The FY 2023 NDAA

Healthcare Focus

Moshe Schwartz, President,
Etherton and Associates

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Agenda

- The Fiscal Year 2023 National Defense Authorization Act
  - General Themes
  - Health Care
- The FY 2023 Budget
- The Road Ahead
  - The FY 2024 NDAA
  - The FY 2024 Budget
  - Other Administration Actions
  - The Government Accountability Office Weighs In

Congress

- What Got Done
  - The National Defense Authorization Act – 86 days late
  - Omnibus Appropriations Act – Even later
  - SBIR and STTR Extension Act of 2022 (P.L. 117-183) – Just barely
  - CHIPS and Science Act (PL 117-167) – But how will it get implemented?
  - Preventing Organizational Conflicts of Interest in Federal Acquisition Act (PL 117-324)
- What Will Get Done – Eventually
  - The NDAA and Appropriations
  - Debt Ceiling – But how painful will it be?
- Where is the Bipartisan Consensus?
  - More China Restrictions
  - Cybersecurity
  - Supply Chains
  - Healthcare

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The National Defense Authorization Act for Fiscal Year 2023 (P.L. 117-263)

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FY23 NDAA Overview

- Signed by the President December 23, 2022
- Title VII – Health Care Policy (42 provisions)
- Is This the New Normal?
  - Will the Senate get off the floor?
  - The NDAA as a December bill
  - The NDAA as the Omnibus Authorization Act - 4,408 pages
    - Division F—Intelligence Authorization Act for FY 2023
    - Division G—Homeland Security
    - Division H—Water Resources
    - Division I—Department of State Authorizations
    - Division J—Oceans and Atmosphere
    - Division K—Don Young Coast Guard Authorization Act of 2023

China
Industrial Base/Supply Chain
Cybersecurity
+
Acquisition Streamlining

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FY23 NDAA Observations

- Progressive Priorities Dropped
- Shifting to Buy Allies
- Drove the Appropriations Debate

This Administration *Does Not* Wait For Congress

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Industrial Base & Supply Chain

Mobilizing the Industrial Base

- Sec. 859. Demonstration Exercise of Planning for Industrial Mobilization and Supply Chain Management
  - Requires DoD to conduct an exercise of industrial mobilization and supply chain management planning in support of an operation, by December 31, 2024
    - The demonstration must include a fielded program still in production, from each military department, defense agency, and field activity, as associated with the chosen exercise

Stockpiling & Provenance

- Sec. 1412. Modify Authorities Under the Strategic and Critical Materials Stockpiling Act
  - Amends the Strategic and Critical Materials Stockpiling Act
    - In 50 USC 98d by expanding the authority of the Stockpile Manager to make purchases, and extend the period of obligation from two years to 'until expended'
    - In 50 USC 98b by requiring the president to notify Congress only when planning to acquire materials to increase stockpile quantity (previously, notification was required for any quantity change), and shortening the waiting period between notification and acquisition

- Sec. 1414. Authority to Acquire Material for the National Defense Stockpile
  - Authorizes the National Defense Stockpile Manager to use up to $1 billion of authorized appropriations to procure identified strategic and critical materials
  - The authority is available during fiscal years 2023 through 2032

Industrial Base & Supply Chain

Inching Away From Buy American to Buy Allies

- *Sec. 851.* Adding New Zealand to the NTIB

- Sec. 852. Modifying Miscellaneous Limitations on Procurement of Non-Domestic Goods
  - Amends 10 USC 4864, requiring DoD to periodically review the limitations on procuring specified items

- *The Administration*
  - DFARS Case 2022-D012: New Qualifying County-Lithuania (March 2022)
  - DFARS notice: Austria (2022-26712)
  - The Buy American Office

Industrial Base & Supply Chain

Restricting Sources

- Sec. 817. Modification to Prohibition on Foreign-Made Unmanned Aircraft Systems
  - Amends section 848 on the FY2020 NDAA by
    - Expanding the prohibition on operating or procuring unmanned aircraft systems to include Russia, Iran, and North Korea
    - Prohibiting DoD from contracting with an entity that operates equipment in performance of a DoD contract that is from
- Sec. 857. Procurement Requirements Related to Rare Earths and Strategic and Critical Materials
  - Directs DoD to require contractors to provide provenance for permanent magnets containing rare earths or strategic and critical minerals that are in delivered systems
  - Expands the prohibition of procuring from Communist Chinese Military Companies (section 1211 of the FY06 NDAA)
- Sec. 5949. Prohibition on Certain Semiconductor Products and Services
  - Prohibits federal agencies from
    - Acquiring or contracting for electronic parts, products, or services that include covered semiconductor products or services
    - Contracting with an entity to procure or obtain electronic parts or products that use any electronic parts or products that include covered semiconductor products or services (applies only to critical systems)
- Sec. 855. Codifying the Prohibition on Procuring from the XUAR Region in China
  - Codifies section 848 of the FY2022, making permanent the prohibition on DoD to procure certain items from the XUAR region

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It is not just about security…It is about decoupling

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Health Care in the NDAA

FY23 NDAA, Title VII – Health Care Provisions

- Subtitle A—TRICARE and Other Health Care Benefits (9 sections)
- Subtitle B—Health Care Administration (24 sections)
- Subtitle C—Studies and Reports (19 sections)

Health Care Administration

- Sec. 708. GAO Study on Certain Defense Health Agency Contracts (H. 759B)
  - Requires GAO to submit a report to the armed services committees within two years of enactment on
    - TRICARE managed care support contracts
    - TRICARE contracts entered into by DHA between October 1, 2017, and September 30, 2022, with a value greater than $500 million
- Sec. 717. Other Transaction Authority For Studies and Demonstration Projects Relating to Delivery of Health and Medical Care (H. 724; S. 748)
  - Amended 10 USC 1092, allowing DoD to conduct studies and demonstration projects on the health care delivery system of the uniformed services using Other Transaction Authority (which is exempt from most acquisition regulations)
  - Requires DoD to brief the armed services committees within 180 days of enactment, on how the authority will be used

Health Care Administration

- Sec. 720. Modifying the Requirement to Transfer R&D and Public Health Functions to DHA (H. 722/723; S. 724)
  - Allows a military department to retain certain public health functions that would otherwise be transferred to DHA under 10 USC 1073c if the Secretary of Defense determines that the function
    - Addresses a need unique to the military department; and
    - Directly supports operating forces and is required to execute strategies supporting national security and defense
  - Requires DoD to submit to the armed services committees by March 1, 2023, a briefing on those functions the Secretary has determined may be retained by the military departments

Health Care Administration

- Sec. 724. Feasibility Study and Plan to Establishing a Military Health System Medical Logistics Directorate, and Education and Training Directorate (S. 721/725)
  - Requires the Secretary of Defense, in consultation with the military departments and the Joint Chiefs of Staff, to
    - Conduct a study on establishing within DHA a “Medical Health System Education and Training Directorate” and a “Military Health System Education and Training Directorate”
    - Develop a plan for establishing the directorates
  - Requires DoD to submit to the armed services committees within one year of enactment,
    - The results of the study
    - The plan to establish the directorates

Reports

- Sec. 743. Updates to Prior Feasibility Studies on Establishment of New Command on Defense Health (H. 742; S. 721)
  - Requires DoD to update prior studies on the "feasibility of establishing a new defense health command under which the Defense Health Agency would be a joint component"
    - Requires DoD to consider a unified combatant command and a specified combatant command
  - Requires DoD to
    - Brief the armed services committees within 180 days of enactment on the method by which the studies will be updated
    - Provide a final briefing and a report within one year of enactment on the updates to the prior studies

Supply Chains

- Sec. 860. Risk Management for DoD Pharmaceutical Supply Chains (H. 858/S. 871)
  - Requires the Under Secretary of Defense (Acquisition and Sustainment), within one year of enactment, to
    - Develop and implement guidance for risk management of DoD supply chains for *pharmaceutical materiel for the Department*
    - Identify (in coordination with HHS) supply chain information gaps for relying on foreign suppliers of drugs, including active pharmaceutical ingredients and final drug products, and
    - Provide a report to the armed services committees that ~~includes vulnerabilities in the DoD~~ drug supply chain and recommendations to address information gaps any risks related to reliance on foreign suppliers
  - Requires DHA, within one year of the above guidance being issued, to
    - Publish implementing guidance for DoD supply chain pharmaceuticals
    - Establish a working group to identify critical pharmaceuticals, assess supply chain risks, and establish allocation policies during supply disruption

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Miscellaneous

International Cooperation

- Sec. 736. Establishing a Partnership Program with Ukraine for Trauma Care and Research (H. 777)

Not Included

- House Sec. 778. Grant Program for Increased Cooperation on PTSD Research with Israel

House Provisions Not Adopted

- Sec. 735. Improving Military Medical Treatment and Other Facilities
  - Would have required DoD to study deficiencies of or needed improvements to military medical treatment and other facilities
- Sec. 776. Pilot Program on Ensuring Pharmaceutical Supply Stability
  - Would have required DLA to establish a three-year pilot program to acquire and maintain a 180-day supply of at least 30 commonly used generic drugs at risk of shortage" in the military health program
  - GAO is reviewing the *Warstopper* program to determine the feasibility of expanding it to ensure medication supply stability for deploying forces and families during a public health emergency
- Sec. 746. Report on Feasibility of Certain Licensing models for DoD-owned Vaccines and Medical Interventions for COVID–19
  - Requires DoD to brief the armed services committees by February 1, 2024 on the feasibility of a license model to grant manufacturers nonexclusive licenses to manufacture such vaccines or agents

Not Adopted in the NDAA – But in Law

- Sec. 741. Three-year extension of DOD-VA Health Care Sharing Incentive Fund
  - The authority in 38 USC 8111 was extended from September 30, 2023, to September 30, 2026, in section 103 of Division E of the Continuing Appropriations Act, 2023 (P.L. 117-180)
  - Section 721 of the FY2003 NDAA (P.L. 107-314), amended 38 USC 8111, establishing a joint incentive program to identify and provide incentives to implement, fund, and evaluate creative health care coordination and sharing initiatives between VA and DOD

- Sec. 742. One-year extension of Joint DoD-VA Medical Facility Demonstration Fund
  - The authority in section 1704 of the FY 2020 NDAA was extended from September 30, 2023, to September 30, 2024, in section 104 of Division E of the Continuing Appropriations Act, 2023 (P.L. 117-180)
  - Section 1704 of the FY2020 NDAA established the joint medical facility demonstration fund

The FY23 Budget

Funding

- National Institutes of Health – $47.5 billion (+$2.5B vs. FY 22 levels; -$1.5B vs. President's budget request)
  - An increase of at least 3.8% for each Institute and Center to support biomedical and behavioral research
- CDC – $9.2 billion (+$760 million vs. FY 22 levels; -$1.5B vs. request)
- ARPA-H – $1.5 billion (+$500 million vs. FY22 levels; -$3.5B vs. request)
- Veterans Affairs – $134.7 billion (+$22.5B vs. FY22 levels; -$329 million vs. request)
  - $128 billion in advance FY 2024 funding for Veterans Medical Care (equal to request)

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Defense Department

- $39.2 billion for medical and health programs
  - Including more than $550 million for cancer research

- DoD announced $1.2 billion in new investments in biomanufacturing and the intent to invest $1 billion in bio-industrial domestic manufacturing over the next 5 years

Select provisions: FDA reforms

PROVISIONS	FUNDING	OVERVIEW
Emerging Technology program establishment & centers of excellence	• N/A	• Up to 5 eligible higher education institutions may be designated as "National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing" • A program to support the adoption and development of "innovative approaches to drug design and manufacturing," including grant awards
Rare Disease Endpoint Advancement Pilot Program establishment	• N/A	• A pilot program wherein the FDA may facilitate interaction with rare disease drug development program sponsors to further the development of efficacy endpoints—including intermediate and surrogate endpoints—for such drugs • This program must include 3 public workshops on rare disease endpoint development prior to FY2027; applications are allowed until FY2028
Accelerated approval pathway reforms	• N/A	• The FDA can require studies to be initiated prior to accelerated approval • Sponsors for such drugs must report on trial progress every 6 months • An intra-agency council composed of various directors must be established to oversee accelerated approval utilization and provide guidance
Device cybersecurity	• $65 M (total)	• Applications or submissions for specified "cyber devices" must include proof of compliance with new cybersecurity requirements • Requirements include a plan to monitor postmarket vulnerabilities/exploits, a software bill of materials, procedures and processes to provide reasonable assurance of cybersecurity, and other potential requirements

SOURCE Senate Appropriations Committee, Fierce Biotech, Legal Information Institute.

Provisions: Public Health Prevention & Response

PROVISIONS	FUNDING	OVERVIEW
Increased manufacturing capacity for certain critical antibiotic drugs	• N/A	• Contracts may be awarded to increase domestic manufacturing capacity for antibiotics—as well as key starting materials or ingredients—that display supply chain vulnerabilities • This contracting authority ceases to be available after 3 years, and the entire provision itself is terminated in 8 years post-enactment
Security countermeasure procurement	• $820 M	• A "security countermeasure" is a drug, device, or biological product with high priority for dealing with biological, radiological, chemical, or nuclear agents that pose a "material threat" as determined by the HHS Secretary • Procurement funding under this provision will remain available until used
Strategic National Stockpile funding	• $965 M	• The Strategic National Stockpile is maintained by the Secretaries of HHS, ASPR, and Homeland Security alongside the CDC Director; they have broad authorization to stockpile drugs, vaccines, and other products/supplies for public health emergencies • This is a $120 M funding increase relative to FY2022

SOURCE Senate Appropriations Committee, Fierce Biotech, Legal Information Institute.

The Road Ahead

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What Will the FY 2024 NDAA Look Like?

China

Cybersecurity (SBOMs?)

Supply Chain

What will the FY 2024 Budget Look Like?

- Fact Sheet: The President's Budget for FY 2024
  - Cuts Taxes for Families with Children and American Workers
  - Lowers Health Care Costs
  - Reduces Prescription Drug Costs for All Americans
  - Expands Access to Quality, Affordable Health Care

- Budget Request Specifics
  - $1.7 billion for dedicated Cancer Moonshot activities across HHS
  - $7.8 billion (total investment) at the National Cancer Institute
  - $2.5 billion for ARPA-H (an increase of $1 billion)

Administration Efforts

- ARPA-H
- National Biodefense Strategy & Implementation (Oct. 2020)
- Executive Orders
  - EO 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy* (Sept. 12, 2022)
    - Bolster and coordinate Federal investment in key R&D areas of biotechnology and biomanufacturing
    - Improve and expand biomanufacturing production, increase pilots and prototypes in biotechnology and biomanufacturing
    - Require certain agencies to submit reports within 180 days to identify high-priority basic research and technology development needs and opportunities for public-private collaboration
    - Require OSTP within 100 days to develop an implementation plan for the recommendations in the reports
  - EO 14087, *Lowering Prescription Drug Costs for Americans* (Oct. 14, 2022)
- Industrial Base, generally

National Biodefense Strategy & Implementation

- Focuses on biological threats, enhancing pandemic preparedness, and achieving global health security
  - "Biological threats…are among the most serious threats facing" the U.S. and the world
  - "Significant and urgent need to achieve sustained investments and transformative improvements in the ability…to assess, prevent, prepare for, respond to, and recover from the next biological incident"

- Goals
  - Enable risk awareness and detection to inform decision-making across the biodefense enterprise
  - Ensure biodefense enterprise capabilities to prevent bioincidents
  - Ensure biodefense enterprise preparedness
    - Modernize and expand the footprint of domestic health infrastructure
    - Invest in domestic public health capacities
    - Invest in rapid tests, PPE, and vaccines (including design, testing, and surge capacity)
    - Fund basic research, innovation, and the development of tools and technology
  - Rapidly respond to limit the impacts of bioincidents
  - Facilitate recovery to restore the community, the economy, and the environment after a bioincident

Cybersecurity

- The Administration
  - HHS released a Cybersecurity Implementation Guide for the Health Care and Public Health Sector (March 2023)
    - Covers the five most prevalent threats in the HPH Sector and 10 cybersecurity practices to help mitigate these threats
    - Builds on previous administration efforts, including The National Infrastructure Protection Plan (NIPP)
  - The Health Care and Public Health (HPH) Sector is a critical infrastructure industry partner
- Congress
  - *Cybersecurity is Patient Security: Policy Options in the Health Care Sector* (Nov. 2022)
    - Senator Mark Warren
    - Section on protecting health care research and development from cyberattacks

GAO Weighs In

- Biodefense: Actions Needed to Address Long-Standing Challenges (March 2023)
  - Lack of clear procedures and planning to analyze data in a way that leveraged resources and advanced national biodefense capabilities
  - Challenges in coordinating response capabilities, managing information, and in planning and conducting exercise efforts
  - DHS Faces Biodefense Technology Challenges – including with *BioWatch*
  - GAO is working on a report on DHS's National Biosurveillance Integration Center

- Drug Manufacturing: FDA Should Fully Assess Its Efforts to Encourage Innovation (March 2023)
  - FDA has three efforts focused on increasing advanced manufacturing for drugs: 1) industry engagement, 2) policy and guidance, and 3) Research
  - FDA lacks information on whether its industry engagement and policy and guidance efforts encourage adoption of advanced manufacturing
  - Regulatory challenges contributed to uncertainty about when and whether a drug manufactured using advanced manufacturing will be approved, weakening the business case for advanced manufacturing. U
    - Unfamiliarly of FDA application review staff with advanced manufacturing may lead to delays in approval

Congress Gets a Vote

Committee	Democratic Leader	Republican Leader
Senate Health, Education, Labor and Pensions	*Bernie Sanders (VT)*	*Bill Cassidy, MD (LA)*
Senate Finance, Subcommittee on Health Care	*Debbie Stabenow (MI)*	*Steve Daines (MT)*
House Energy and Commerce, Subcommittee on Health	*Anna Eshoo (CA)*	*Brett Guthrie (KY)*
House Ways and Means, Subcommittee on Health	*Lloyd Doggett (TX)*	*Vern Buchanan (FL)*
Senate Appropriations Committee	*Patty Murray (WA)*	*Susan Collins (ME)*
House Appropriations Committee	*Rosa DeLauro (CT)*	*Kay Granger (TX)*

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Congress Gets a Vote

We need to continue full speed ahead to boost federal research dollars so that we can keep this critical momentum going and realize the returns on our investment…. What is not helpful is a stop-and-go policy, where Congress some years provides a lot of money, then retrenches in the next year.

Senator Collins on funding for NIH

Questions?