IMPROVING RESILIENCY IN U.S. PHARMACEUTICAL SUPPLY

National Security Perspectives from the "Last War" about the "Next War" We May have to Fight

"AMATEURS TALK TACTICS (OR POLICY), BUT PROFESSIONALS TALK LOGISTICS"

Attributed to everyone from Napolean Bonaparte to General Omar Bradley

Research Letter | Climate Change and Health

Threats of Weather Disasters for Drug Manufac-

Mahnum Shahzad, PhD^{1,2}; Leticia M. Nogueira, PhD, MPH³; Anita Wagner, PharmD, MPH, DrPH^{1,2}

Author Affiliations | Article Information

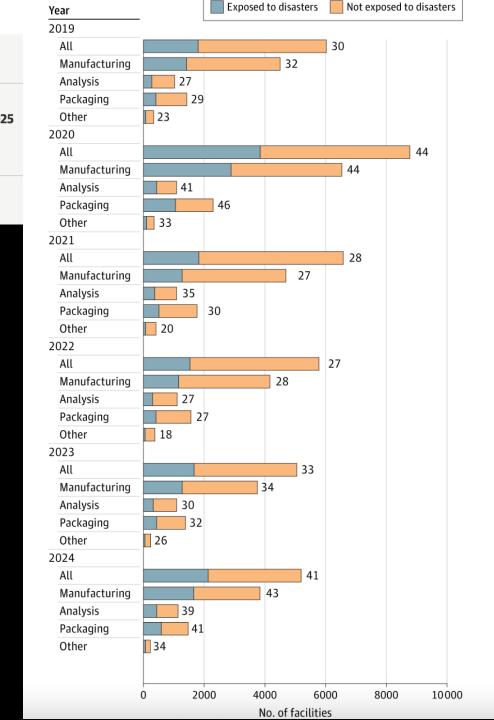
turing Facilities in the US



JAMA

Published Online: August 20, 2025 2025;334;(15):1390-1392. doi:10.1001/jama.2025.13843

Figure 1. Number and
Proportion of Drug Production
Facilities in US Counties With at
Least One Disaster Declaration



CLAUSEWITZ EMPHASIZED THAT UNDERSTANDING THE KIND OF WAR ONE IS FIGHTING IS CRUCIAL FOR MAKING SOUND DECISIONS IN BOTH STRATEGY & POLICY.



Absolute (Total) versus Limited Wars

- **Absolute wars** strive for complete victory and total domination: violence is used without restraint to completely destroy the enemy's ability to resist, seeking unconditional victory & the total achievement of aims.
- Limited wars pursue more specific political goals which do not require total destruction of the enemy: may aim to gain territory, alter political relations, or force concessions
- **Hybrid wars** military strategy that blends conventional and irregular warfare with cyberattacks, disinformation, and economic pressure to achieve strategic goals

Permissive versus non-permissive environments: unrestricted or highly restrictive

Non-kinetic versus kinetic: Tariffs-cyber-explosive-electromagnetic pulse

2023 BIPARTISAN STRATEGIC POSTURE REVIEW CONGRESSIONALLY MANDATED

AMERICA'S STRATEGIC POSTURE

The Final Report of the Congressional Commission on the Strategic Posture of the United States

Madelyn R. Creedon, Chair

Marshall S. Billingslea

Rose E. Gottemoeller

Rebeccah L. Heinrichs

Robert M. Scher

Franklin C. Miller

Jon L. Kyl, Vice Chair

Gloria C. Duffy

Lisa E. Gordon-Hagerty

John E. Hyten

Matthew H. Kroenia

Leonor A. Tomero

"The United States faces a strategic challenge requiring urgent action. Given current threat trajectories, our nation will soon encounter a fundamentally different global setting than it has ever experienced: we will face a world where two nations possess nuclear arsenals on par with our own. In addition, the risk of conflict with these two nuclear peers is increasing. It is an existential challenge for which the United States is ill-prepared, unless its leaders make decisions now to adjust the U.S. strategic posture."

WHAT KIND OF WAR COULD RESULT? REGARDLESS IT IS ALMOST HERE

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"Today, the U.S.-led international order is under threat from the Chinese and Russian authoritarian regimes, which seek to disrupt and displace this order and create a new version conducive to their authoritarian regimes, premised on values antithetical to those held by the United States and like-minded Allies and partners worldwide."

THE LAST WAR: COVID-19 PANDEMIC

- Limited: effects principally affect people
- Semi-permissive: global supply chains affected slow but operating
- Non-kinetic: effects: cyber, disinformation

THE CURRENT CONFLICT: HYBRID WAR

- Limited:
- Permisssive: global supply chains unaffected
- Non-kinetics: cyberattacks, disinformation, & economic pressure (Tariffs)

THE NEXT WAR: WORLD WAR III?

- Absolute (total):
- Non-permissive: Everything disrupted
- Kinetic & non-kinetic

- Nuclear war: Civil defense bunkers should be ready for use in Switzerland:
 - According to the Federal Intelligence Service, the risk of tactical nuclear weapons being used in the Ukrainian theatre of war is becoming increasingly serious.

defense facilities must nodernized and kept nal.

WHAT OTHERS THINK & SAY SWISS SURGEON GENERAL SEPTEMBER 2025 BERN, SWITZERLAND

PHARMACEUTICAL NATIONAL SECURITY CONSIDERATIONS WHOLE OF NATION RESPONSIBILITY

- Objectives of Resilient Health Care supply chains
 - 1. Protecting the American public (baseline routine health care needs)
 - a) e.g. Generics, specialty cancer treatments
 - 2. Preserving the national health care system during uncertainty: National Disaster Medical System
 - a) e.g. normal saline PPE
 - 3. Enhancing health care provision for specific risks/threats (CBRN)
 - a) unique non-commercial market products e.g. smallpox vaccine, radiological protectants



ASPR's SUPPLY CHAIN CONTROL TOWER (SCCT)

The Supply Chain Control Tower aims to enable visibility for medical supply chain monitoring and readiness for informed decision making in response environments.



- PROVIDE INSIGHTS

山口 INFORM RESPONSE

SCCT HISTORY

2020

SCCT Established (Mar) Addition of N/S, Test Kits & Tx (Fall) Manning Brief (started Fall; sunset Jun 2023)

SCLOC COP (started Jan) Addition of State Stockpiles (Mar) 1st Hurricane Analysis (Elsa) (June) Industry Elicitations (Summer) Action 11 POAM Dev. (Nov) Action 11 POAM Accepted (Dec)

2022

IBAs (pharma, gowns, NBR, N95) (2021-2022) POAM 11 Steering Committee Stood Up (Mar) Infant Formula Support for Operation Fly Formula (May)

SCCT Strategic Planning (Jun) 2022 Fed-HealthIT Innovation Award (Summer)

Distributor Sustainment Begins (Oct) 2 Year Strategy Development (Nov) Pediatric RSV Support (Dec)

2023

PPE Vulnerability Assessment (Jan) Pharmaceutical Model Dev. (Jan) Promoted to Division (Feb) Revamped Vision App (Mar) Synergy (Apr) Product Inclusion Criteria List (Jun)

Macroeconomic Analysis for PPE (Jun)

MPL 360 Dashboard (Aug)

Demand models developed for PPE

Manufacturers

Limited Visibility

Supply Chain

Total commercial delivered Rx units tracked since Jan 2020

Additional products analyzed

Control Tower



Distributors

Previously collected during COVID-19 PHE

Full Visibility from Data Provided by Participating Partners

U.S. GOVT. PARTNERS





FEMA



SCCT FACTS (as of September 2023)

Raw Materials

No Visibility within

SCCT



T

Products Tracked by SCCT

Total commercial

delivered PPE

units tracked

Including select COVID Rx, and test kits

PPE. Tx. needles & syringes

States

3.55GB Data Ingested/Day 4.2TB Ingested since 2020

0::::

0::::

Commercial Partners sharing data

Regional reports to support rapid supply

∰ @≡ ⊞ Applications in SCCT Platform Including Synergy, Gateway, ASPR Response Coordination Center (ARC)

since 2021 Including PPE Vulnerability Assessment. Industrial Based Assessments (IBAs), and PPE Macroeconomi Analysis Phase 1



Delivered from 6 key reports on a weekly-monthly basis between 2020-2023

Analyses to support RFI responses using the Vision application

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Sr. Leader Supply Chain reports delivered to the White House

Supply Chain Situational Awareness updates

chain assessments



Supply Chain Control Awareness Reporting

• Objectives: Share updates, provide information, and ensure situational awareness of the medical supply chain

in support of all-hazards

Stakeholders: Intra-ASPR

Global & U.S. Supply Chain Updates



Provides global and national situational awareness updates that have the potential to impact the U.S. medical supply chain



Special Assessments

Provides in-depth analysis for specific events that the SCCT is tracking (i.e., Hurricanes, National Security Events, etc.)



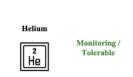
Supply Chain Monitoring

Provides an analysis on select products whose supply chain data has recently experienced deviation from baseline



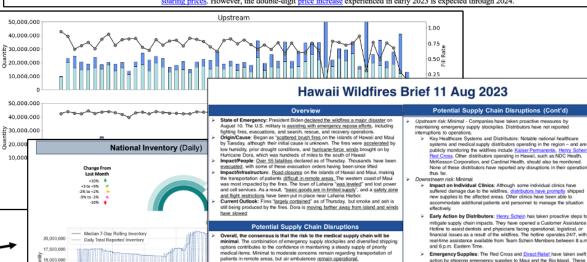
PPE Demand Modeling Estimates

Provides demand modeling estimates for healthcare worker PPE based on COVID-19 projections



7,500,000

- Medical supply chain leaders sound the alarm over the potential impact of the U.S. selling its helium reserve, fearing it could
 worsen an existing shortage critical for life-saving diagnoses. Helium, crucial for keeping MRI machines cold, is vital for
 approximately 40 million scans annually in the U.S.
- With the gas already in short supply, shutting down the U.S. helium reserve could heighten reliance on foreign sources, potentially leading to concerns about shortages due to geopolitical tensions and shipping delays.
- Bipartisan senators seek a pause in the sale, delayed to January 2024, with concerns about negotiation complexities and maintenance backlog.
- CGA proposes a three-year delay to address issues related to the sale.
- While the shortage has not been observed to impact hospital operations, U.S. hospitals and medical facilities continue to grapple with soaring prices. However, the double-digit price increase experienced in early 2023 is expected through 2024.



supplies include respiratory medications, N-95 masks, and medications for managing chronic diseases. Ongoing monitoring and contingency planning are still crucial to address any potential disruptions.



LESSON OBSERVED OWS CYBER VULNERABILITY OCT TO MARCH 2020

Businessweek | Technology

The Untold Story of a Massive Hack at HHS in Covid's Early Days

Former officials at the US Department of Health and Human Services attribute the cyberattack to a state-level actor.

First official ASPR action after the President's April 2020 approval establishing OWS was creating cyber-overwatch of entities, supply chain, data security

LESSON OBSERVED OWS SUPPLY CHAIN DEPENDENCY DEC 2020

D-Day

June 6, 1944

Dec 12, 2020



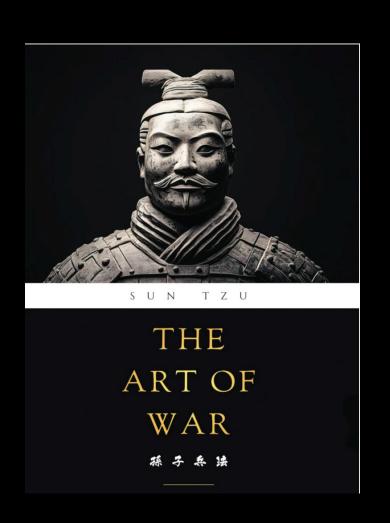
ASPR action before the formal arrival of OWS Team was securing contracts, procuring 1 Billion needles & syringes and setting up an air bridge flying product from China

PHARMACEUTICAL NATIONAL SECURITY ACTIONS WHOLE OF NATION RESPONSIBILITY

- Defense in depth: "end-to-end layered resilience"
 - Active monitoring of the supply chain with demand monitoring prediction
 - a) Identify gaps
 - b) Eliminate dependencies
 - 2. Distributed & redundant manufacturing
 - 3. Enhanced "hardness"
 - Cyber-defenses, physical and personal security, EMP

Requires unparalleled Public-Private Partnership

SUN TZU EASTERN MILITARY STRATEGY



"If you know the enemy and know yourself, you need not fear the result of a hundred battles. If you know yourself but not the enemy, for every victory gained, you will also suffer a defeat. If you know neither the enemy nor yourself, you will succumb in every battle."