KOUNTOUPES DENHAM CARR & REID

KDCR Weekly Healthcare Supply Chain Tracker

116th Congress

Legislation

H.R. 8987, Enhancing the Security of the U.S. Pharmaceutical Supply Chain Act of 2020 [link]

- Date Introduced: 12/16/20
- Sponsor: Rep. John Joyce (R-PA)
- Summary: Would amend the Public Health Service Act to incentivize the manufacture of certain medicines in the United States and to enhance the security of the United States pharmaceutical supply chain.

S. 4952, Mobilize America to Manufacture Equipment Required for Independence from Communist Adversaries Act (Mobilize AMERICA Act) [link]

- Date Introduced: 12/2/20
- Sponsor: Sen. Joni Ernst (R-IA)
- Summary: The Mobilize AMERICA Act would provide a significant incentive for the private sector to on-shore and increase domestic manufacturing of critical medical supplies, ensuring that the U.S. has the capacity to produce and acquire vital supplies necessary to combat public health emergencies without excessively relying on foreign countries. Would establish a grant program to allow manufacturers to expand domestic production of drugs, vaccines, personal protective equipment, and other medical supplies that are critical during a pandemic or public health emergency.

H.R. 8905, Supply Chain Security and Pharmaceutical Authentication Act of 2020 [link]

- Date Introduced: 12/8/20
- Sponsor: Rep. Jefferson Van Drew (R-NJ)
- Summary: To amend the Federal Food, Drug, and Cosmetic Act to reduce the threat of counterfeit drugs to the pharmaceutical supply chain, and to make the pharmaceutical supply chain more robust, while ensuring the authenticity, content, purity, and manufacturing location and batch number of drugs (including COVID-19 therapeutics and vaccines) and allowing patient verification of authenticity, and for other purposes.

S.Res.777 – A resolution expressing the sense of the Senate on the need for common sense solutions to improve health care delivery and affordability for all people of the United States [link]

- Date Introduced: 11/18/20
- Sponsors: Sens. David Perdue (R-GA) and Kelly Loeffler (R-GA)
- Summary: A resolution expressing the sense of the Senate on the need for common sense solutions to improve health care delivery and affordability for all people of the United States. Solutions include incentivizing domestic manufacturing and ending drug shortages and ensuring transparency in the drug supply chain.

H.R. 8785, Building Back American Manufacturing (B-BAM) Act [link]

- Date Introduced: 11/19/20
- Sponsors: Reps. Abby Finkenauer (D-IA) and Conor Lamb (D-PA)
- Summary: To expand Buy America policies to improve America's ability to manufacture critical supplies during times of emergency and reduce reliance on foreign countries in critical supply chains. Would create a council of heads of key government departments and representatives from industry, labor, research institutions, and state and local government. The committee would be tasked with developing policies to reduce dependency on foreign manufacturers and supply chains; assessing the production of critical supplies and sourcing of their materials; assessing the effectiveness of current federal policies which support and incentivize domestic manufacturing; developing plans on how to ensure readiness in the event of future global supply chain disruptions; strengthening existing policies like Buy America laws; studying ways to increase demand for American made products; and determining future workforce needs and new investments in high skilled American workers in order to support increased domestic production.

H.R.8644, Secure America's Medicine Act of 2020 [link]

- Date Introduced: 10/20/20
- Sponsors: Reps. Jason Smith (R-MO) and Bradley Schneider (D-IL)
- Summary: This bill would require the Secretary of Health and Human Services (HHS) to begin procuring critical medications the Federal Government should ensure are readily available for the American public in the event of another national health emergency.

H.R. 14, Commitment to Defeat the Virus and Keep America Healthy Act [link]

- Date Introduced: 10/30/20
- Sponsors: Rep. Richard Hudson (R-NC), Minority Leader Kevin McCarthy (R-CA), Rep. Kevin Brady (R-TX), Rep. Greg Walden (R-OR), and Rep. Kay Granger (R-TX)
- Summary: A coronavirus relief package that includes the following bills regarding the pharmaceutical supply chain:
    - H.R. 6930, Manufacturing API, Drugs, and Excipients in America Act
    - H.R. 8588, Improving the American Drug Supply Chain Act
    - H.R. 8479, Essential Medicines Strategic Stockpile Act
    - H.R. 4866, National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act
    - H.R. 6531, Medical Supplies for Pandemics Act
    - H.R. 7767, Domestic Medical and Drug Manufacturing Credit Act

H.R. 8479, Essential Medicines Strategic Stockpile Act of 2020 [link]

- Date Introduced: 10/1/20
- Sponsors: Reps. Buddy Carter (R-GA) and Lisa Blunt Rochester (D-DE)

- Summary: The bill establishes a three year pilot program that creates public-private partnerships to stockpile certain generic medications to prevent shortages. During the pilot program, the Department of Health and Human Services (HHS) will work with stakeholders and other government agencies to establish a list of 50 generic medications that are essential in public health emergencies. Medical product distributers can then contract with HHS to stockpile the medications within their own supply chains. These entities will be required to continuously cycle the additional product through their supply chain to avoid any expiration issues while maintaining a 6-month supply of the product for the federal government to access at any time.

H.R. 11, Commitment to American GROWTH Act [link]

- Date Introduced: 10/9/20
- Sponsors: Rep. Kevin Brady (R-TX) and Minority Leader Kevin McCarthy (R-CA)
- Summary: Lowers the tax rate on the income from the domestic manufacturing and sales of active pharmaceutical ingredients (API) and medical countermeasures while provided a bonus R&D credit for countermeasures. It creates a 30 percent tax credit for new investments in advanced medical manufacturing equipment or machinery used in the U.S. to manufacture medicines or medical devices. It also provides a refundable R&D for pre-revenue medical research companies – such as small biotech firms on the frontlines of cures research. And it amends the passive loss rules so that investors in certain infectious disease drug development firms can use the tax attributes of these pre-revenue firms to offset their income from other sources.

H.R. 8588, Improving the American Drug Supply Chain Act [link]

- Date Introduced: 10/13/20
- Sponsors: Reps. Richard Hudson (R-NC) and Lisa Blunt Rochester (D-DE)
- Summary: To study the drug supply chain and identify obstacles to domestic manufacturing and potential incentives to bring more manufacturing back to the U.S.

S.4775, Delivering Immediate Relief to America's Families, Schools and Small Businesses Act [link]

- Date Introduced: 9/30/20
- Sponsor: Sen. McConnell (R-KY)
- Summary: Includes a provision to provide $31 billion to the Public Health and Social Services Emergency Fund to respond to the coronavirus, develop countermeasures and vaccines, and purchase medical supplies and therapeutics, with a focus on US-based manufacturing. These funds would remain available until September 30, 2024.

H.R.8324/S.4578, Make PPE in America Act [link/link]

- Date Introduced: 9/21/20
- Sponsors: Rep. Budd (R-NC), Rep. Schakowsky (D-IL) and Sen. Portman (R-OH), Sen. Peters (D-MI)
- Summary: The bill requires the Defense Logistics Agency to issue longer-term contracts to make Personal Protective Equipment in America.

H.R. 12, China Task Force Act [link]

- Date Released: September 30, 2020

- Authors: The House China Task Force (Leader McCarthy (R-CA), Chairman McCaul (R-TX), and Reps. Kinzinger (R-IL), Barr (R-KY), Stewart (R-UT), Stefanik (R-NY), LaHood (R-IL), Banks (R-IN), Cheney (R-WY), Curtis (R-UT), Gallagher (R-WI), Gonzalez (R-OH), Joyce (R-PA)t, Reschenthaler (R-PA), Riggleman (R-VA), and Waltz (R-FL))
- Summary: The Report recommends passing the following legislation and proposals:
    - Section 712, a bipartisan provision of H.R. 6395 in the FY2021 NDAA, which would require the next National Security Strategy to include the provision of drugs, biologics, vaccines, and critical medical equipment.
    - Section 1808(f) of H.R. 6395 in the FY2021 NDAA, a bipartisan provision reflecting the text of H.R. 6399, the Securing America's Vaccines for Emergencies (SAVE) Act. This legislation would require the President to deliver a national strategy for use of the Defense Production Act in order to ensure the supply of medical articles essential for national defense.
    - Section 750L, a bipartisan provision of H.R. 6395 in the FY2021 NDAA, which would require DoD, in consultation with other relevant federal agencies, to conduct a targeted study and submit a classified report to Congress on DoD's Joint Development Formulary (JDF), which would include a core list of pharmaceutical items that are required for contingency operations, identify barriers that may limit DoD from procuring necessary items, and identify international military partners who can help manufacture them.
    - The Administration should quickly implement section 3112 of the CARES Act, which requires drug manufacturers to report drug and API volume and will provide needed insight into the amount of drug products the U.S. received from foreign countries.
    - H.R. 6670, the Prescription for American Drug Independence Act, which would require the National Academies to establish a committee of drug supply chain experts, convene a public symposium to analyze the impact of U.S. dependence on foreign manufacturing of critical drugs, and recommend strategies to reduce dependency on foreign manufacturing while still ensuring a diversified supply chain.
    - Legislation to require the National Academies of Science, Engineering, and Medicine to conduct a study on why pharmaceutical manufacturing has moved off-shore, what products (such as APIs) were or were not historically manufactured in the U.S., and what market incentives would need to change to increase domestic drug manufacturing.
    - H.R. 4866, the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act, which directs the FDA to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing to work with the FDA and industry to craft a national framework for continuous manufacturing implementation.
    - H.R. 6531, the Medical Supplies for Pandemics Act, that would allow the Strategic National Stockpile to enter into joint ventures with domestic manufacturers to establish new or expanded manufacturing lines for personal protective equipment.
    - Legislation to continue to promote policies intended to prevent and mitigate drug shortages, such as legislation that would allow the government to enter contracts with pharmaceutical distributors in which the distributors would secure, manage, and replenish a supply of drugs that are at high-risk of shortage.
    - H.R. 6930, the Manufacturing API, Drugs, and Excipients (MADE) in America Act, to require a GAO study to assess whether the differing regulatory requirements across countries creates inefficiencies in drug manufacturing, enhance transparency of facility inspection timelines, and codify FDA's advanced manufacturing technologies program.

- H.R. 7767, the Domestic Medical and Drug Manufacturing Tax Credit, which cuts the U.S. tax rate in half for income from domestic manufacturing and sale of APIs and medical countermeasures through a tax credit and provides a 30 percent investment tax credit for new investments in advanced manufacturing equipment used in the U.S. to manufacture drugs and medical products.
- H.R. 7555, the More Cures Act, and H.R. 7556, the Startups for Cures Act, which create R&D incentives for biotech companies that are engaged in infectious disease drug development or research and provide refundable R&D credits for infectious disease vaccine and drug research for pre-revenue biotech companies in order to remove obstacles that prevent innovators from starting U.S. companies to work to cure diseases.
- H.R. 7537, the Infectious Disease Therapies Research and Innovation Act of 2020, which creates earlier investment and stronger research in critical therapies and vaccines by amending the passive loss rules currently in the tax code in order to help these smaller firms raise private funds from more investors at an earlier stage.
- H.R. 7505, the American Innovation Act of 2020, which would make it easier for America's innovators to start new drug companies that can research and develop new cures and treatments by providing special tax treatment for start-up costs and by preserving valuable tax attributes like R&D credits.

Updated HEROES Act [link]

- Date Introduced: September 28, 2020
- Summary: Requires the President to appoint a Medical Supplies Response Coordinator to serve as POC for the health care system, supply chain officials, and states on medical supplies, including PPE, devices, drugs, and vaccines. Clarifies that the medical device identifier or national product code shall be included with any required shortage reporting, which will help facilitate identification of acceptable alternatives. Provides authority to the FDA to require manufacturers to provide the agency with information pertinent to an extension of medical device shelf life dates in case of shortages during public health emergencies. Extends FDA's administrative destruction authority to medical devices, particularly for counterfeits. Requires drug manufacturers to report foreign drug manufacturing sites and to report quarterly on the volume of drugs manufactured. Requires NASEM to conduct a symposium of experts to discuss recommendations to encourage domestic manufacturing of critical drugs and devices of greatest priority to providing health care. Provides FDA with an enforcement mechanism to require timely notifications related to a permanent discontinuance or interruption in the manufacturing of certain drugs. Provides FDA with an enforcement mechanism to require drug manufacturers to deelop a risk management plan. Directs FDA to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing. NCEs will work with FDA and industry to craft a national framework for the implementation of continuous manufacturing of drugs. SNS improvements.

H.R. 7999, Supply Chain Accountability Act of 2020 [link]

- Date Introduced 8/11/20
- Sponsor: Rep. Don Beyer (D-VA)
- Summary: This bill requires the Department of Health and Human Services (HHS) to address shortages of personal protective equipment and delays in testing for COVID-19 (i.e., coronavirus disease 2019) that are reported by health care providers, public health agencies, or certain nursing facilities. Specifically, HHS must implement a process to respond to these reports within 30 days

and outline the actions being taken to resolve the shortages and delays. HHS must also provide its response to the congressional delegation that represents the district or districts from which the reports originated.

S. Amdt.2652, Senate GOP Targeted Coronavirus Relief Package [link]

- Date Introduced: 9/8/20
- Summary: Authorizes improvements and supports for sustained on-shore manufacturing surge capacity and capabilities to produce needed medical countermeasures, such as vaccines and therapeutics, to respond to public health threats like COVID-19. Authorizes grants for the establishment of state stockpiles of medical products and supplies needed during a public health emergency. Makes improvements to the Strategic National Stockpile by encouraging partnerships with those in the medical product supply chain to increase manufacturing and stockpiling with capacity.

COVID-19 Second Wave Preparedness Report, Part III: Health Care Supply Chain [link]

- Date Introduced: 8/20/20
- Authors: Energy and Commerce Republicans, led by Ranking Member Walden (R-OR) and Oversight and Investigations Subcommittee Ranking Member Guthrie (R-KY)
- Summary:
    - States should consider building independent medical supply stockpiles to be better prepared to manage critical shortages of medical resources.
    - Congress and the Executive Branch should clarify the role of the Strategic National Stockpile (SNS) during a global pandemic or biological event which affects the whole country, including mechanisms for coordinating health care resources to the states and territories, to provide a shared understanding of the SNS' role in that situation.
    - Congress and the Executive Branch should examine the use of the SNS in the first wave of the pandemic, the coordination of the SNS' response activities with FEMA, and potential overlaps in authorities and responsibilities among HHS, FEMA, and DoD, and put in place any needed changes or processes to most effectively replenish and manage the SNS.
    - Congress and the Executive Branch should explore whether any of the HHS plans for enhanced SNS IT communication and supply management can be expedited for implementation before the fall.
    - Congress and the Executive Branch should review HHS' procurement and acquisition processes and staffing to assess if barriers prevent the SNS from using HHS Defense Production Act (DPA) authorities, which provide mechanisms for priority rating SNS agreements and orders or allocate distribution of a contractor's stock inventory.
    - Congress and the Executive Branch should consider whether, and if so, what, potential therapeutics for COVID-19 should be included in the SNS once authorized or approved by FDA.
    - In order to ensure the stability of supply chains, Congress and the Executive Branch should evaluate how federal agencies coordinate contracting considerations, and ensure that they clearly communicate their actions and plans regarding medical supply chain coordination efforts to ensure process transparency.

- Congress and the Executive Branch should review critical medical equipment temporary tariff exclusions to determine if additional exclusions are needed, and if any approved exclusions need to be extended to assist in the response to the pandemic.
- The Executive Branch should monitor testing supplies for diagnostic and surveillance testing needs. In considering allocation and distribution, the Executive Branch should examine whether use of its DPA allocations authority or other mechanisms, such as voluntary

H.R. 8059, Strengthening our Health Security Through Resilient Medical Supply Chains Annual Review Act [link]

- Date Introduced: 8/17/20
- Sponsors: Rep. Trone (D-MD) and Rep. Joyce (R-PA)
- Summary: A bill to direct the Secretary of Homeland security to submit to Congress a report on the security and resilience of the US medical supply chains, and for other purposes.

S.4467/HR.7527, Medical Manufacturing, Economic Development, and Sustainability (MMEDS) Act of 2020 [link/link]

- Date Introduced: 8/6/20
- Sponsors: Sen. Rubio (R-FL) and Reps. Gonzalez-Colon (R-PR), Serrano (D-NY), Bishop (R-UT), Shalala (D-FL), King (R-NY), Soto (D-FL), Fitzpatrick (R-PA), and Diaz-Balart (R-FL).
- Summary: This bill would encourage companies currently producing medical and pharmaceutical equipment abroad to relocate to the U.S. The bill would also enact a tax credit of federal income tax liability for wages and eligible pharmaceutical manufacturing facilities in economically distressed zones, including Puerto Rico.

S. 4324, Restoring Critical Supply Chains and Intellectual Property Act (in HEALS) [link]

- Sponsor: Sen. Graham (R-SC)
- Date Introduced: 7/27/20
- Summary: Any purchases by HHS of covered items for the SNS must be manufactured domestically and from components grown, reprocessed, reused, or produced in the U.S. Items covered include PPE and clothing, sanitizing supplies and ancillary medical supplies, and any other textile medical supplies and textile equipment. HHS will immediately begin increasing procurements of domestic PPE for the SNS incrementally and reach 100% domestic sourcing as soon as practicable within five years. HHS also must submit a plan to Congress within 90 days detailing how they will reach 50% domestic sourcing in one year, 75% in 18 months, and 100% in two years. Established a $7.5 billion medical manufacturing project tax credit to buildout and retrofit factories to meet increased PPE demand.

S. 4322, Safely Back to School and Back to Work Act (in HEALS) [link]

- Sponsor: Sen. Alexander (R-TN)
- Date Introduced: 7/27/20
- Summary: Improves and supports sustained manufacturing surge capacity and capabilities to produce needed medical countermeasures, such as vaccines and therapeutics, to respond to public health threats like COVID-19. Establishes state stockpiles of medical products needed during a public health emergency. Requires states to submit a stockpiling plan to the HHS Secretary for

maintaining the state stockpile. Requires HHS to provide guidance and technical assistance to states on maintaining their stockpiles. Ensures that state stockpiles will be appropriately administered and maintained by directing the Secretary to establish an auditing process and withholding funds if a state fails to submit a state stockpiling plan or meet certain benchmarks. Improves the SNS by partnering with medical product manufacturers, distributors, or other entities to increase the stockpiling and manufacturing capacity of reserve amounts of medical products provided during or in advance of a public health emergency. Requires HHS to publish guidance on how states and tribes can request and access resources from the SNS.

S. 4368, Protecting American Heroes Act [link]

- Date Introduced: 7/29/20
- Sponsor: Sen. Brown (D-OH)
- Summary: Would ensure the Strategic National Stockpile can respond to a public health emergency that affects all 50 states at once. Requires all supplies in the stockpile to be produced in the U.S. with certain exceptions based on availability and require domestic producers who manufacture supplies to give advance notice before they go out of business. Would create a position of Executive Deputy Assistant Secretary of the Strategic National Stockpile to put stockpile decisions in the hands of a high-level, qualified career professional and increase congressional awareness of SNS supply chains through enhanced, regular reporting requirements. Lastly, it would make funding for the Strategic National Stockpile mandatory and extend DPA authority to the HHS Secretary during a public health emergency.

S. 4359/H.R. 7853, The Resilient Manufacturing Task Force Act [link/link]

- Date Introduced: 7/29/20
- Sponsors: Sens. Coons (D-DE), Rubio (R-FL), Cornyn (R-TX), and Hassan (D-NH)/Reps. Stevens (D-MI) and Balderson (R-OH)
- Summary: The legislation establishes a task force to identify critical vulnerabilities in existing U.S. supply chains and develop a plan for a National Manufacturing Guard, a volunteer organization of American experts from across the private sector, which will train for supply chain and other manufacturing emergencies.

H.R. 7841, The American PPE Supply Chain Integrity Act [link]

- Date Introduced: 7/29/20
- Sponsors: Rep. Patrick McHenry (R-NC) and Rep. Bill Pascrell (D-NJ)
- Summary: This bill requires the federal government to purchase medical supplies and personal protective equipment from the United States, with exceptions for small purchases. Specifically, the bill requires the Department of Health and Human Services, the Department of Homeland Security, and the Department of Veterans Affairs to purchase specified medical supplies (including disinfecting wipes and natural fiber products) and personal protective equipment (including surgical masks, face shields, and foot coverings) from products that are 100% grown, reprocessed, reused, or produced in the United States. The bill makes an exception for purchases for amounts not greater than $150,000. The bill applies the Berry Amendment (which requires the Department of Defense to give preference in procurement to domestically produced, manufactured, or home-grown products) to specified supplies and equipment, such as surgical dressing materials, hospital and surgical clothing, and textile medical supplies and equipment.

S.4320, Coronavirus Response Additional Supplemental Appropriations Act, 2020 [link]

- Date Introduced: 7/27/20
- Sponsor: Sen. Shelby (R-AL)
- Summary: This bill would add an additional amount of $29,000,000,000 to the "Public Health and Social Services Emergency Fund" to remain available until September 30, 2024, to prevent, prepare for, and respond to coronavirus, domestically or internationally. This includes the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity, addressing blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the U.S. Commissioned Corps, and other preparedness and response activities.

S. 4264, U.S. MADE Act of 2020 [link]

- Date Introduced: 7/22/20
- Sponsors: Sens. Graham (R-SC), Moore Capito (R-WV), and Rounds (R-SD)
- Summary: The U.S. MADE Act of 2020 is modeled after the Berry Amendment and outlines PPE acquisition requirements for the Strategic National Stockpile. The legislation also establishes an investment credit for qualifying PPE manufacturing projects. Modeled after the 48C Advanced Manufacturing Tax Credit, eligible U.S. manufacturers will receive a thirty percent credit against equipment costs associated with PPE manufacturing. Would declare the following items national priorities:
    - Testing swabs; surgical and respirator masks; face shields; surgical and isolation gowns; sanitizing and disinfecting wipes; gauzes and bandages; privacy curtains, beds, and bedding

S. 4241, The Slave-Free Business Certification Act [link]

- Date Introduced: 7/20/20
- Sponsors: Sen. Hawley (R-MO)
- Summary: Compels companies to disclose the steps they are taking to eradicate forced labor, slavery, and human trafficking from their supply chains. Directs major companies to undergo independent audits to ensure they are not complicit in forced labor and trafficking in their supply chains. Mandates public reports to the Department of Labor on the results of their independent audits. Requires CEOs to certify that their supply chains are free from slave labor or that they have reported all instances of forced labor in their companies

H.R. 7574, Strengthening America's Strategic National Stockpile Act of 2020 [link]

- Date Introduced: 7/13/20
- Sponsors: Reps. Slotkin (D-MI), Brooks (R-IN), Eshoo (D-CA), Carter (R-GA), Dingell (D-MI), Walorski (R-IN), DeGette (D-CO), McKinley (R-WV), Butterfield (D-NC), Van Drew (R-NJ), Soto (D-FL), Upton (R-MI), Malinowski (D-NJ), Hudson (R-NC), Schrier (D-WA), Gianforte (R-MT), Cisneros (D-CA), Neguse (D-CO), Burgess (R-TX)

- Summary: The bill includes provisions originally introduced as part of Rep. Slotkin's Made in America Medical Supply Chain Initiative, as well as other bipartisan provisions to boost domestic manufacturing of our medical supplies as a matter of national security.

H.R. 7614, House Appropriations FY2021 Labor-HHS Appropriations Bill [link]

- Date Introduced: 7/7/20
- Sponsors: Rep. DeLauro (R-CT)
- Summary: The bill includes a new provision requiring a weekly report on the inventory of ventilators and personal protective equipment in the Strategic National Stockpile, as well as an annual professional judgment budget for necessary expenditures to maintain the minimum level of relevant supplies, including in the case of a pandemic.

H.R. 7610, House Appropriations FY2021 Ag-FDA Appropriations Bill [link]

- Date Introduced: 7/6/20
- Sponsors: Rep. Bishop (D-GA)
- Summary: The Committee directs FDA to work with Congress on ensuring they have the necessary tools and resources to prevent drug and device shortages. The Committee directs FDA to provide a briefing to the Committee on the state of the drug and medical device supply chain and any additional authorities or capabilities that are needed to assist FDA in mitigating shortages or identifying potential disruptions of these medical products. The Committee directs FDA to develop a report that addresses the vulnerabilities of the U.S. medical supply chain. This report should include recommendations on the following: (1) an identification of finished drugs and their essential components including raw materials, chemical components, and active ingredients necessary for the manufacture of medicines where supply is dependent on a single or limited number of providing countries; (2) recommendations for how to diversify supply away from predominant dependency on sources of supply in other countries and how to further the adoption of U.S.-based advanced manufacturing for active pharmaceutical ingredients and chemical precursors; and (3) discussion of legislative, regulatory, and policy changes necessary to close gaps in the FDA's ability to assess critical supply chain risks and encourage domestic manufacturing, including advanced manufacturing, of critical components and finished drug products. The Committee is aware of automated microbial detection systems in health care manufacturing and their ability to mitigate risks to the safety of the American drug supply due to expanding reliance on global supply chains. The Committee encourages FDA to understand how these critical technologies can increase the efficiency and safety of the domestic medical product manufacturing and supply chain.

S. 4175, The Pharmaceutical Supply Chain Defense and Enhancement Act [link]

- Date Introduced: 7/2/20
- Sponsors: Sen. Warren (D-MA) and Sen. Smith (D-MN)
- Summary: This bill would require the FDA Commissioner and Secretary of Defense to develop a list of "critical drugs" essential for public health and national security. Would lower the cost of domestic production by providing $1 billion a year for 5 years to the Biomedical Advanced Research and Development Authority (BARDA), to dramatically upgrade our national capacity to manufacture "critical drugs." Would create a market for domestically-produced pharmaceuticals by requiring DoD, VA, HHS, and BOP to purchase American-made drugs and providing funding to subsidize the purchase of these drugs. Would boost supply chain transparency by requiring

drug makers to annually report to the FDA information about the source of APIs and starting materials used to make drugs consumed in the United States. Would require the FTC and the Treasury Department to study the role of foreign investment in the U.S. pharmaceutical industry within one year of the Act's passage.

S. 4191, U.S. Pharmaceutical Supply Chain Review Act [link]

- Sponsors: Sen. Rubio (R-FL) and Sen. Warren (D-MA)
- Summary: This legislation tasks the federal government with studying the effects of this overreliance. Specifically, this bill directs the Federal Trade Commission (FTC), along with the Secretary of the Treasury, acting through the Committee on Foreign Investment in the United States (CFIUS), to conduct a study on the United States' overreliance on foreign countries and the impact of foreign direct investment in the U.S. pharmaceutical industry. Specifically, the agencies must provide Congress with a report on the following within 1 year of passage of the Act:
    - How overreliance on foreign counties for pharmaceutical products impacts the United States' supply chain and domestic manufacturing capacity
    - How foreign direct investment from abroad affects the nation's ability to produce drugs, as well as their key components
    - How foreign direct investment in U.S. genome sequencing technologies affects domestic capacity to sequence or store DNA
    - The number of foreign investment transactions in the pharmaceutical industry and the sequencing or storage of DNA in the United States that CFIUS has reviewed in the past ten years

S.4158, PPE Supply Chain Transparency Act of 2020 [link]

- Date Introduced: 7/2/20
- Sponsors: Sen. Hawley (R-MO)
- Summary: A bill to examine the extent of the reliance of the United States on foreign producers for personal protective equipment during the COVID-19 pandemic and produce recommendations to secure the supply chain of personal protective equipment.

S. 4049/H.R. 6395, National Defense Authorization Act for Fiscal Year 2021 [link/link]

- Date Introduced: 6/23/20
- Sponsors: Sen. Inhofe (R-OK)/ Rep. Smith (D-WA)
- SA 2422
    - Sponsor: Sen. Marco Rubio (R-FL)
    - Summary: To support supply chain innovation and multilateral security
- SA 2423
    - Sponsor: Sen. Bernie Sanders (I-VT)
    - Summary: An amendment to provide, manufacture, and distribute high quality face masks for every individual in the United States during the COVID-19 emergency using the Defense Production Act and other means.
- Amendment text

S. Res. 625, A resolution encouraging the Government and the people of the United States to "Buy American" [link]

- Date Introduced: 6/16/20
- Sponsors: Sens. Scott (R-FL), Baldwin (D-WI), Loeffler (R-GA), Murphy (D-CT), Rounds (R-SD), Brown (D-OH), Moore Capito (R-WV), Smith (D-MN), Cramer (R-ND), Peters (D-MI), Hawley (R-MO), Stabenow (D-MI), Blumenthal (D-CT) and Reed (D-RI)

S.3942, Securing America's Medical Supply Chain and Advancing the Production of Life Saving Medicines Act [link]

- Date Introduced: 6/11/20
- Sponsors: Sen. Loeffler (R-GA)
- Summary: Establishes the position of Chief Pharmaceutical and Medical Supply Chain Negotiator in the Office of the United States Trade Representative, to be responsible for conducting trade negotiations and enforcing trade agreements related to foreign governments that fail to appropriately reward United States innovation with respect to pharmaceuticals, to advance domestic production of life-saving medicines, and to secure the United States medical supply chain to eliminate reliance on foreign governments.

"Preparing for the Next Pandemic" White Paper by HELP Chairman Alexander (R-TN) [link]

- Date Published: 6/9/2020
- Supply Chain Recommendations:
    - Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.
    - States should establish distribution plans and procedures to better inform and communicate with health care providers that request supplies. The Strategic National Stockpile should provide states, territories, and tribes with guidance on best practices to coordinate and distribute medical supplies, including procedures to request resources from the federal stockpile.
    - Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.
    - The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.
    - Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.
    - Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies

S. 3945, BEAT CHINA Act [link]

- Date Introduced: 6/11/20
- Sponsors: Sens. Loeffler (R-GA), Ernst (R-IA), and Cruz (R-TX)
- Summary: Companion bill to H.R.6690 of the same name. This bill would amend the tax code to provide incentives to companies to relocate the manufacturing of pharmaceuticals, medical devices and supplies to the United States. Medical supply and pharmaceutical companies that move from a foreign country to the United States can have non-residential real property purchases considered to be 20-year property instead of 39 years, a change that will allow companies to be eligible for "bonus depreciation" and the purchase of the property to be fully deducted in the first year. Qualifying companies will also be able to exclude from gross income any gain earned on the disposition of assets in the country the company is moving from. This will prevent companies from taking unnecessary hits from taxes if they choose to move to the United States. In order for companies to qualify for these tax incentives and to ensure the domestic production of materials, companies must adhere to at least the same production levels in the United States as they had in the country they're leaving.

S.3829, Global Health Security and Diplomacy Act of 2020 [link]

- Date Introduced: 5/21/20
- Sponsors: Sens. Jim Risch (R-ID), Chris Murphy (D-CT), and Ben Cardin (D-MD)
- Summary: A bill to advance the global health security and diplomacy objectives of the United States, improve coordination among the relevant Federal departments and agencies implementing United States foreign assistance for global health security, and more effectively enable partner countries to strengthen and sustain resilient health systems and supply chains with the resources, capacity, and personnel required to prevent, detect, mitigate, and respond to infectious disease threats before they become pandemics, and for other purposes.

S.3827, Medical Supplies for Pandemics Act of 2020 [link]

- Date Introduced: 5/21/20
- Sponsors: Sens. Tillis (R-NC), Bennet (D-CO), and Hyde-Smith (R-MS)
- Summary: Would authorize $500 million annually through fiscal year 2023 to implement a supply chain flexibility manufacturing program to create incentives for the domestic manufacturer of medical supplies to enhance supply chain elasticity; establish and maintain domestic reserves of critical medical supplies like personal protective equipment and diagnostic tests; and work with distributors of medical supplies to manage domestic reserves held by the Strategic National Stockpile by refreshing and replenishing supply stocks.

Made In America 6-Bill Package

- Date Introduced: 5/14/20
- Sponsor: Rep. Slotkin (D-MI)
- Includes:
    - H.R.6875 [link] - To direct the Comptroller General of the United States to conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the Strategic National Stockpile, and for other purposes.
    - H.R.6876 [link] – To amend the Public Health Service Act to ensure that the contents of the Strategic National Stockpile remain in good working order and, as appropriate, conduct maintenance services on contents of the stockpile, and for other purposes.
    - H.R.6877 [link] - To direct the Assistant Secretary for Preparedness and Response to issue a report to Congress regarding all State, local, Tribal, and territorial requests for

supplies from the Strategic National Stockpile related to COVID-19, and for other purposes.
  - H.R.6878 [link] - To direct the Secretary of Health and Human Services to develop and implement improved, transparent processes for the use and distribution of supplies in the Strategic National Stockpile, and for other purposes.
  - H.R.6879 [link] – To enhance American production of certain medical supplies, and for other purposes
  - H.R.6880 [link] - To direct the Administrator of the Federal Emergency Management Agency to coordinate the development of plans, designs, and guidance relating to the production, in accordance with other applicable law, of certain homeland security-critical supplies to address potential national emergencies and disasters, and for other purposes.

H.R.6952, [No Titlet, link]
- Date Introduced: 5/19/20
- Sponsor: Rep. Brad Schneider (D-IL)
- Summary: To direct the President to appoint a Medical Supplies Response Coordinator to coordinate the efforts of the Federal Government regarding the supply and distribution of certain supplies and equipment relating to COVID-19.

S. 3780, The Help Onshore Manufacturing Efficiencies for Drugs and Devices Act (HOME) Act [link]
- Introduced: 5/20/20
- Sponsors: Sen. Gary Peters (D-MI)
- Summary: Would help reduce U.S. reliance on foreign sources for critical drugs and medical supplies and ramp up American manufacturing capacity. The bill would establish a Center for Domestic Advanced Manufacturing of Critical Drugs and Devices charged with facilitating investments in advanced manufacturing capabilities for critical drugs and devices throughout the United States. The Center, located within HHS, would: assess, in coordination with the Department of Homeland Security and DOD, supply chain vulnerabilities for critical drugs and devices; award funding to qualified manufacturers to invest in advanced manufacturing and increased domestic production of critical drugs and medical supplies in the U.S.; and encourage federal agencies to enter into long-term, high-volume contracts for these products.

S. 3781, The Pharmaceutical Accountability, Responsibility, and Transparency (PART) Act [link]
- Introduced: 5/20/20
- Sponsors: Sen. Gary Peters (D-MI)
- Summary: Would expand reporting requirements for manufacturers and require quarterly disclosures to the Food and Drug Administration (FDA) on critical manufacturing data such as which medications and what in amount – including active pharmaceutical ingredients – are produced domestically and abroad. Manufacturers would also be required to report any increased demand or export restriction to proactively address potential shortages. The FDA would be required to share critical manufacturing data with the Defense Department (DOD) and the Assistant Secretary for Preparedness and Response (ASPR).

H.R. 6930, The MADE in America Act [link]
- Introduced: 5/19/20
- Sponsors: Rep. Buddy Carter (R-GA)
- Summary: The MADE in America Act incentivizes the domestic manufacturing of drugs, API, PPE, and diagnostics in order to make the U.S. supply chain less dependent on foreign countries like China. This is achieved through a new tax credit that would only apply to manufacturers operating in certain Opportunity Zones across the United States. This will work to bring manufacturing back to the United States through incentives aimed at leveling the playing field.

Additionally, the legislation includes measures aimed at mitigating drug shortages including improving FDA reporting of facility inspections, working more closely with overseas regulators and streamlining FDA standardization processes for overseeing pharmaceutical manufacturing and the supply chain.

H.R. 6885, Safe and Secure Medicine Supply for Hardworking Americans Act [link]

- Introduced on May 15th, 2020
- Sponsors: Rep. Flores (R-TX)
- Summary: Penalizes foreign manufacturing facilities if they produce tainted drugs, as well as the companies that import those drugs into the U.S. Places tariffs on imported drugs from certain countries to discourage companies from manufacturing drugs outside the U.S. Creates a registry of all FDA approved drugs and any active ingredients manufactured outside the U.S. Requires drug labels to indicate the country of origin for each active ingredient. Provides incentive grants to drug manufacturers to increase their manufacturing capacity and workforce in the U.S.

S. 1055/H.R. 2083, Homeland Procurement Reform Act [link/link]

- Introduced on 4/4/19 in the Senate and on 5/15/19 in the House.
- Sponsors: Sen. Jeanne Shaheen (D-NH), Chris Murphy (D-CT), Doug Jones (D-AL), Maggie Hassan (D-NH), Mike Rounds (R-SD), and Jerry Moran (R-KS). Sponsored by Rep. Luis Correa (D-CA), Brian Mast (R-FL), Jim McGovern (D-MA), Chris Pappas (D-NH), and Bennie Thompson (D-MS) in the House.
- Summary: Would require the Department of Homeland Security to increase the amount of PPE it procures from American companies. DHS would ensure the items are purchased at a fair and reasonable price and study the adequacy of uniform allowances provided to employees. These restrictions would narrow the field that DHS is able to procure from and drive DHS procurement towards predominately U.S. companies that are able to meet the standards outlined in the bill.

H.R.6800, The Heroes Act [link]

- Sponsors: Reps. Lowey (D-NY), Scott (D-VA), Pallone (D-NJ), Waters (D-CA), Engel (D-NY), Nadler (D-NY), Grijalva (D-AZ), Maloney (D-NY), Velázquez (D-NY), Takano (D-CA) and Neal (D-MA)
- Introduced: 5/12/20
- The bill calls for supply chain improvements including:
    - Section 30511. Medical Supplies Response Coordinator. Requires the President to appoint a Medical Supplies Response Coordinator. A Medical Supplies Response Coordinator would serve as the point of contact for the health care system, supply chain officials, and states on medical supplies, including personal protective equipment (PPE), medical devices, drugs, and vaccines. The appointee is required to have health care training and an understanding of medical supply chain logistics.
    - Section 30512. Information to be included in list of devices determined to be in shortage. Clarifies that the medical device identifier or national product code shall be included with any required shortage reporting, which will help facilitate identification of acceptable alternatives.
    - Section 30513. Device shelf life dates. Provides authority to the Food and Drug Administration (FDA) to require manufacturers to provide the agency with information pertinent to an extension of medical device shelf life dates in cases of shortages or material slowdowns during public health emergencies.

- Section 30514. Authority to destroy counterfeit devices. Extends FDA's administrative destruction authority to medical devices. This would allow FDA to destroy certain imported medical devices, such as counterfeit tests or masks, in instances where FDA believes such medical devices are adulterated, misbranded, or unapproved and may pose a threat to the public health as they currently do for drugs.
- Section 30515. Reporting requirement for drug manufacturers. Requires drug manufacturers to report foreign drug manufacturing sites and to report quarterly on the volume of drugs manufactured.
- Section 30516. Recommendations to encourage domestic manufacturing of critical drugs. Requires National Academies of Science, Engineering, and Medicine (NASEM) to conduct a symposium of experts to discuss recommendations to encourage domestic manufacturing of critical drugs and devices of greatest priority to providing health care.
- Section 30517. Failure to notify of a permanent discontinuance or an interruption. Provides FDA with an enforcement mechanism to require timely notifications related to a permanent discontinuance or interruption in the manufacturing of certain drugs and the reasons for such discontinuance or interruption, as required under current law.
- Section 30518. Failure to develop risk management plan. Provides FDA with an enforcement mechanism to require drug manufacturers to develop a risk management plan, as required under current law
- Section 30519. National Centers of Excellence in Continuous Pharmaceutical Manufacturing. Directs FDA to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing (NCEs). NCEs will work with FDA and industry to craft a national framework for the implementation of continuous manufacturing of drugs, including supporting additional research and development of this technology, workforce development, standardization, and collaborating with manufacturers to support adoption of continuous manufacturing of drugs.
- Section 30520. Vaccine manufacturing and administration capacity. Requires the Secretary of HHS to award contracts, grants, cooperative agreements, and enter into other transactions, as appropriate, to expand and enhance manufacturing capacity of vaccines and vaccine candidates to prevent the spread of COVID-19. It also requires a report on the vaccine supply necessary to stop the spread of COVID-19, the manufacturing capacity to produce vaccines, activities conducted to enhance such capacity, and plans for continued support of vaccine manufacturing and administration.

H.R.6858, COVID-19 Emergency Medical Supplies Enhancement Act of 2020 [link]

- Introduced: 5/13/20
- Sponsors: Rep. Vargas (D-CA), Waters (D-CA), Crow (D-CO), Ryan (D-OH), Trahan (D-MA), and Slotkin (D-MI)
- Summary: To enhance authorities under the Defense Production Act of 1950 to respond to the COVID-19 emergency, to provide additional oversight of such authorities, and to require a strategy on securing supply chains for medical materials, and for other purposes.

H.R. 6731, Securing America's Pharmaceutical Supply Chain Act [link]

- Introduced: 5/5/20
- Sponsors: Rep. Pete Stauber (R-MN)

- Summary: This bill allows an executive agency to purchase a drug approved or licensed by the Food and Drug Administration only if the drug is over 50% sourced, manufactured, and assembled in the United States. The requirement may be waived if the drug is not available in sufficient quantity or quality as over 50% sourced, manufactured, and assembled in the United States; or during an emergency. It also instructs the U.S. Trade Representative (USTR) to modify U.S. product coverage under all free trade agreements and the World Trade Organization Agreement on Government Procurement to exclude coverage of essential medicines and medical countermeasures.

H.R. 6690, BEAT China Act [link]

- Introduced: 5/1/20
- Sponsors: Rep. Chip Roy (R-TX)
- Summary: This legislation offers a few specific changes to the tax code and will allow qualifying companies to obtain beneficial tax treatments for manufacturing in U.S. territories. It looks to incentivize moving pharmaceutical manufacturing back to the United States and its territories. Medical supply and pharmaceutical companies moving from a foreign country to the United States can have non-residential real property purchases considered to be 20-year property instead of 39 years, a change which will allow companies to be eligible for "bonus depreciation" and the purchase of the property to be fully deducted in the first year. Qualifying companies will also be able to exclude from gross income any gain earned on the disposition of assets in the country the company is moving from. This will prevent companies from taking unnecessary hits from taxes if they choose to move to the U.S. In order for companies to qualify for these tax incentives, and to ensure domestic production of materials is ramped up, companies must adhere to at least same production levels in the U.S. as levels of the country they move from.

H.R. 6670, Prescription for American Drug Independence Act [link]

- Introduced: 5/1/20
- Sponsors: Reps. Eshoo (D-CA), Brooks (R-IN), Ryan (D-OH), and Posey (R-FL)
- Summary: Requires the National Academies of Sciences, Engineering, and Medicine to convene a committee of experts to analyze the impact of U.S. dependence on the manufacturing of drugs and make recommendations to Congress within 90 days.

H.R. 6660, LOSS Act [link]

- Introduced: 5/1/20
- Sponsors: Reps. Blunt Rochester (D-DE), Carter (R-GA), Jackson Lee (D-TX), and Katko (R-NY)
- Summary: Amends the Federal Food, Drug, and Cosmetic Act to require the holders of approved applications for drugs to conduct a risk assessment to identify and evaluate risks to their supply chain and develop, maintain, and implement risk mitigation plans to address such risks.

H.R.6711/S.3627, Medical Supply Transparency and Delivery Act [link/link]

- Introduced by Reps. Ryan (D-OH), Crow (D-CO), Porter (D-CA), and Slotkin (D-MI) on April 29th. Introduced by Sens. Schumer (D-NY), Baldwin (D-WI), and Murphy (D-CT) on April 29th.
- The bill would:
    - Require publicly reported national assessments on a weekly basis to determine national critical equipment supply and requirements.

        - These reports will also identify industry sectors and manufacturers most ready to fill orders, stockpiles that can be refurbished or repaired, manufacturers that could expand production into PPE and medical supplies, and supplies and equipment that can be redistributed to new hotspots.
    - These reports would also include direct outreach with essential employees and healthcare workers.
        - Establish an Executive Officer to oversee acquisition and logistics for COVID-19 equipment production and delivery.
        - The Executive Officer will have all the authorities available under the DPA.
        - The Executive Officer is required to issue major purchase orders under DPA for supplies identified in the assessments, oversee all distribution of critical medical supplies, and make recommendations to the President on increasing national production capacity of supplies.
        - The Executive Officer will be a civilian position appointed by the Secretary of the Defense and will be authorized additional uniformed and DOD civilian personnel in supporting roles.
        - The Executive Officer will ensure that all unused supplies in excess of need will be turned over to the Strategic National Stockpile.
        - The Executive Officer will terminate after confirming to Congress that all State and territorial medical supply needs have been met and national stockpiles have been replenished.
    - Increase transparency regarding the distribution of supplies and equipment.
        - The Executive Officer is required to publicly post all states' requests for assistance, metrics and criteria for amount and destination of distribution, metrics for determining hotspots and areas of future concern, and production and procurement benchmarks.
        - Require a comprehensive plan for COVID–19 testing, including viral and antibody testing.
        - Establish a comprehensive plan to address necessary supply chain issues in order to rapidly scale up production of a COVID-19 vaccine.
    - Require a GAO report to identify lessons learned and make recommendations on future pandemic response.
    - Establish an Inspector General to oversee implementation of the Act.

S.3537/H.R.6482, Protecting our Pharmaceutical Supply Chain from China Act [link/link]

- Introduced by Reps. Budd (R-NC), Gallagher (R-WI), Cheney (R-WY), and Stefanik (R-NY) on 4/10/20
- Introduced by Sens. Cotton (R-AR), Blackburn (R-TN), and Cruz (R-TX) on 3/19/20
- Summary: This bill would take precautions to track Active Pharmaceutical Ingredients, prohibit purchases from China by the Department of Health and Human Services, Veterans Affairs, and the Department of Defense over a two year phase-in, create transparency in the supply chain, and provide incentives for manufacturing pharmaceuticals and device manufacturing in the US.

S.3568/H.R.6390, Medical Supply Chain Emergency Act [link/link]

- Sponsors: Sen. Chris Murphy (D-CT) on 3/23/20 and Rep. Tim Ryan (D-OH) on 3/25/20
- Summary: This bill would:

- Direct the President to use existing authorities under the Defense Production Act of 1950 with respect to the production of ventilators, N-95 respirator masks, and specified personal protective equipment to address COVID-19 (i.e., coronavirus disease 2019).
- The President must (1) make a determination that such items are essential for the national defense, (2) identify private-sector capacity to produce these items, and (3) exercise authorities under the act to require emergency production of them at a reasonable price. In addition, the President shall coordinate the allocation of these items based on requests from governors and the needs of the states as determined by the number of COVID-19 cases and the proportion of the population at higher risk of the disease in a given state.
- The bill makes specified funds available for these efforts. Equipment produced under these authorities but unused at the termination of the COVID-19 emergency declared on March 13, 2020, shall be deposited into the Strategic National Stockpile.

S.3538/H.R. 6393, Strengthening America's Supply Chain and National Security Act [link/link]

- Introduced by Sens. Rubio (R-FL), Warren (D-MA), Cramer (R-ND), Murphy (D-CT), and Kaine (D-VA) on 3/19/20 and Reps. Waltz (R-FL) and McGovern (D-MA)
- Bill would:
  - Direct the Department of Defense (DoD) to determine the extent of its dependency on foreign entities for drugs, active pharmaceutical ingredients (API), and pharmaceutical components. Additionally, DoD would be required to determine whether this creates a national security issue and to make recommendations to eliminate U.S. dependency on foreign sources.
  - Requires drugmakers to provide the Food and Drug Administration (FDA) with information to determine volume of APIs used in pharmaceuticals.
  - Restores Buy American Act's intent for DoD and Department of Veterans Affairs (VA) purchases.

S. 3343/H.R. 6049, Medical Supply Chain Security Act [link/link]

- Introduced by Senator Hawley (R-MO) and Reps. Gallagher (R-WI) and Pocan (D-WI)
- Bill would:
  - Require that manufacturers report imminent or forecasted shortages of lifesaving or life-sustaining medical devices to the FDA just as they currently do for pharmaceutical drugs. This new information on devices would be added to the FDA's annual report to Congress on drug shortages.
  - Allow the FDA to expedite the review of essential medical devices that require pre-market approval in the event of an expected shortage reported by a manufacturer.
  - Give new authority to the FDA to request information from manufacturers of essential drugs or devices regarding all aspects of their manufacturing capacity, including sourcing of component parts, sourcing of active pharmaceutical ingredients, use of any scarce raw materials, and any other details the FDA deems relevant to assess the security of the U.S. medical product supply chain.

H.R.6062 - To amend certain provisions in the Federal Food, Drug, and Cosmetic Act relating to the discontinuance or interruption in the production of life-saving drugs so as to apply such provisions with respect to life-saving devices, and for other purposes [link]

- Sponsors: Reps. Schneider (D-IL), Hice (R-SC), Schakowsky (D-IL), and Pascrell (D-NJ)
- Bill would:
    - Require manufacturers to report an expected shortage of a critical or life-saving medical device
    - Require the FDA to post online a list of medical devices currently in shortage
    - Grant FDA authority to import medical devices in case of a shortage

S. 2723, Mitigating Emergency Drug Shortages Act [link]

- Sponsors: Senators Collins (R-ME), Smith (D-MN), Portman (R-OH), Cardin (D-MD), and Gillibrand (D-NY)
- Bill would:
    - In the event of a shortage, FDA is permitted to not only expedite the review of drug marketing applications, but to prioritize review of supplements and abbreviated new drug applications (ANDAs) for generic drugs as well as inspections.
    - Reporting of an interruption or discontinuance of a drug is expanded from manufacturers of the finished dosage form to include also manufacturers of a drug's active pharmaceutical ingredients (APIs). Reports are expanded to additional categories: full disclosure of the problems resulting in the shortage, information concerning the extent of the shortage, its expected duration, and expected impact on distribution and availability in pharmacies.
    - Requires manufacturers to report contingency and redundancy plans to FDA for drugs that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery.
    - The information contained in drug shortage lists required to be maintained by FDA would be expanded to include regional shortages. Listed reasons for shortages would be expanded to include shortages of particular strengths and dosage forms.
    - GAO will produce a report examining the FDA's intra-agency coordination, communication, and decision-making in assessing drug shortage risks and taking corrective action.
    - Requires HHS and DHS to conduct a risk assessment of national security threats associated with the lack of adequate domestic capacity and capability for the manufacturing and distribution of critical drugs, their APIs, and associated medical devices used for preparation or administration.

S. 3478/H.R. 6282, Commission on America's Medical Security Act [link/link]

- Sponsors: Sens. Alexander (R-TN), Durbin (D-IL), Murray (D-WA), Romney (R-UT), Jones (D-AL), Blunt (R-MO), Smith (D-MN), Baldwin (D-WI), Reed (D-RI), Klobuchar (D-MN), and Blumenthal (D-CT), as well as Reps. Ruiz (D-CA), Underwood (D-IL), and Roe (R-TN)
- Bill would:

- Assess the dependence of and vulnerabilities to the United States, including the private commercial sector, states, and Federal agencies, on critical medications, medical devices, and medical equipment that are sourced from or manufactured in foreign countries.
- Provide recommendations and an action plan to improve the resiliency of the supply chain for critical drugs, devices, and equipment, including to increase domestic manufacturing capabilities, supplies and stockpiles, and improve information collection and contingency planning.
- Consult, in the development of its report, with federal agencies—including HHS, DHS, DoD, Commerce, State, DOJ, and VA—as well as public health, medical, and commercial industry stakeholders.

H.R. 5982, Safe Medicine Act [link]

- Sponsors: Reps. Posey (R-FL), Ryan (D-OH), Fitzpatrick (R-PA), and Meadows (R-NC)
- Bill would:
  - Direct the HHS Secretary to study our dependence on Chinese pharmaceuticals
  - Direct HHS to provide recommendations for weaning the American people off this dangerous dependence
  - Authorize FDA to issue black-box warnings informing consumers of any risk they are taking when using pharmaceuticals from countries with systemic issues of supervision.

H.R.6080, Preventing Drug Shortages Act [link]

- Sponsors: Reps. Peters (D-CA), Engel (D-NY), Guthrie (R-KY), Eshoo (D-CA), Hudson (R-NC), McCaul (R-TX), Schrader (D-OR), Bilirakis (R-FL), and Joyce (R-PA)
- Bill would:
  - Enhance transparency throughout the drug supply chain process and strengthening FDA interagency efforts to fend off drug shortages
  - Empower the FDA to enforce greater reporting standards on drug and active pharmaceutical ingredient makers to identify and correct vulnerabilities in their supply chains.

H.R. 4710, Pharmaceutical Independence Long-Term Readiness Act [link]

- Sponsors: Reps. Garamendi (D-CA), Hartzler (R-MO), Escobar (D-TX), Gianforte (R-MT), Fitzpatrick (R-PA), and Stefanik (R-NY)
- Introduced: 10/17/19
- Summary: Would direct the Department of Defense to include a section in each national defense strategy that outlines steps to address gaps in the U.S. pharmaceutical manufacturing base and strengthen pharmaceutical supply chains with single points of failure.

S.3432/H.R.6708- Securing America's Medicine Cabinet Act of 2020 [link/link]

- Sponsors: Sens. Marsha Blackburn (R-TN) and Bob Menendez (D-NJ), Reps. Buchanan (R-FL), Gonzalez-Colon (R-PR), McKinley (R-WV), Roe (R-TN), and Cartwright (D-PA)
- Introduced: 3/10/20 in the Senate and 5/5/20 in the House
- Summary: Would encourage pharmaceutical drug manufacturers to spur innovations similar to those in other industries such as automotive, aerospace and semiconductors and bring drug manufacturing back to the United States, where ingredients and processes can be more easily verified. Authorizes $100 million to develop centers of excellence in advanced pharmaceutical

manufacturing in order to develop these innovations as well as train the workforce needed in this industry. These centers will be partnerships between institutes of learning and the private sector. Would create an Advanced Manufacturing Technologies unit within the Food and Drug Administration to prioritize issues related to national security and critical drug shortages, as well as bring pharmaceutical manufacturing jobs to the United States.

H.R. 6386, No Chinese Handouts in National Assistance (CHINA) Act [link]

- Sponsors: Rep. Gaetz (R-FL) and Rep. Yoho (R-FL)
- Introduced: 3/25/20
- Summary: Would prohibit any funds made available in Appropriations acts for FY2020 from being used to compensate any individual or business controlled by the Chinese government. The Act adopts the definition of government control established in Section 721(a) of the Defense Production Act of 1950.

H.R. 6431, Made in America Emergency Preparedness Act [link]

- Sponsors: Rep. Fitzpatrick (R-PA), Rep. Brindisi (D-NY), Rep. Reed (R-NY), Rep. Gottheimer (D-NJ), Rep. Hurd (R-TX), Rep. Suozzi (D-NY), Rep. Phillips (D-MN)
- Introduced: 4/3/20
- Summary: Authorizes the creation of a National Commission on United States Preparedness for National Emergencies. This Commission would be modeled on the9/11Commission and would look at the national emergency response by the United States government and private sector to this pandemic. The Commission would report findings to Congress and the President on what steps and items are necessary to ensure America's affective response to future national emergencies. The Commission would also be required to provide a report and recommendations to the President on goods that are essential to a response to a national emergency and must be manufactured in the United States. To ensure that our federal procurement supply chains are more self-sufficient and can rely on more domestic sources of production, this bill also mandates that by 2025, federal agencies responsible for responding to national emergencies are procuring essential supplies, like medication and personal protective equipment from domestic sources or manufacturing in the US.

H.R. 6531, Medical Supplies for Pandemics Act of 2020 [link]

- Sponsors: Rep. Dingell (D-MI) and Rep. Walorski (R-IN)
- Introduced: 4/17/20
- Summary: Would authorize $500 million annually through fiscal year 2023 to implement a supply chain flexibility manufacturing program to create incentives for the domestic manufacturer of medical supplies to enhance supply chain elasticity and establish and maintain domestic reserves of critical medical supplies, like personal protective equipment and diagnostic tests. It would also create incentives to work with distributors of medical supplies to manage domestic reserves held by the Strategic National Stockpile by refreshing and replenishing supply stocks.

Indicated Proposals/Policy Ideas

Commitment to America Agenda

- Author: Rep. Kevin McCarthy (R-CA)

- Date Introduced: 9/15/20
- Summary: Minority Leader McCarthy and other House GOP leaders introduced the Commitment to America agenda, a broad outline of their policy priorities. The agenda includes modernizing the U.S. medical stockpile to prepare for future pandemics and implementing China Task Force recommendations to move the supply chain for medicine, PPE, and technology out of China. It advocates for an increase in U.S. manufacturing.

MADE in America Act (no bill #)

- Proposed by Sen. Tim Scott (R-SC)
- Senate version of Buddy Carter's house bill
- Summary: The legislation incentivizes the domestic manufacturing of drugs, API, PPE, and diagnostics in order to make the U.S. supply chain less dependent on foreign countries like China. This is achieved through a new tax credit that would only apply to manufacturers operating in certain Opportunity Zones across the United States. This will work to bring manufacturing back to the United States through incentives aimed at leveling the playing field, rather than through punitive and ultimately counter-productive mandates. Additionally, the legislation includes measures aimed at mitigating drug shortages including improving FDA reporting of facility inspections, working more closely with overseas regulators and streamlining FDA standardization processes for overseeing pharmaceutical manufacturing and the supply chain.

Not-yet-introduced from Sen. Lindsey Graham (R-SC)

- Press date: 5/15/20
- Authorizes the imposition of sanctions with respect to the People's Republic of China for its obstruction or failure to cooperate in investigations relating to the outbreak of COVID– 19. The FDA Commissioner shall submit a list of all brand name and generic drugs and corresponding active pharmaceutical ingredients that the Commissioner determines are critical to the health and safety of United States consumers; and are exclusively produced, or incorporate active pharmaceutical ingredients produced, in the People's Republic of China, to the appropriate congressional committees. The FDA Commissioner must certify that the pharmaceutical industry in the People's Republic of China is being regulated for safety, either by authorities of the Government of the People's Republic of China or by the Food and Drug Administration, to the same degree as the United States pharmaceutical industry.

Minority Leader McCarthy

- Press Date: 4/26/20
- Summary: In an op-ed for Medium, McCarthy indicated two goals the U.S. must achieve:
    - Modernizing the strategic national stockpile (1)
        - Give the strategic national stockpile authority to sell items to other federal agencies, who can use them in a timely and needed fashion, and then use the proceeds to replenish
        - Streamlined and effective procurement – government must have a readily available plan to activate advanced manufacturing capacity for commercially available products
        - Contingency should allow the government and private sector to identify ways to seamlessly shift production to critical medical equipment to meet the needs of citizens during an emergency.
    - Bringing pharmaceutical manufacturing back to the U.S. (2)
        - Expand expensing to cover more types of investment for all industries domestically—including pharmaceutical manufacturing, along with tax

incentives for companies interested in manufacturing biopharmaceutical products in the U.S. so they can do so.

- Increasing flexibility for crowdfunding and micro-offerings and regulatory simplification for bank lending
- Streamlining permitting and cutting red tape for building manufacturing plants for the goal of building them in less than 18 months