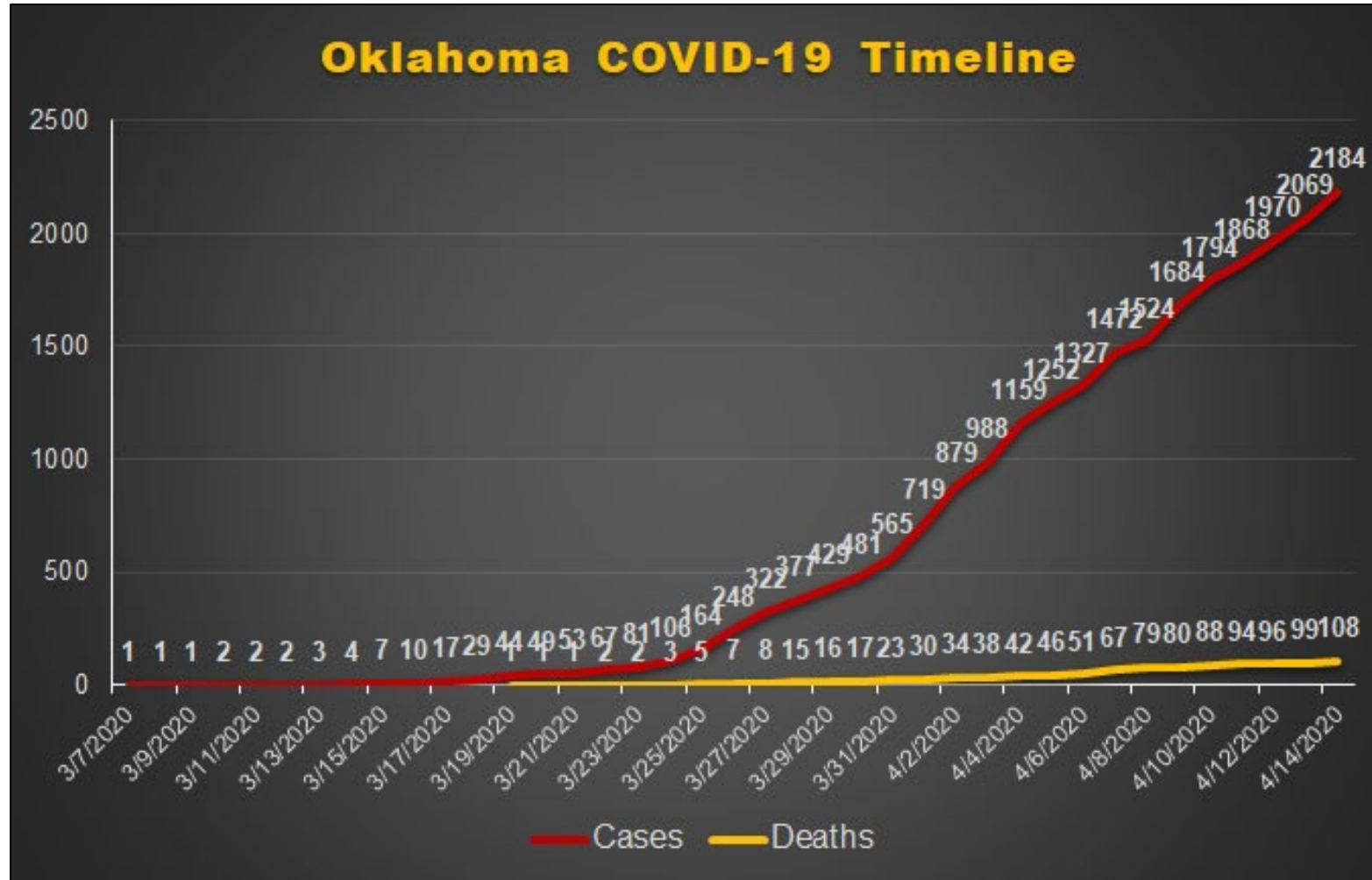
# What do we know about COVID-19

- On 31 December 2019, the WHO China Country Office was informed of cases of pneumonia of unknown etiology (unknown cause) detected in Wuhan City, Hubei Province of China.

First case in the US diagnosed on January 22, 2020.

First case diagnosed in Oklahoma on March 7, 2020.

# Oklahoma Curve



From an April 15, 2020, lecture.

In Oklahoma, the mortality rate in confirmed cases currently sits at 4.9%.

# COVID in early 2020

- We weren't entirely sure how it was being transmitted.
- We definitely did not have sufficient PPE for healthcare workers, let alone the general public.
- We did not have any vaccines for coronaviruses.
- Other than symptomatic treatment, we had no drugs to help.



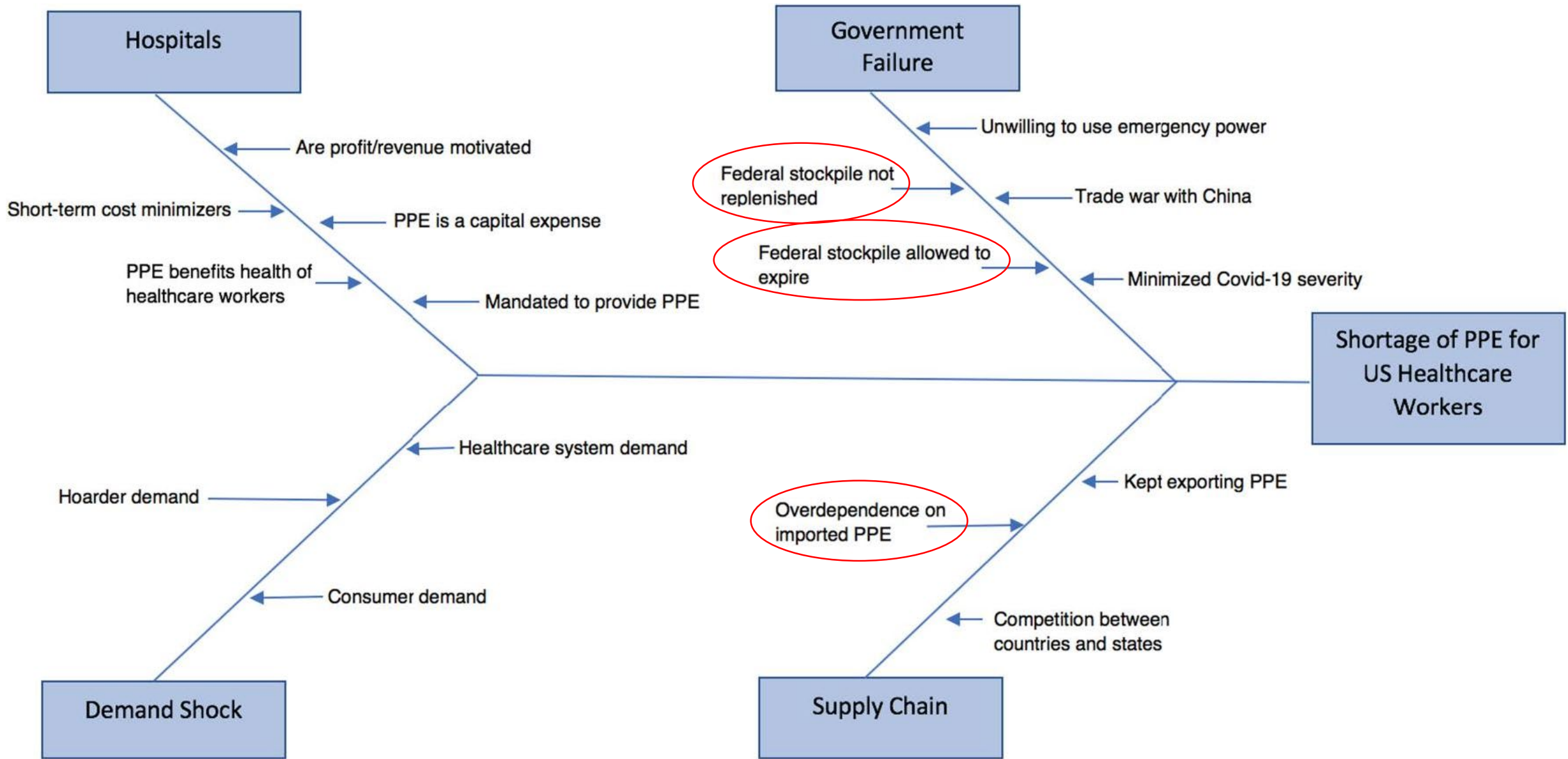
# JAMA Health Forum™

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Insights | COVID-19

## Personal Protective Equipment Shortages During COVID-19—Supply Chain-Related Causes and Mitigation Strategies

Preeti Mehrotra, MD, MPH; Preeti Malani, MD, MSJ; Prashant Yadav, MBA, PhD



# \$5.4M in PPE never received, Oklahoma audit finds

Cailey Gleeson - Thursday, February 10th, 2022



An investigative audit found the Oklahoma State Department of Health invested more than \$5.4 million in personal protective equipment and other supplies early on in the pandemic that the state has no record of receiving, [News on 6](#) reported Feb. 9.

The missing products included \$2.1 million paid to PPE Supplies for N95 masks; \$890,417 paid to A&K Distributors for respirators; and \$2.2 million to seven different vendors for various types of services and supplies, according to the audit.



By –  
Jennifer  
Peltz,  
Associated  
Press

By –  
David A.  
Lieb,  
Associated  
Press

Leave your  
feedback

## States trash masks and pandemic gear as huge stockpiles linger and expire

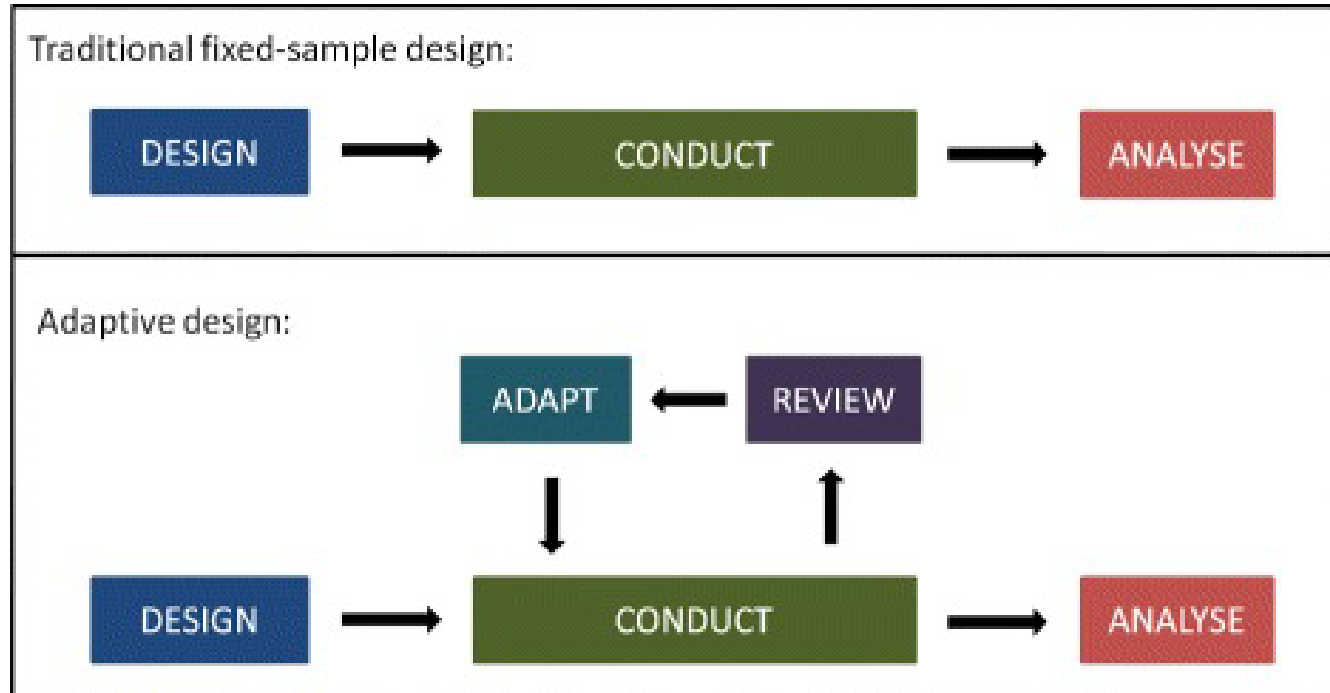
Health Dec 20, 2023 5:26 PM EDT

***“What a real waste. That’s what happens when you don’t prepare, when you have a bust-and-boom public health system,” where a lack of planning leads to panicked over-purchasing in emergencies, said Dr. Georges Benjamin, executive director of the American Public Health Association. “It shows that we really have to do a better job of managing our stockpiles.”***

# Accelerating Clinical Trials – Adaptive Design

Adaptive design allows for continual review and modifications after initiation such as the addition or cessation of treatment arms as data becomes available, in comparison to a common control group, without undermining validity. This novel approach allows for flexibility in adding/dropping arms from the trial in real-time and provides the ability to release results in a rolling manner.

# Adaptive Clinical Trial



## Characteristics of Adaptive Clinical Trial Design:

- refining the sample size
- abandoning treatments or doses
- changing the allocation ratio of patients to trial arms
- identifying patients most likely to benefit and focusing recruitment efforts on them
- stopping the whole trial at an early stage for success or lack of efficacy.

*Used in the development of initial COVID-19 antivirals, monoclonal antibodies, repurposing of existing immunomodulatory therapy and assisted in the disproof of ineffective medical therapies.*

[J Antimicrob Chemother.](#) 2023 Nov; 78(Suppl 2): ii18–ii24.

PMCID: PMC10667002

Published online 2023 Nov 23. doi: [10.1093/jac/dkad312](https://doi.org/10.1093/jac/dkad312)

PMID: [37995353](https://pubmed.ncbi.nlm.nih.gov/37995353/)

## Innovative approaches to COVID-19 medical countermeasure development

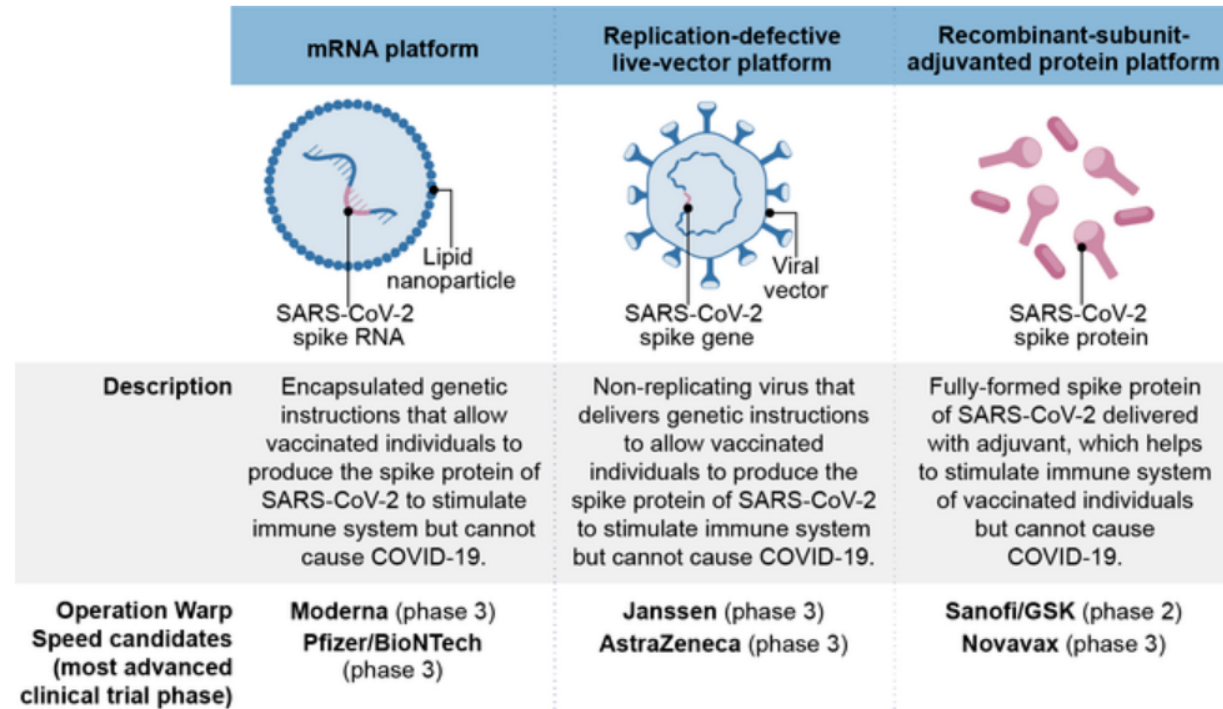
[Gavin H Harris](#) and [Amesh A Adalja](#)<sup>✉</sup>

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- Antiviral medications
- Monoclonal antibodies
- Immunomodulatory therapy
- Ineffective medical countermeasures

Operation Warp Speed (OWS)—a partnership between the Departments of Health and Human Services (HHS) and Defense (DOD)—aimed to help accelerate the development of a COVID-19 vaccine. GAO found that OWS and vaccine companies adopted several strategies to accelerate vaccine development and mitigate risk. For example, OWS selected vaccine candidates that use different mechanisms to stimulate an immune response (i.e., platform technologies; see figure). Vaccine companies also took steps, such as starting large-scale manufacturing during clinical trials and combining clinical trial phases or running them concurrently. Clinical trials gather data on safety and efficacy, with more participants in each successive phase (e.g., phase 3 has more participants than phase 2).

Vaccine Platform Technologies Supported by Operation Warp Speed, as of January 2021



Source: GAO (analysis); Adaptation of images depicting vaccine technologies with permission from Springer Nature: *Nature* ("The Race for Coronavirus Vaccines: A Graphical Guide," Ewen Callaway) © 2020. | GAO-21-319



**Figure 1: Traditional Vaccine Development Timeline Compared To Potential Operation Warp Speed (OWS) Timeline**

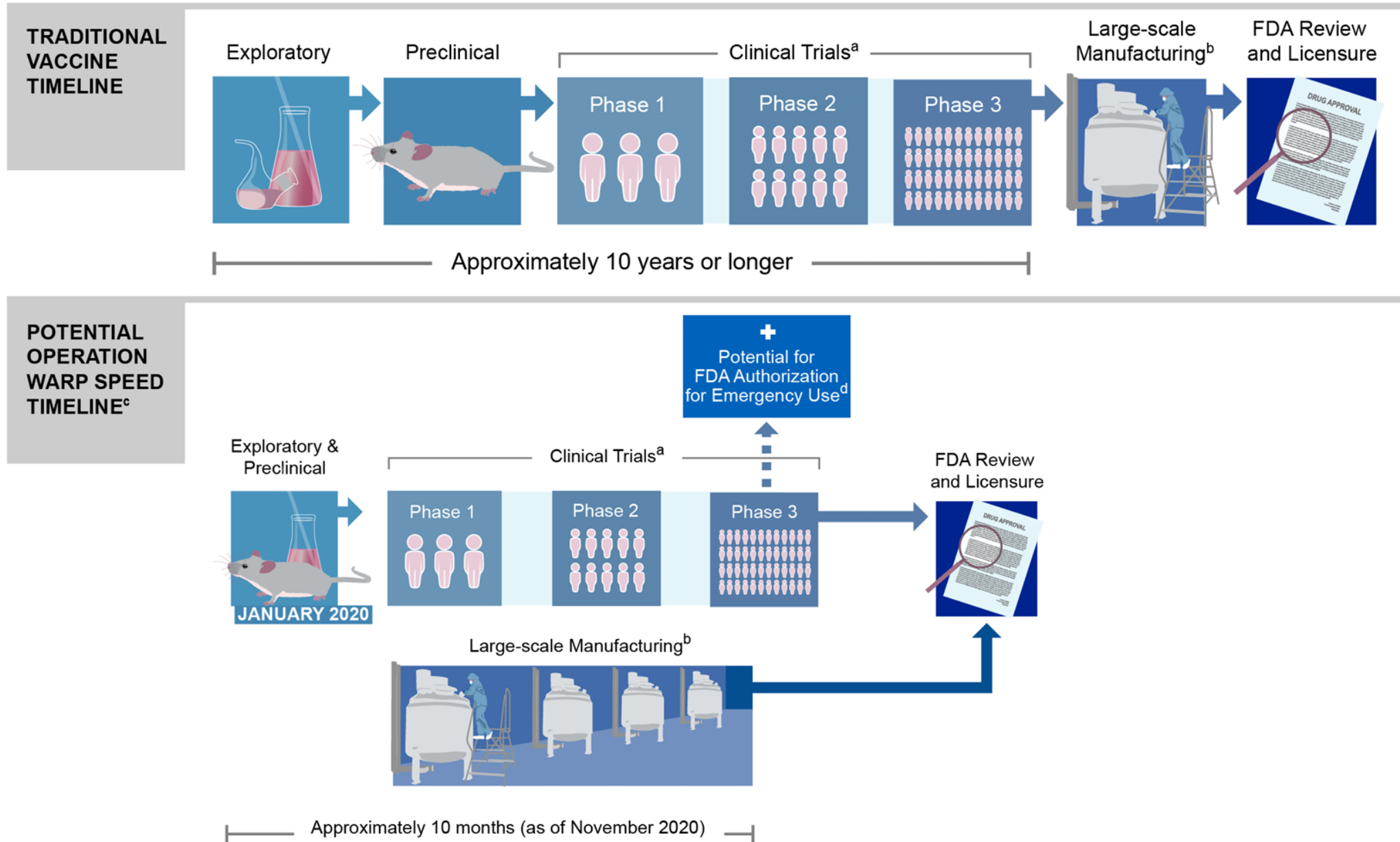


Table 1.

COVID-19 therapeutic medical countermeasures

Current recommended therapeutics for outpatients	Current recommended therapeutics for inpatients	Previously recommended therapeutics	Ineffective therapeutics
Paxlovid (nirmatrelvir/ritonavir)	Veklury (remdesivir)	Evusheld (tixagevimab/cilgavimab)	Hydroxychloroquine
Lagevrio (molnupiravir)	Corticosteroids (dexamethasone, methylprednisolone)	REGEN-COV (casirivimab/imdevimab)	Ivermectin
Veklury (remdesivir)	JAK inhibitors (barticitinib, tofacitinib)	Bebtelovimab	Fluvoxamine
CP	Interleukin-6 inhibitors (Sarilumab, tocilizumab)	Bamlanivimab ± estevimab	
	CP	Sotrovimab	

[Open in a separate window](#)

Source: HHS.gov; Covid19treatmentguidelines.nih.gov.

### COVID Medical Countermeasures

- PPE
- Initial PCR-based tests
- Provided free rapid antigen tests
- All vaccine doses were initially free
- Provided free antiviral medications
- Supported multiple clinical trials

# CDC Confirms First Case of Ebola Diagnosed in the U.S.

SEPTEMBER 30, 2014 AT 7:30 PM ET BY DAVID HUDSON



**Summary:** The Centers for Disease Control and Prevention (CDC) announces the confirmation of the first Ebola case in the United States in a person who traveled from West Africa.

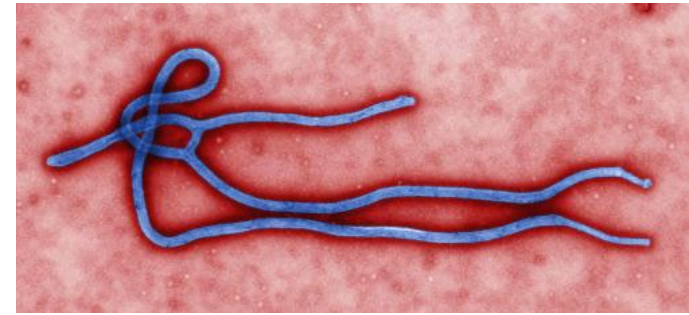
*Note: For updated information on the Administration's response to Ebola, please visit [WhiteHouse.gov/Ebola-Response](http://WhiteHouse.gov/Ebola-Response).*



President Barack Obama talks on the phone with Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention, in the Oval Office, Sept. 30, 2014. Dr. Frieden updated the President on the recently-diagnosed Ebola case in Dallas, Texas. (Official White House Photo by Pete Souza)

Today, the Centers for Disease Control and Prevention (CDC) [announced the confirmation of the first Ebola case in the United States](#) in a person who traveled from West Africa.

# Ebola



- Ebola Virus Disease (EVD) is a rare and deadly disease in people and nonhuman primates.
- The viruses that cause EVD are located mainly in sub-Saharan Africa. Ebola is caused by an infection with a group of viruses within the genus Ebolavirus. (Also see Note on terminology below)
- Transmission: People can get EVD through direct contact with an infected animal (bat or nonhuman primate) or a sick or dead person infected with Ebola virus.

# FDA – Countermeasures for Ebola

- Vaccine development (Ervebo).
- Therapeutics (monoclonal antibodies and mAB mixtures)
- Diagnostics (rapid antigen test of blood)
- Fraudulent product warnings.

WELLNESS

## Oklahoma infectious disease unit ready to respond

**K.S. McNutt**

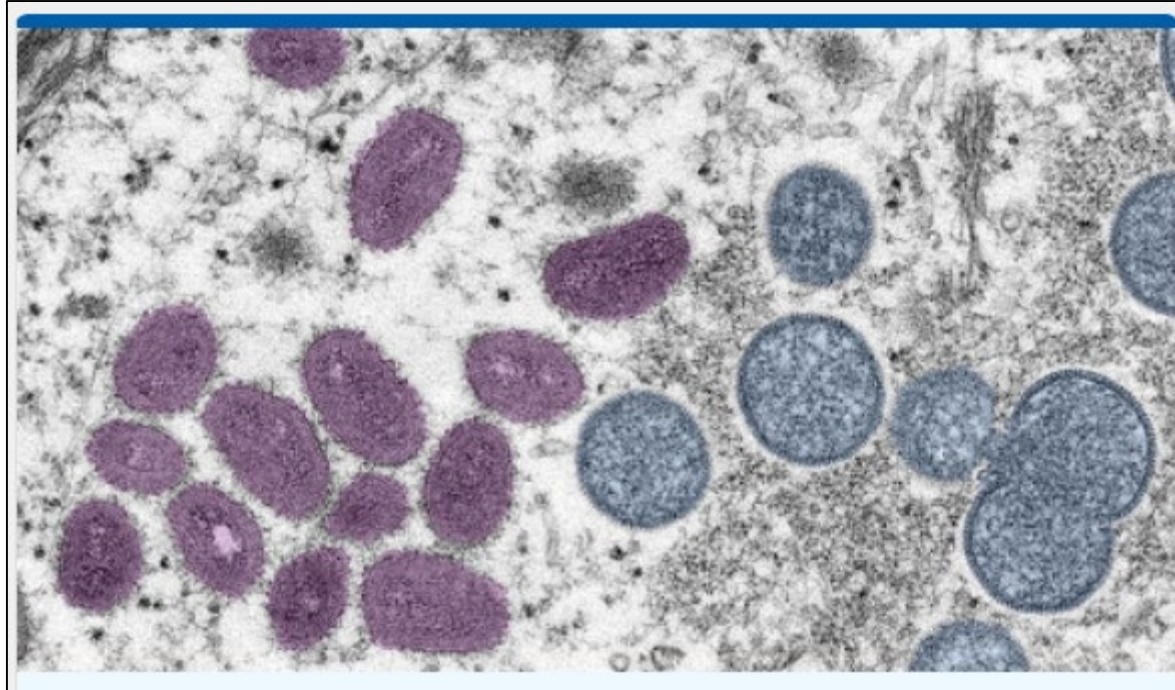
Published 12:00 a.m. CT Jan. 21, 2015 | Updated 9:43 p.m. CT Jan. 21, 2015



Health officials say Oklahoma is ready to respond quickly and confidently if someone tests positive for dangerous infectious diseases like Ebola.

“We have a unit. We have teams in place. We have training that’s ongoing, training that will continue until it’s needed — and hopefully never is needed,” Chuck Spicer, president and CEO of OU Medical System, said Wednesday.

# Mpox



# Mpox Countermeasures

- Medical countermeasures (MCMs) developed to treat smallpox have been used to treat mpox.
- Antivirals (Tecovirimat, brincidofovir)
- Vaccinia Immune Globulin Intravenous
- Vaccines (Jynneos)



# Other threats

- Anthrax
- Influenza
- COVID or other coronaviruses
- Chemical exposures
- MDR bacterial and fungal infections
- Burn and blast injuries
- And the list goes on.....

# BARDA BROAD AGENCY ANNOUNCEMENT (BAA)

We partner with companies and teams offering solutions to a broad range of national health security threats.

[REVIEW SOLICITATION →](#)



The Biomedical Advanced Research and Development Authority (BARDA) provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks; pandemic influenza (PI), and emerging infectious diseases (EID).

# Going forward

- As the world moves beyond the pandemic phase of the COVID-19 health emergency, BARDA is strengthening its capacity to stay at the forefront of public health security through accelerating innovations to develop medical countermeasures (MCMs).
- BARDA's actions continued to build strength and preparedness for what comes next, leveraging and accelerating innovative approaches across the board - from new approaches to partnering to supporting advanced development of new MCM technologies that can improve access and effectiveness.

## ACTIVE AREAS OF INTEREST

	CBRN VACCINES	
	CBRN ANTIVIRALS AND ANTITOXINS	
	ANTIMICROBIALS	
	RADIOLOGICAL/NUCLEAR THREAT MEDICAL COUNTERMEASURES	
	CHEMICAL MEDICAL COUNTERMEASURES	
	<b>BURN AND BLAST MEDICAL COUNTERMEASURES</b>	
	DIAGNOSTICS	
	INFLUENZA AND EMERGING INFECTIOUS DISEASES (IEID) VACCINES	
	INFLUENZA AND EMERGING INFECTIOUS DISEASES (IEID) THERAPEUTICS	
	IMMUNECHIP+	
	FLEXIBLE AND STRATEGIC THERAPEUTICS (FASTX)	



Chemical, Biological, Radiological and Nuclear (CBRN)



## CHEMICAL MEDICAL COUNTERMEASURES



- 5.1 Pulmonary Agents
- 5.2 Opioids and Other Respiratory Depressants
- 5.3 Vesicants
- 5.4 Nerve Agents and Organophosphorus (OP) Pesticides
- 5.5 Knockdown Agents/Cellular Asphyxiants
- 5.6 Novel MCM Delivery Mechanisms
- 5.7 Innovative Approaches to Understanding Chemical Injury in Humans

# Biomedical Advanced Research and Development Authority (BARDA)

## *COVID priorities:*

### BARDA'S PROJECT NEXTGEN FOCUS AREAS

**Better Protection and Longer Lasting Vaccines:** Vaccines that provide broader protection against variants of concern and a longer duration of protection.

**Vaccines that are Easier to Administer and Reduce Spread of the Virus:** Including mucosal vaccines such as those delivered intranasally, which could have the potential to dramatically reduce infection and transmission, in addition to preventing serious illness and death.

**Pan-Coronavirus Protection:** Pan-coronavirus vaccines which protects against several different coronaviruses.

**Modernized, More Resilient Treatment:** New and more durable monoclonal antibodies that are resilient against new variants as they arise.

**Innovative Solutions for Faster, Lower Cost, Rapidly Deployable Technologies:** Advancing new technologies that will improve access and enable faster, lower cost, rapid, and flexible production of vaccines and therapeutics.

**“Enhancing the Nation's PUBLIC HEALTH SECURITY and emergency preparedness by facilitating communication on innovative products and solutions between federal agencies and public stakeholders.”**

<https://medicalcountermeasures.gov/nextgen>

# Medical Countermeasures - summary

- The US has developed a list of countermeasures to target a risk's threat, vulnerability, or both.
- Medical countermeasures are FDA-regulated and may be used in a public health emergency for a terrorist attack or with accidental release of a biological, chemical, or nuclear agent, or a naturally occurring emerging infectious disease.
- Many medical countermeasures are associated with a strategic national stockpile.
- Distribution and dispensing of MCMs needs coordinated planning between local, state, and federal agencies to facilitate an efficient public health response.



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