

RECOMMENDATIONS ON MANUFACTURING SUPPLY CHAIN COMPETITIVENESS

July 12, 2022

The Honorable Gina M. Raimondo United States
Department of Commerce 1401 Constitution
Avenue, N.W. Washington, D.C. 20230

Dear Secretary Raimondo:

We want to thank you for the opportunity to serve on the Advisory Committee on Supply Chain Competitiveness (ACSCC). When you convened us on January 20, 2022, you asked us to provide our ideas, engagement, and partnership to address the complex supply chain challenges faced by our nation. Over the following months, the Manufacturing Supply Chain Competitiveness Subcommittee identified specific recommendations where the Biden-Harris Administration could focus its efforts: targeted investments and policy changes to strengthen resiliency, sustainability, and competitiveness in critical U.S. industries. We recommend five main areas of investment and policy:

- Improving the availability of workers;
- Adjustments to immigration policies;
- Helping critical industries identified in the President's 100-Day Report;
- Stimulating resiliency of strategic industries; and
- Forward-looking recommendations for ensuring America leads in important industries for the future.

The ideas provided to you in this binder span five areas that offer an opportunity to leverage the unique assemblage of assets available to the Biden-Harris Administration. Within each area, the Subcommittee provided 1- and 2- page detailed proposals on strategically focused investments to help U.S. domestic manufacturing, especially in critical industries, to be sustainable, robust, and capable of supplying both the U.S. and global markets.

The Subcommittee recommends removing disincentives and barriers to work to improve the availability of workers in manufacturing. The Subcommittee also recommends reducing the administrative burden of the H-2A visa program to encourage more domestic production of fruits and vegetables, and allocating additional work visas to fill shortages in critical industries. Leveraging FDA capabilities to expand resiliency in the U.S. medical devices supply chain and augmenting U.S. small and medium enterprise (SME) printed circuit board (PCB) manufacturing are aimed at stimulating demand in critical industries. We also recommended taking advantage of major changes in manufacturing process technologies to recapture domestic manufacturing in several sectors identified in the President's 100-day

Report. Finally, the Subcommittee recommends creating a universal regulatory approval process to ensure global access to medical products, and increasing investments in synthetic and industrial biology over the long term to ensure the U.S. maintains its competitive leadership in important industries.

Again, on behalf of the Manufacturing Supply Chain Competitiveness Subcommittee, we are honored to serve and respectfully submit these recommendations for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Revathi Advaiti". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Revathi Advaiti

Chair, Manufacturing Competitiveness Subcommittee

revathi@flex.com

A1. Social Security Tax Penalty Suspension

1. RECOMMENDATION

Suspend the penalty for people who work while collecting Social Security retirement or survivor benefits prior to reaching full retirement age.

2. PROBLEM

Reduce pressure caused by the shortage of workers in many industries, especially food (grocery) and manufacturing, that was exacerbated by the pandemic. Remove the economic disincentive for those who retired early to come back to work. Help people who are struggling with inflation and who don't have sufficient retirement savings or income.

3. BACKGROUND

See Code of Federal Regulations § 404.434. Excess earnings; method of charging (70 FR 28813, May 19, 2005)

For people who choose to work after they have begun collecting social security benefits, \$1 is deducted from benefit payments for every \$2 earned above the annual limit (\$19,560 in 2022) up until they reach full retirement age (67 for people born in 1960 and later). This is a disincentive to work at a time when many businesses are facing challenges hiring people.

Many people retired early during the pandemic. This will encourage people to come back to work where there is a shortage of skills or where the pandemic gave people cause to retire early. For example, experienced shop floor leadership is a constant need in manufacturing.

People wouldn't necessarily have to come back for 40 hours per week. Many retirees are feeling the impact of rising inflation and might like to engage in part-time work to supplement their retirement income. Many people do not have sufficient retirement savings, and until they reach full retirement age, this will help them.

4. IMPLEMENTATION SUGGESTIONS

Limit this to people who retired before July 1, 2022. An alternative is to raise the maximum income limit from \$19,560 to \$75,000 {or TBD} for people to qualify.

A2. Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) Income Penalty Suspension

1. RECOMMENDATION

Suspend the benefit penalty for people with disabilities who work while collecting Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI) and guarantee continued access to Medicare and Medicaid.

2. PROBLEM

Reduce pressure caused by shortage of workers in many industries, especially food (grocery), and manufacturing that was exacerbated by the pandemic. Remove the economic disincentive for those with disabilities who are able to work to take on additional hours. Help people who are struggling with inflation who don't have sufficient income.

3. BACKGROUND

See Social Security Act Sec. 1611. [42 U.S.C. 1382] Eligibility for and Amount of Benefits and Sec. 203. [42 U.S.C. 403] Reduction of Insurance Benefits

The decrease in effective hourly wages due to benefit penalties and the risk of losing critical benefits such as healthcare and childcare provide powerful barriers to disabled Americans who may otherwise be enthusiastic and capable members of the workforce.

People with disabilities may qualify for the SSI or SSDI programs, both of which can include cash benefits to the recipients. Under current policy, benefit recipients lose \$0.50 of benefits for every dollar earned over \$85.00 per month. Further, recipients lose all cash benefits if their earnings are at a "Substantial Gainful Level". In 2022, the program has set "substantial" income as monthly gross income over \$1,350 (\$2,260 if you are blind), roughly equivalent to working 22 hours per week at \$15.00 per hour or 17 hours per week at \$20.00 per hour.

The system provides disincentives to disabled Americans for working more than a handful of hours per week. As an example, consider someone receiving SSI benefits which are \$841 monthly in 2022. If they worked 40 hours per week and were paid the federal minimum wage (\$7.25 per hour), **they would only effectively earn a marginal \$3.89 per hour due to the reductions in benefits.** This does not pay that individual for the value of their labor nor does it adequately protect them from the pain of inflation.

Additionally, there is a lack of clear communication regarding when people with disabilities may lose access to Medicare, Medicaid and other benefits if they start work. The Social Security Act categorizes individuals who engage in substantial gainful activity as "not disabled" and evaluates individuals on a case-by-case basis. Thus, if a person receiving disability benefits accepts a job, they face significant and mercurial risk of "not appearing disabled enough" and losing benefits, including health and/or childcare.

The ability to work more presents benefits to more than American industries and supply chains, it offers benefits to the disabled Americans themselves. Work can provide a sense of purpose, community and

connection, all of which are especially valuable to a population which has traditionally been marginalized and isolated.

4. IMPLEMENTATION SUGGESTIONS

Highlight people with disabilities who are willing to share their stories about how and why they want to work more but are unable to due to SSI/SSDI income caps.

Work with local and federal employment support programs, such as Plan to Achieve Self-Support (PASS), and the disabled empowerment community to communicate penalty suspensions, encourage employment, and support disabled Americans seeking work.

Consider a dollar cap on income and/or potentially limiting to certain types of disabilities to protect against fraud.

A3. Public Private Partnership to Encourage Employment of Formerly Incarcerated People

1. RECOMMENDATION

Partner with private sector champions to build a coalition of businesses dedicated to hiring formerly incarcerated people (FIP). The coalition should develop hiring processes and support resources to encourage employment of FIP and publish hiring goals as a means of accountability.

The coalition can be a complement to recent administration actions to help FIP find jobs, such as the DOJ-DOL partnership and expansions of federal job opportunities and loan programs. By developing best practices and demonstrating the positive impact of hiring FIP, it can fight untrue stigmas and encourage others in critical industries to access this under-utilized workforce.

2. PROBLEM

Barriers to FIP employment are a problem. A 2016 estimate suggested that GDP was reduced \$78-87 billion due to the exclusion of people with felony convictions from the workforce.¹

While certain industries have restrictions on hiring FIP (banks, healthcare, childcare), most, including critical supply chain fields do not. Employers in long haul logistics, agriculture, and manufacturing, for example, are all able to hire FIP. Rather than structural or regulatory issues, the under-hiring of FIP is often caused by negative stigmas and the lack of support networks which assist in transitions from prison to employment and settlement in communities. Many FIPs are ready and willing to work and would benefit from employment - a steady job provides purpose and has tremendous mental health as well as economic benefits.

3. BACKGROUND

FIP face an uphill battle reentering society and achieving gainful employment. According to a 2018 study, FIP have a 27% unemployment rate, which is higher than the general unemployment rate during the great depression.² Even when employment is achieved, it can often be in low-wage roles and industries and FIP are at risk of exploitation and underpayment from employers.³

Unlike other recommendations from the manufacturing subcommittee, joblessness among FIP is not a problem that can be solved with a “quick fix” suspension of penalties or removal of a regulatory hurdle. In fact, there are already federal programs to encourage businesses to hire FIP. Job programs like careeronestop.org (sponsored by the DOL) offer specific job search help to ex-offenders. Perhaps more impactfully, “qualified ex-felons” have been included in the targeted groups of the Work Opportunity Tax Credit, which offers up to \$2,400 of tax credits per employee to businesses who hire FIP.

Additionally, the Biden-Harris Administration has taken multiple steps to expand Second Chance opportunities to FIP. Notably, in April 2022 the administration released its Incarceration to Employment strategy which offered a guide to businesses for how to effectively employ FIP and called for a number of pre-and-post-release programs to aid in reentry and employment. The administration also recently announced a partnership between the DOJ and LOD to provide job skills training and individualized employment and reentry plans for people incarcerated in Bureau of Prisons (BOP) facilities, expanded access to federal employment, and removed barriers to SBA loans.⁵

Despite these efforts, businesses often choose not to hire FIP. While systematically excluding job applicants who have criminal records may constitute employment discrimination under Title VII of the Civil Rights Act, as long as hiring managers review applicants on a case-by-case basis they are allowed to have policies that weigh against hiring convicted felons. Additionally, by hiring FIP a business may expose itself to negligent hiring liability, which can make a business responsible if one employee injures another. While a rare occurrence, the potential significant costs may cause small business owners to apply extra scrutiny to FIP, even those convicted of nonviolent crimes.

4. IMPLEMENTATION SUGGESTIONS

Many FIPs benefit from extra support, guidance, and training, especially during the initial stages of employment. By investing in these services, businesses can unlock incredible talent and lower employee churn. Nehemiah Manufacturing in Cincinnati is a leader in Second Chance hiring and has implemented these best practices:

- Incorporating a social worker into the hiring process to add perspective on applicants' potential futures with the company and identify individual support needs
- Sending employees with little-to-no experience to an additional two-week job skills training program run by a local nonprofit
- Offering medical, dental, and life insurance benefits to full time employees
- Ensuring each new hire has an employment coach from the company or a local nonprofit
- Buying bus tokens and organizing carpools to facilitate employee commutes
- Buying a 4-family housing unit to provide temporary housing to employees in need
- Guaranteeing low or zero-interest loans for employees to purchase housing or cars (over time these would transition to traditional bank loans)
- Engaging a local attorney to help with employee legal needs
- Investing in employee health and fitness, including hiring a nurse practitioner to visit employees
- Investing in continuing education for employees

Businesses can be encouraged to join the coalition by incorporating membership into their ESG initiatives. By committing to (and following through) hiring FIP, businesses can better serve their communities and stakeholders. Additionally, incarcerated people in America are disproportionately Black and Latino - company initiatives to hire FIP can be a part of their larger efforts to better serve these traditionally marginalized groups.

In addition to employers, the coalition should include labor representatives and members of local, state, and national government and nonprofit organizations dedicated to employing FIPs. These stakeholders all play important roles in providing a path to employment and rehabilitation.

Long-term initiatives such as “ban the box” measures should be continued to reduce roadblocks to FIP employment but short-term growth in hiring likely will need to be sparked by a private sector catalyst. Some additional recommendation include:

- Work with DOL to identify and target funding to expand programs already showing success in reaching, placing and retaining workers from disadvantaged and underserved communities in good (and particularly manufacturing) jobs, and to connect employers with these programs

- Work with the White House, DOL and DOJ to help convene employers, labor and other key manufacturing stakeholders to raise employer awareness of, disseminate, and spur implementation of the recommendations for employers in the newly released 2022 White House [*Incarceration to Employment Strategy*](#)

A4. Increase the supply of trucking capacity by encouraging slip seating among owner operators

1. RECOMMENDATION

Encourage the use of slip seating among owner operators by providing tax incentives on the incremental income they produce.

2. PROBLEM

There is a severe shortage of trucking capacity, especially for drayage and in regional markets.

3. BACKGROUND

Equipment costs for owner-operators are substantial, and daily driving restrictions limit how much time a driver can spend on the road. Federal Motor Carrier Safety Administration regulations (76 FR 8133) mandate no more than 11 hours after 10 consecutive hours off duty, and may not drive more than 60/70 hours on duty in 7/8 consecutive days. This means equipment utilization is never more than 45%. One simple way to increase capacity is by enabling drivers to share a truck, a practice known as slip seating. In this model, drivers aren't assigned to a particular tractor, but rather they use whatever is available at the time.

For long haul trucking, some drivers might not like the practice because they have to remove their personal belongings after each shift, but for dedicated or regional loads this could substantially increase capacity. Nonetheless, a real opportunity exists for owner operators, if they can be helped to recognize the business opportunity that increased utilization of their capital assets would bring. We should be clear to the owner operators that this is not a pooling of equipment, rather it is a way for them to grow their business by extending the use of their own equipment in a way they control.

Motor Carrier Companies could also receive a tax incentive for running company drivers in a pool of trucks. Coupled with reducing the age for qualified intermodal drivers will increase eligibility and opportunity.

4. IMPLEMENTATION SUGGESTIONS

Help owner operators overcome objections vis-à-vis equipment care and maintenance by restricting to their own pools, not a cross-operator pool. Include motor carrier companies that run company drivers across a pool of trucks.

This could be implemented as a tax incentive either on income, or in some way to decrease insurance costs.

B1. Slow or reverse the trend of increasing dependence on imports for fresh fruits and vegetables by streamlining the H-2A visa program and enabling multi-year certification

1. RECOMMENDATION

Grant multi-year certification to A-rated migrant farm workers after their first or second year under the H-2A visa program, allowing both employers and workers to plan better and reduce administrative costs. Encourage the organization and training of workers in sending countries.

2. PROBLEM

According to McKinsey, the most pressing pandemic-related challenge faced by farm operations was the availability of workers. This reflects a lack of domestic workers who are interested in this kind of employment. Resulting higher U.S. farm costs have driven increasing import dependence for fresh fruits and vegetables, much of which has gotten caught in bottlenecks along import trade lanes. This further reduces resilience in the U.S. food supply chain, driving up costs for American consumers who also find it more challenging to find the good they desire for their homes.

3. BACKGROUND

Food costs are rising for Americans who face daily challenges to find the food and groceries they are accustomed to. Most domestic farming and processing supply chains depend on migrant workers, including those under sponsored visa programs like H-2A. Yet only three in 10 workers in the domestic agricultural workforce are U.S. citizens. High comparative labor costs have put domestic farmers at a competitive disadvantage. According to the USDA, 60% of fresh fruit and 35% of fresh vegetables consumed in America are now imported. From 2017 to 2020, aggregate vegetable imports grew from \$13.2 billion to \$19.2 billion. Congested import trade lanes and this higher dependency on imports translates into less resiliency and a higher trade deficit.

The H-2A Temporary Agricultural Worker visa program allows domestic employers or agents of those employers to apply to bring in workers using an I-129 Petition for a Nonimmigrant Worker. The Department of Labor must determine that:

There are not sufficient able, willing, and qualified U.S. workers available to perform the temporary and seasonal agricultural employment for which nonimmigrant foreign workers are being requested; and employment of H-2A workers will not adversely affect the wages and working conditions of similarly employed U.S. workers. The statute and Departmental regulations provide worker protections and employer requirements concerning wages and working conditions. The Department's Wage and Hour Division has responsibility for enforcing provisions of worker contracts.

The Department can reduce the number of workers requested if U.S. workers seek these positions. In FY19 through FY21, reductions decreased from approximately 0.3% to below 0.25% of total positions requested, suggesting that domestic workers were simply not available or interested to fill these positions. A National Council of Agricultural Employers survey of 50 state workforce agencies found only 337 domestic applicants for 97,000 positions advertised between March 1 – May 15, 2020, the

height of the initial shortages during the pandemic. In FY21, 317,000 seasonal farm jobs were certified, up 15 percent from FY20.

Agricultural employers find the H-2A program cumbersome, and one grower commented that as he used it more, it was increasingly unwieldy. Multi-year certifications of H-2A visas to A-rated farm workers after their first or second year will reduce the administrative burdens to employers. It will also provide more certainty to both employers and workers, give workers an incentive to learn English and partake in training that will improve their productivity and earnings. It could also lead to new business models such as the organization of work crews in sending countries.

4. IMPLEMENTATION SUGGESTIONS

Work with the Department of Labor to implement multi-year certification on a five-year trial. Consider measures to regulate this at a Federal level to minimize the amount of stacking of state regulations on top. State implementation vary considerably.

B2. Add Additional Work Visa Allocations for Highly Educated Immigrant Students in Key Advanced Manufacturing Fields

1. RECOMMENDATION

Recommend to the Administration additional H-1B visa allocations for international graduate degree candidates at American universities to work in key fields: data analytics, machine learning, artificial intelligence (AI) in particular applied to manufacturing systems and process improvement, advanced automation and robotics, digital simulation, systems thinking, mathematical programming and optimization, additive manufacturing technologies.

2. PROBLEM

Many international students of American universities wish to work in the United States after they graduate, but are unable to do so because of visa restrictions. Many receive advanced degrees and have the latest knowledge in fields critical to national security, supply chain resiliency, and national economic competitiveness. Fields of study noted above are in particular need of more talent. Increasing graduates' ability to work in America and contribute to the economy will make the country more competitive, safe, and resilient in an era of global competition.

3. BACKGROUND

See the Immigration and Nationality Act (INA) as amended by the Immigration Act of 1990 (IMMACT) and various subsections (e.g., § 212(n) and § 214) of the INA (8 U.S.C. § 1182(n); § 1184))

The United States' higher education system is the best in the world and our nation attracts hundreds of thousands of the brightest, most driven, international students each year to undergraduate, graduate, and Ph.D. programs. In 2017 alone, there were over 229,000 international science and engineering graduate students in the U.S.¹ An increasing percentage of the United States' most educated scientists are foreign-born. In 1993 approximately 28% of science and engineering post-doctoral researchers were foreign born, by 2017 this percentage had increased to 49%.²

The typical process for an international student at an American university who wishes to work in the United States involves two programs: Optional Practical Training (OPT), which is temporary employment that is directly related to an F-1 student's major area of study, and the H-1B visa. International students who graduate from an American university are granted one year to work in the United States under OPT. This can be extended to three years if the student graduates with a degree included in the fields described above. During their working time covered by OPT, students may apply for an H-1B visa, which are permits for highly educated international workers with specialized skills. A student must be sponsored by an employer to apply for an H-1B visa and the visas are issued by lottery.

There is currently an annual cap of 65,000 H-1B visas issued every year, with 20,000 additional visas for foreign professionals who graduate with a master's degree or doctorate from a U.S. institution. There were about 275,000 H-1B applications in 2021 and some are designated for employees from certain countries, leaving the average applicant with an approximate 23% chance of acceptance.

Students who seek to start their own companies must apply for O-1 visas and only have one year to do so under OPT. Those students cannot receive the STEM OPT extension.

These processes add uncertainty and administrative burdens on international students and potential employers, many of whom resort to hiring expensive lawyers and consultants to manage H-1B sponsorships due to the program's complexity. For example, students who decide to pursue entrepreneurial tracks expect to spend at least \$10,000 in processing and attorney's fees to acquire an O-1 visa. Many students simply decide to work in another country where they can build their careers and establish roots without worrying about losing the ability to work.

The cap on H-1B visas was instituted to protect American workers and it is important not to lose sight of that objective. Expanding H-1B access should not be taken lightly and should be focused on the critical skill shortages mentioned. Additionally, limiting the expansion to graduate degree candidates at American universities ensures the program will impact a small subset of highly educated individuals and rewards those who have shown enough interest in America to travel here to study.

4. IMPLEMENTATION SUGGESTIONS

A common frustration of international students is that there is a lack of centralized, clear communication regarding requirements for H-1B and O-1 visas. Simply publishing a "playbook" guide which explains necessary application steps and timelines and connects students to resources such as lawyers and trade groups could make working in the United States more accessible.

OPT could be extended to 3 years for international students graduating with degrees in fields noted from American institutions who pursue O-1 visas. This would encourage innovation and entrepreneurship and could retain a significant amount of brainpower in the United States.

C1. Develop/Upgrade U.S. Small and Medium Enterprise (SME) Printed Circuit Board (PCB) Manufacturing

1. RECOMMENDATION

Leverage DOD or other government purchases to develop and upgrade the capabilities of small and medium enterprise (SME) domestic printed circuit board (PCB) manufacturers by establishing a predictable demand signal in the U.S. PCB market for critical products destined for domestic use. Partner with domestic PCB manufacturers, original equipment manufacturer (OEM) and Electronic Manufacturing Services (EMS) companies to reduce future obsolescence for DOD systems thru research and development cooperation. Partner with the Manufacturing USA network, IPC International and America Makes initiatives to provide the required training.

2. PROBLEM

E.O. 14017 and the DOD response identified three key areas that depend on electronic assemblies: kinetic capabilities, energy storage and batteries, and microelectronics.¹ PCBs are the foundation of any electronic assembly, and are found in a wide range of products, *e.g.*, computers, telecommunications equipment, medical equipment, aerospace and defense systems, automotive, and products across a wide range of industries. A sudden supply disruption of this commodity from Asia would have a dramatic and immediate impact on the development and production of critical products across all segments. There is also potential risk in the long lead times for PCBs shipped from overseas. Because of lags in delivery times, potential quality issues cannot be quickly addressed and corrected, resulting in longer overall development times and cost to the end customers.

The PCB market is projected to grow by \$12.86 Billion between 2020 and 2025, with 93% of that growth in the APAC region.² The dependence on overseas-made PCBs for U.S. electronics is projected to get worse.

3. BACKGROUND

The U.S. PCB manufacturing industry, which once accounted for more than 30 percent of total global production, today accounts for only 4 percent. The industry and the substrate manufacturers are characterized by thin margins and little ability to invest in their facilities, equipment, and the research and development that could return the industry to levels that support national and economic security, since most U.S. firms have turned to lower cost overseas production. Since 2000, the U.S. share of global PCB production has dropped from over 30% to 4%.³ With this regional shift in the supply chain, only four of the top 20 electronics manufacturing services (EMS) companies are based in the United States.² PCBs are custom designed and fabricated to meet each product's unique electrical routing,

¹ "Securing Defense-Critical Supply Chains," An action plan developed in response to President Biden's Executive Order 14017,

<https://media.defense.gov/2022/Feb/24/2002944158/-1/-1/1/DOD-EO-14017-REPORT-SECURING-DEFENSE-CRITICAL-SUPPLY-CHAINS.PDF>

² "Printed Circuit Board (PCB) Market Size to Grow by USD 12.86 Bn | Rising Adoption Of Smartphones to Boost Market Growth | 17,000+ Technavio Research Reports" <https://www.prnewswire.com/news-releases/printed-circuit-board-pcb-market-size-to-grow-by-usd-12-86-bn--rising-adoption-of-smartphones-to-boost-market-growth-17-000-technavio-research-reports-301434184.html>

³ "Flaws in U.S. Approach to Electronics Manufacturing Require Urgent Changes, or Nation Will Grow More Reliant on Foreign Suppliers, New Report Says" <https://www.ipc.org/news-release/flaws-us-approach-electronics-manufacturing-require-urgent-changes-or-nation-will-grow>

impedence, interconnect, stack up requirements, and specific product performance needs. Depending on design complexity, PCB fabrication requires multiple process steps, including multiple imaging, etching, plating, lamination, drilling, coating, printing, and testing processes. The customized nature of PCBs drives extensive research and development (R&D), from material selection, required fabrication methods, stack-up, fabrication capabilities, and other special assembly process requirements.

There is now a bill to address the PCB industry: HR 7677, The Supporting American Printed Circuit Boards Act of 2022, which calls for:

- The domestic manufacture of PCBs and IC Substrates
- Research and development, facilities and workforce initiatives, and
- Tax incentives for the purchase of domestic PCBs.

There is also an opportunity to revitalize the domestic Printed Circuit Board (PCB) industry through the deployment of advanced manufacturing and assembly technologies for PCBs and IC Substrates such as Ultra High-Density interconnects (UHDI) and Hybrid Electronics Integration including novel and flexible substrates and bare and thin die electronics board assembly.

We could also incent new process innovations, using new environmentally friendly chemistries and new types of raw materials. These might include biodegradable substrates, high-temperature materials, and clean alternative materials. U.S. domestic PCB manufacturers could control the disposition of chemistries, define cleaner fabrication process steps, and ensure environmentally compliant waste disposal, recycling, and repurposing. Domestic PCB manufacturers could also use advanced technologies to improve the product, improve the fabrication process, and reduce the environmental impact.

With the customized nature of PCB and extensive investment in R&D, domestic PCB manufacturers need predictable demand, cost, and returns to compete successfully for the global market share. Ensuring that domestic manufacturing can thrive will secure continued access to this critical commodity.

Small and Medium Enterprise (SME) domestic Printed Circuit Board (PCB) manufacturers need help to build new capabilities and modernize the supply base by providing (1) stable demand from US domestic customers including Defense, and (2) education and workforce preparation.

4. IMPLEMENTATION SUGGESTIONS

Work with DOD and other departments to establish a procurement program that provides predictable demand for domestic SME Printed Circuit Board (PCB), including the defense industry. DOD could use domestic PCB manufacturers and EMS companies on demonstration programs for advanced electronics assemblies, using the latest electronics assembly processes, materials, and components. Establish production partnerships or establish demonstration projects that will create demand-pull.

C2. Leverage FDA Supply Chain Visibility to Expand U.S. Resiliency Strategy

1. RECOMMENDATION

Convene a targeted inter-agency/industry workshop to identify gaps and drivers affecting healthcare products supply chain to provide actionable direction on short and long-term infrastructure investments to protect continuity of patient care and leverage key learnings across expanded industry areas. Efforts to increase supply chain resiliency and preparedness for future pandemic emergencies will benefit from broader landscape assessments, identification of choke points and examination of infrastructure elements currently underway through FDA's new supply chain programming. No single entity - industry, government and stakeholders alike - can solve this puzzle alone.

2. PROBLEM AND OPPORTUNITY

Like many industries, medical technology and pharmaceutical manufacturers continue to experience supply chain disruptions because of the Covid-19 pandemic. The pandemic caused unprecedented surges in demand for healthcare products, and as a result strained the availability of and access to raw materials, such as semiconductor chips, silicones, resins and packaging materials. Compounding the difficulties were labor constraints and transportation disruptions, all of which affected production of critical healthcare products.

Throughout the pandemic, the FDA examined vulnerabilities in real time through voluntary engagement with medical device, drug, healthcare and supplier partners and boasts integrated data fundamental for avoiding product shortages in the future. This birds-eye view, combined with the Department of Commerce's global industry analysis expertise, served to strengthen collaborations across the U.S. government and inform actionable solutions for the healthcare industry and beyond.

3. BACKGROUND

U.S. healthcare organizations seek increased transparency on supply chain vulnerabilities and potential consequences of macroeconomic events such as the Russia-Ukraine conflict and China Covid-Zero lockdowns to ensure they deliver the best possible patient care. Meanwhile, healthcare product manufacturers are assessing regional and local economies, re-thinking industrial bases and manufacturing architectures and protecting infrastructure elements such as sterilization, a vital aspect of maintaining public health and frequently overlooked aspect of medical device supply chains.

4. IMPLEMENTATION SUGGESTIONS

Convene a one-day, inter-agency workshop organizing long-term activities/partnership that may include:

- Standardize mapping protocol(s) for monitoring and assessing gaps
- Centralize communication flow for industry-government supply constraints
- Confirm public-private roles/responsibilities in responding to supply chain shortages
- Establish 'protected' materials list and monitoring infrastructure to track key stress points
- Identify pandemic and healthcare supply chain learnings to be replicated cross-industry

Key participants include the Dept. of Commerce, FDA, select U.S. government partners, select medical device/pharmaceutical companies/hospitals and health systems. In tandem, the Secretary should consider working with agency on a focused federal workforce development program to support these initiatives.

C3. Leverage Federal Food Purchasing to Increase Supply Chain Resiliency

1. RECOMMENDATION

Review and adjust purchasing criteria that Agricultural Marketing Services (AMS) uses for USDA Food Programs⁴ and other procurement guidance to support producer diversity and improve labor and safety standards in the food production and manufacturing supply chain. Implement standards that send long-term buying signals that increase the number and geographical diversity of suppliers and improve supply chain resilience.

2. PROBLEM

While increasing aggregation and deregulation of American meatpacking and food production has led to multifactor productivity gains, it has also led to significant concentration as crop and animal producers seek economies of scale. This exposes American output to geographic concentration risk from drought, extreme weather events, or other localized disruptions. Executive Order 14017: America's Supply Chains directed the USDA to conduct an assessment of risks embedded in U.S. agri-food supply chains and identify potential opportunities to build resilience. The report stated:⁵

Weak links in supply chains occur at “choke points” in food production, manufacturing, and distribution. In some agribusiness sectors like meatpacking, a small number of facilities accounts for a large share of regional or national food processing capacity. Even temporary shutdowns of one or more of these facilities (from fire, electricity disruption, labor shortages, cyber-attacks, worker illness, etc.) can threaten significant supply chain disruption. ... During the COVID-19 pandemic, meat processing supply chains came under stress when several large meat processing facilities were forced to close due to illness among workers. Such incidents temporarily caused major disruptions to supply chains and led to price volatility. And, while the meatpacking sector experienced some of the most significant disruptions during the COVID-19 pandemic, reduced production capacity was widespread throughout the food sector.

3. BACKGROUND

In recent decades, the American food industry has been characterized by increasingly concentrated production driven by advancements in technology, deregulation, and cost savings from economies of scale and gains from mechanization.⁶ Larger operations continue to expand their footprint, and the processing stage has the fewest number of companies.⁷ Concerns about producer concentration have been studied for many years.⁸ It was the subject of a series of workshops conducted jointly by the U.S.

⁴ Commodity Supplemental Food Program (CSFP), Food Distribution Program on Indian Reservations (FDPIR), The Emergency Food Assistance Program, and USDA Foods in Schools (USDA-FIS), see <https://www.fns.usda.gov/usda-foods/usda-foods-expected-be-available>

⁵ <https://www.ams.usda.gov/sites/default/files/media/USDAAgriFoodSupplyChainReport.pdf>

⁶ “Why an agricultural boom does not help rural America,” *The Economist* (April 9, 2002, <https://www.economist.com/united-states/2022/04/09/why-an-agricultural-boom-does-not-help-rural-america>)

⁷ Rogers, Richard T. “Structural change in US food manufacturing, 1958–1997.” *Agribusiness* 17, no. 1 (2001): 3-32.

⁸ Hendrickson, Mary, Harvey James, and William D. Heffernan. “Vertical integration and concentration in US agriculture.” *Encyclopedia of food and agricultural ethics* 1 (2013): 1-10.

Department of Agriculture (USDA) and the Department of Justice (DOJ) in 2010.⁹ While producer specialization and growth in scale have led to productivity gains, it has left the sector vulnerable to disruptions.

The USDA response to Executive Order 14017 offered a wide range of recommendations to address (1) concentration and consolidation, (2) labor needs, (3) ecological and climate risk, (4) livestock and poultry disease threats, (5) transportation bottlenecks, and (6) trade disruptions. It also announced its “Food Systems Transformation Framework” to build better resilience by reducing concentration.¹⁰ These were largely supply side initiatives. To enhance the effectiveness of FDA programs, the Secretary of Commerce should recommend establishing *demand side signals* via the USDA Food Programs to motivate market-based responses, much as its Local Food Purchase Assistance Cooperative Agreement Program (LFPA) did under the American Rescue Plan.¹¹

USDA total outlays in 2022 were estimated at \$230 billion, of which 74% was for nutrition assistance.¹² While a large percentage of overall spending delegates food choices to consumers, the buying programs offer an opportunity to send demand signals. The 2022 budget states that USDA buying programs support 30 million school lunches per day, and 16 million school breakfasts per day.¹³ While purchase decisions are local, this is an opportunity to prescribe a broadening of the supply base by working with distributors who fulfill these needs. Since AMS’s stated mission is to “facilitate the competitive and efficient marketing of agricultural products in domestic and international markets, while ensuring fair trading practices,” the Department could also ask that it update this to include “resiliency via supply diversity.” It could, for example, review the Packers and Stockyards program to ensure consistency with these goals. High labor and safety standards will also enhance resilience.

4. IMPLEMENTATION SUGGESTIONS

The administration can address concentration and encourage job creation by asking USDA to contract with a larger number of high-quality domestic providers, and limit the overall share of major contracts awarded to single producers.

Federal preferences can set industry best practices by requiring producers and manufacturers to meet high labor, workplace and safety standards. Organizations such as the AMS and USDA should work with labor and producers to set these standards. In order to prevent fraud, waste, and abuse, the administration should add conditions to purchasing preferences, for example by capping them at a multiple of market prices. The Food and Nutrition Service (FNS) should eliminate the “significant cost differential” exception to Buy America requirements for the National School Lunch Program and School Breakfast Program.

⁹ <https://www.justice.gov/atr/events/public-workshops-agriculture-and-antitrust-enforcement-issues-our-21st-century-economy-10>

¹⁰ <https://www.usda.gov/media/press-releases/2022/06/01/usda-announces-framework-shoring-food-supply-chain-and-transforming>; “USDA announces Food Systems Transformation Framework to enhance food supply chains” (6.1.22) <https://www.aeaweb.org/forum/2649/announces-systems-transformation-framework-enhance-supply>

¹¹ <https://www.usda.gov/media/press-releases/2021/12/06/usda-establishes-food-purchase-program-transform-food-system-build>

¹² 2022 USDA Budget Summary, <https://www.usda.gov/sites/default/files/documents/2022-budget-summary.pdf>

¹³ *ibid.*

In conjunction with developing federal purchasing preferences, the administration can also reinforce the examination of anticompetitive practices.¹⁴ This would be aligned with the Commerce Department's antitrust efforts and could be executed through more effective enforcement of current legislation, such as the Packers and Stockyards Act.

¹⁴ <https://www.usda.gov/media/press-releases/2022/02/03/usda-doj-launch-online-tool-allowing-farmers-ranchers-report>

D1. Use Advance Market Commitment purchases to foster the development of new platform technologies and incent domestic manufacturing of critical medicines

1. RECOMMENDATION

Use Advance Market Commitment (AMC) purchases for Health and Human Services/Assistant Secretary for Preparedness & Response (HHS/ASPR) as well as DoD purchases for Medical Countermeasures to incent the development of new continuous-flow and on-demand process technology platforms for domestic manufacturing of medicines and incent their deployment.

2. PROBLEM

Reliance on foreign countries for vital imports is a huge vulnerability in the U.S. medicine supply chain, and represents a significant national security risk. Generic medicines account for 90% of prescriptions in the U.S. (>131 million). Trade disruption with Asia could disrupt 85% of our essential medicines. An aggressive race to the bottom in price has driven the vast majority of generic medicine and active pharmaceutical ingredient (API) manufacturing overseas, where lower production costs and government subsidies, particularly for exports, have attracted the lion's share of demand.

3. BACKGROUND

The COVID-19 pandemic highlighted critical U.S. drug supply chain vulnerabilities. While shortages have plagued U.S. health systems for more than a decade, 29 out of the 40 drugs used to combat the coronavirus were critically short at the height of the pandemic. Shipments were delayed, or never arrived, as many were seized by government officials in the country of origin or stolen. As a result, costs increased as much as 400%. Rising energy prices, climate change, event disruptions (*i.e.*, pandemic, weather, war), and perennial shortages are challenging global, centralized supply chains.

The U.S. has strong commodity and specialty chemical manufacturing but imports most of its fine chemicals (an intermediate stage between commodity and specialty chemicals). The medicine marketplace is particularly vulnerable because both APIs and the underlying precursors are fine chemicals. Economic incentives that drive this gap include high labor, regulatory and environmental costs associated with U.S.-based fine chemical production.

The history of high-volume manufacturing of products is dominated by the transition to continuous manufacturing. While laboratory scale flow reactors have been common on the lab bench for many years, the pharmaceutical industry has been slow to transition. Yet the advantages are manifold. Continuous flow processes show much better selectivity for a target product, resulting in better yields and quality with less waste, along with lower use of catalysts, solvents, and other materials. The transition to new continuous flow and small-batch on-demand process technology platforms offers the U.S. a *unique opportunity* to change the game, and leap-frog incumbents who are saddled with their batch installed base. It will also leverage American strength in machine-learning technologies applied to process optimization, capacity utilization and clinical insights generation to support production of complex medicines.

Advanced manufacturing technologies, including breakthroughs in programmable chemistry and cell-free protein synthesis systems, could be transferred, and scaled, to form a distributed manufacturing network so that available capacity is efficiently leveraged.

4. IMPLEMENTATION SUGGESTIONS

Leverage and expand DoD's investments in battlefield medicine solutions to build domestic resilience while accelerating and de-risking Pentagon, ARPA-H, and DARPA initiatives. Use AMC purchase agreements to fulfill the needs of HHS/ASPR and DoD Medical Countermeasures stock with long-term contracts to assure stable cash flow for U.S. start-ups that are trying to pioneer this technology. Advanced market commitments jumpstart a broader marketplace and teaming with the FDA to accelerate learning and improvement cycles while reducing regulatory burden would be helpful. Consider investing in flexible capacity – multi-use production facilities that have several common denominators and can be used across many different production processes could be very valuable. Continuous manufacturing flex capacity could be designed and built for significantly less capital than conventional facilities and maintained in a "warm start" mode. This is particularly relevant for antibodies for infectious diseases or vaccines, including mRNAs. We should ensure that such commitments support technology outcomes that can also provide the appropriate regulatory oversight to enable early deployment and pilot programs while ensuring a path to longer-term regulation.

D2. Develop/Upgrade U.S. SME Additive Manufacturing Casting Capabilities by Purchasing Defense Logistics Agency Shortage Parts

1. RECOMMENDATION

Leverage Defense Logistics Agency (DLA) purchases to upgrade the capabilities of small and medium enterprise (SME) domestic casting firms by mandating the use of 3D solid modeling software and additive manufacturing technology in their casting processes as a condition of purchase. Partner with the Manufacturing USA network, America Makes, American Foundry Society, and the AM Forward initiative to provide hands-on training. Recommend that DOD consider best commercial practices such as the Automotive Industries Action Group APQP (Advanced Product Quality Planning) and Production Part Approval Process (PPAP).

2. PROBLEM

E.O. 14017 on America's supply chains and the DoD response identified metal castings and forgings as key focus areas. Strategic defense platforms, the U.S. transportation sector (both internal combustion engine as well as electric vehicles), and many infrastructure projects have a critical dependence on metal castings. In 2020, The Defense Logistics Agency (DLA) identified 30,061 castings and forgings out of 32,597 maintenance, repair, and operations (MRO) parts. Many of these castings and forgings are high importance/low-volume and minimal demand items that support critical go-to-war weapon systems and platforms that affect military readiness, but are difficult to procure. DoD purchasing efforts are hindered by lost, hard to locate and poor condition tooling, fragmented supply chains, and a diminishing domestic supply base. As more high-volume production has moved off-shore, U.S. producers, particularly SMEs, lack the impetus and resources to adopt advanced process technologies such as additive manufacturing in their molding processes and tooling construction without training support and demand assurances.

3. BACKGROUND

The U.S. metalcasting industry is a critical part of the U.S. manufacturing ecosystem. Highly engineered castings are used to produce 90% of all durable goods and nearly all manufacturing machinery. All major metals can be cast with the most common being iron, carbon steel, stainless steel, aluminum, magnesium, zinc, titanium, and copper-based alloys.

The industry is comprised mostly of SMEs with 80% of domestic metalcasters employing fewer than 100 workers. There are approximately 1,750 foundries in the U.S. that collectively employ 490,000 workers. Industries that are dependent on castings include defense, aerospace, agriculture, architectural and construction, transportation equipment, energy, hydropower, and many more.

The DoD attributed challenges in the domestic casting and forging capabilities in part to offshoring and waves of industry consolidation since the mid-20th century, adding:

Domestic producers need predictable demand, costs, and returns to compete successfully for global market share. In some cases, DoD product needs involve specialized, often low-density requirements that can only be addressed by a small portion of the casting and forging market.

Furthermore, the variability of DoD funding (timing and amount) creates challenges for businesses trying to satisfy DoD needs.

There is an opportunity to revitalize the domestic casting sector through the deployment of new process innovations. The application of “digital casting technology” (simulation, printed prototypes, printed tooling, laser metrology) would speed up the onboarding of re-shored production at lower overall costs, particularly for low-volume requirements like DoD needs. This would entail using additive manufacturing technologies (for example binder jet printing) for printed sand molds and cores, and adoption of pattern-less technology like robo-molding and printed expendable patterns for no-tool investment casting. Additive techniques can also have a huge impact on the production of tooling using printed reinforced polymers, printed metals, or printed expendable patterns. A key enabler of the adoption of additive methods is the parallel adoption of requisite 3D modeling software tools.

SME domestic metalcasters need help to build these new capabilities and modernize the supply base by providing (1) stable demand from customers who want products utilizing digital casting technology, and (2) education and workforce preparation. Helping them to adopt digital casting technology today will also develop their skills for direct metal printing in the future.

4. IMPLEMENTATION SUGGESTIONS

Ask DoD to establish a procurement program that provides predictable demand for domestic SME metalcasters that commit to produce parts with digital casting technology. As part of this, focus on conversion of old drawings to digital models. Leverage the American Foundry Society, community and technical schools, and other industry organizations to establish training programs. Potentially use the AM Forward program to establish production partnerships with key OEMs, or to establish demonstration projects that will create demand pull and demonstrable application of the technology.

Consistent with Federal Acquisition Regulations (FAR), ask DoD to consider the lessons from the Automotive Industries Action Group APQP and PPAP that together ensure that engineering design and product specification requirements are met. This may necessitate some changes or deviations from FAR for parts manufactured with advanced technologies, but a modern and consistent parts approval process can help ensure conformance to customer requirements and speed the learning and improvement cycle.

D3. Advance Market Commitment for Titanium

1. RECOMMENDATION

Use Advance Market Commitment purchases for DOD's National Defense Stockpile to foster the rebuilding of domestic titanium feedstock sources through innovative new process technologies that can render the existing processes used overseas obsolete.

2. PROBLEM

The U.S. is the largest consumer of titanium metal feedstocks for high-end applications in aerospace and defense, but we have no remaining domestic production of these feedstocks in the form of primary titanium metal (titanium sponge). VSMPO-AVISMA Corporation, located in Russia, is now the largest integrated titanium producer in the world and produces many specialized titanium products including airplane landing gear and structural components for Boeing and Airbus. That source of titanium metal has now been cut off, and the U.S. is facing a potential supply crisis. We need to re-establish domestic capabilities across the titanium supply chain as a matter of national security.

3. BACKGROUND

Titanium and titanium alloys have unique properties: they are lightweight and have a very high ratio of strength to weight. Their density is typically around 60% that of steel, they withstand high temperatures, and they have a high resistance to corrosion. These properties have made titanium widely used in the aerospace industry, many defense applications, chemical processing vessels and piping, power plant components, desalination plants, and in medical applications like implants and surgical devices.

Titanium alloy forgings are particularly important in aerostructures and engines. Two characteristics of the metal make it particularly attractive for advanced composite aircraft. First it is less likely to cause galvanic corrosion when joined to carbon fiber reinforced plastic (CFRP) parts like body and wing panels or control surfaces. Galvanic corrosion occurs when two dissimilar metals are connected to each other and electrons can flow, and the metals corrode. The carbon fibers in CRFPs are electrically conductive, so attaching them to aluminum alloys makes both the metal and the composite vulnerable to corrosion and deterioration. Titanium alloys are resistant to this. Second, the thermal coefficients of expansion of titanium alloys are very similar to CFRPs, and we know airplanes go through big temperature changes when they are at high altitudes. In the Boeing 787, titanium alloys account for approximately 15% of the airframe by weight. The airframes of U.S. fighter jets, bombers, attack aircraft, transports and helicopters entering service after the year 2000 have an average titanium content of 30%. The properties that make titanium critical for aerospace and defense applications also make titanium alloys attractive in the light-weighting of electric vehicles.

Two ores, ilmenite and rutile, are the principal sources of titanium, with the former making up 90% of production. The first step in the titanium supply chain is to convert titanium ore into titanium sponge, which is achieved via the energy intensive and expensive Kroll process. From titanium sponge, titanium products are produced by melting the sponge into semi-finished goods (ingot, billet). Ingots and billets are then used to create final titanium products (wire, plate, bar, sheet).

The top two producers of titanium sponge, control ~70% of global supply in 2021. The U.S. no longer has any meaningful titanium sponge production. Iluka Resources closed its Old Hickory mine in Virginia in 2016. Allegheny Technologies Inc (ATI) idled its Rowley, Utah titanium sponge facility in 2016 because it could buy imported material for less than its domestic cost of production. And Timet, who operated the last domestic titanium sponge plant in Henderson, Nevada, went through a mass layoff in 2020. All of these operations faced fierce cost pressures from form foreign competition.

There is an opportunity for process innovation to challenge this status quo. For example, one start-up, IperionX, is commercializing an ARPA-E funded project that uses hydrogen-assisted magnesium reduction of titanium oxides to make a low-cost, low-carbon sustainable alternative to the Kroll process, which is energy intensive and high-carbon. A pilot plant is running in Utah. The company is planning to source ores from a large titanium mineral deposit it controls in western Tennessee. Their process produces titanium feedstock that is well suited for use in additive manufacturing (3D printing) or for standard powder metallurgy, where it can be converted to traditional billets, plates, and sheets.

4. IMPLEMENTATION SUGGESTIONS

Contract for U.S. titanium feedstock production with the objective of developing high-tech, low-carbon domestic capabilities.

An Advanced Market Commitment for the National Defense Stockpile might also encourage other domestic firms interested in developing innovative new processing technologies for critical minerals. It might also foster the reopening of the ATI or Timet facilities, or encourage the development of other innovative new processing technologies.

D4. Restore and expand funding for the National Defense Stockpile (NDS) Transaction Fund and use Future Acquisitions to Create Demand for Innovative New Process Technologies

1. RECOMMENDATION

Restore and expand funding for the National Defense Stockpile (NDS) Transaction Fund, stop diversion of NDS funds to other programs, and call for whole of government approach to accelerated research and investment in new technologies for metal extraction from unconventional sources, including geothermal and oilfield brines, and potentially use stockpile purchasing to accelerate the commercialization and scale-up of new extraction and clean processing technologies – an “earth shot” approach.

2. PROBLEM

E.O. 13817 identified 35 commodities and minerals as “critical minerals.”¹⁵ The President’s 100-Day Review under E.O. 14017 highlighted the country’s dependence on critical minerals and materials, and highlighted how these supply chains are at serious risk of disruption from natural disasters, *force majeure* events, and are rife with political intervention and distortionary trade practices, including the use of forced labor. Worse, net import reliance statistics are based on observable direct demand and don’t reflect embedded demand in intermediate goods. The 100-Day Review pointed out that a country’s dominance in the processing of strategic and critical materials gives it *de facto* control over the flow of material through the supply chain.

As noted in the 100-day report:¹⁶

DoD funds the operations of the NDS Program from a revolving fund known as the NDS Transaction Fund. As noted in the President’s Budget Request for Fiscal Year (FY) 2021 and FY 2020, the NDS Transaction Fund will exhaust all of its resources by FY2024 or FY2025, dependent on (1) the pace at which the NDS Program acquires new materials to mitigate current shortfalls; and (2) the proceeds from the sale of existing stocks.

From FY2003 to FY2018, Congress diverted 89.8 percent of the proceeds from NDS Program activities, measured in real dollars, to other defense and non-defense programs, such as the Operations & Maintenance accounts of the Military Services, construction of the World War II Memorial, and the Federal Supplementary Medical Trust Fund.

3. BACKGROUND

DOD has mapped multiple upstream tiers of the strategic and critical materials sector. Its Strategic Materials Assessment and Risk Topography (SMART) tool includes major domestic and international nodes within these supply chains, the output and capacity for primary extraction and downstream processing at these sites, and the relationships between these industry nodes and downstream manufacturing sectors. DOD maintains a stockpile through the NDS, authorized pursuant to the Strategic and Critical Materials Stockpiling Act of 1979 (50 U.S.C. 98 et seq.). But the NDS is not an

¹⁵ <https://www.federalregister.gov/documents/2017/12/26/2017-27899/a-federal-strategy-to-ensure-secure-and-reliable-supplies-of-critical-minerals>

¹⁶ 100 Day Supply Chain Review, pp. 188-189.

economic stockpile, and is intended to offset supply chain risk to defense and essential civilian industry from a national emergency event. It inventories 55 materials with a total value of approximately \$1 billion.

Rare earth elements actually aren't that rare in the earth's crust. The least abundant of these, thulium (Tm) and lutetium (Lu) are 200 times more abundant than gold. The challenges are finding deposits that are sufficiently concentrated and economical to mine. The U.S. has an estimated 2.7 million tons readily available, and Canada has more than 15 million tons. MP Mineral's Mountain Pass mine in California has a high concentration (around 8% by weight in the ore), and decades ago it was the most important source in the world. In 2020, that mine produced 38,000 tons of bastnaesite mineral and monazite concentrate, but all of it was shipped overseas for processing. The company is working to restore processing capacity in the United States. Lynas Rare Earths in collaboration with DOD is building a separation facility in Texas.

The principal minerals lithium is found in are spodumene, petalite, and lepidolite. These are typically mined from open pits in the Asia-Pacific region. But lithium can also be found in brines found in high altitude salars (salt-encrusted depressions) in Bolivia, Argentina, and Chile.¹⁷ Much of the capacity in South America has already been locked up. There are several potential domestic sources. The first is brines around the Great Salt Lake in Utah, Searles Lake, California, and Silver Peak, Nevada. Second, geothermal brines have great potential for offering a range of dissolved minerals including lithium, because they are the product of long-term water-rock interactions at elevated temperatures deep within the earth. Some contain lithium in concentrations as high as 500 mg/liter.¹⁸ The U.S. Department of Energy's Geothermal Technologies Office is sponsoring a study looking at extracting lithium from geothermal brines in the Salton Sea area, led by Lawrence Berkeley National Laboratory.¹⁹ CalEnergy Resources, a subsidiary of Berkshire Hathaway Energy Renewables, is using \$6 million in state grants to add a lithium-extraction pilot project to its existing geothermal plants near Calipatria.²⁰ Geothermal brines have been shown to contain lithium in quantities as much as 240 mg/liter.²¹

Large amounts of lithium are known to be contained in oil field brines in North Dakota, Wyoming, Oklahoma, east Texas, and Arkansas. They are known to be rich in other minerals as well, including magnesium,²² molybdenum, and cobalt,²³ and have also been reported to contain substantial amounts of lithium.²⁴

¹⁷ Evans, R. Keith. "An abundance of lithium." *Santiago: World Lithium* (2008).

¹⁸ Daitch, Pamela Joy, "Lithium extraction from oilfield brine," PhD diss., 2018

¹⁹ "Can the Salton Sea geothermal field prevent the coming lithium shortage," University of California News, <https://www.universityofcalifornia.edu/news/can-salton-sea-geothermal-field-prevent-coming-lithium-shortage>

²⁰ <https://www.desertsun.com/story/tech/science/energy/2021/02/26/california-technically-and-commercially-feasible-extract-lithium-brine-geothermal-plants-already-pul/6839875002/>

²¹ Reich, Rebekka, Klemens Slunitschek, Rosa Micaela Danisi, Elisabeth Eiche, and Jochen Kolb. "Lithium Extraction Techniques and the Application Potential of Different Sorbents for Lithium Recovery from Brines." *Mineral Processing and Extractive Metallurgy Review* (2022): 1-20.

²² Schoewe, Walter H. *Kansas oil field brines and their magnesium content*. Survey, 1943

²³ Saunders, James A., and Charles T. Swann. "Trace-metal content of Mississippi oil field brines." *Journal of Geochemical Exploration* 37, no. 2 (1990): 171-183.

²⁴ Kumar, Amit, Hiroki Fukuda, T. Alan Hatton, and John H. Lienhard. "Lithium recovery from oil and gas produced water: A need for a growing energy industry." *ACS Energy Letters* 4, no. 6 (2019): 1471-1474.

Purchasing critical metals for a strategic stockpile offers an opportunity to provide domestic manufacturers and processors with stable demand over long-term contracts that provide the economic justification for long-term capital investments.

Investing in research and investment in new technologies for metal extraction from unconventional sources like oilfield brines will play to America's strengths in oil field technology, and will provide a nice adjacency that will allow drillers and equipment suppliers to participate in the energy transition.

4. IMPLEMENTATION SUGGESTIONS

Work with the Department of Energy on this plan.

E1. Create a Universal Regulatory Approval Process that Maintains U.S. Competitive Leadership in Ensuring Global Access to New Medical Products

1. RECOMMENDATION

Create a holistic approach to medical product development, validation, and distribution to incentivize global innovation, equity, and resilience that maintains U.S. competitive leadership while ensuring that developing countries have expedited access to diagnostic testing. Secure access to manufacturing equipment and processes to meet surges in demand for medical products. Streamline and harmonize the global regulatory framework to ensure that developed and developing countries have expedited access to medically necessary, properly validated medical products.

2. PROBLEM

Global supply chain shortages of critical medical components and raw materials have created extensive barriers for patients' to receive appropriate medical services in both developing and developed countries. A patchwork of global regulatory approval pathways creates unnecessary delays in providing medical products to developing countries. Specifically, the World Health Organization (WHO) prequalification system (WHO PQ) creates an unintentional barrier to the distribution of medical products because the process is unduly protracted and is often redundant with other regulatory approvals required by developed countries.

3. BACKGROUND

While most developed countries have robust regulatory authorities, regulatory authorities in many developing countries are nonexistent or do not enforce rigorous standards. In 2010, the WHO established its Prequalification of In Vitro Diagnostics (PQ) program “to promote and facilitate access to safe, appropriate and affordable in vitro diagnostics of good quality in an equitable manner,” especially in developing countries. However challenges in the WHO PQ policies and procedures include timelines that are not publicly available, confusion about which products are a priority, and an over-loaded pipeline

In S.4348, the FDA Safety and Landmark Advancements Act (FDASLA), introduced May 26, the Senate included language for diagnostics regulatory reform.²⁵ As part of Sec. 587K, the Health and Human Services (HHS) Secretary must consider whether and to what extent international harmonization is appropriate in promulgating regulations for test design and quality requirements. In addition, there are efforts underway for more global harmonization of the regulation of diagnostics and medical devices through the International Medical Device Regulators Forum (IMDRF), a group of medical device regulators from around the world that come together to accelerate international medical device regulatory harmonization and convergence. IMDRF includes representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan Russia, Singapore, South Korea, United Kingdom, United States, and WHO.

²⁵ On June 8, the Senate Committee on Health, Education, Labor and Pensions (HELP) will consider or “mark up” S. 4348; changes to section 587K are not expected.

4. IMPLEMENTATION SUGGESTIONS

To begin, a pilot could focus on an effort for diagnostics supporting respiratory illnesses such as COVID, Influenza, and Respiratory Syncytial Virus. Addressing the immediate public health need should take advantage of global emergency authorization pathways already in place and more importantly determine success factors for a more streamlined and harmonized regulatory evaluation framework. Then, the U.S. Government, along with IMDRF, should create a universal system for approval of medical products, similar to the stringent regulatory authority (SRA)²⁶. A series of global harmonization meetings would convene to recognize the pre-market review and quality system requirements for regulatory authorities to achieve SRA status with WHO.

- The WHO and other countries would then rely on approval by an SRA such as the U.S. FDA. Then the WHO PQ could waive their review requirements, and that test/product would immediately be made available in other countries.
- If a product is approved by one SRA, other SRAs should either recognize that approval, or create a streamlined expedited review for the test to enter other developed markets.
- If a product has not been approved by an SRA in the country where the product is manufactured, then the product should be required to undergo the WHO PQ review before being marketed in countries without an SLA.
- It could also include an accelerated approval path for use of novel/innovative technology platforms in manufacturing complex medicines.

As a second step, to drive innovation in the U.S., the Government should establish a voluntary public-private partnership (PPP) program for developing and maintaining domestic infrastructure and capacity to help the USG establish and maintain critical infrastructure and distribution models and manage critical supply chain components. Critical supply components would receive expedited approval by the SRA.

²⁶ A stringent regulatory authority (SRA) is a national regulatory authority considered by the World Health Organization (WHO) to apply stringent standards for quality, safety, and efficacy in its process of regulatory review of diagnostics and medical devices for marketing authorization.

E2. Protect the U.S.'s leadership position in synthetic and industrial biology to deliver more effective, accessible therapeutics and environmentally sustainable industrial production.

1. RECOMMENDATION

Launch a national initiative to strengthen the nation's life science R&D ecosystem to strengthen long-term competitiveness, improve bio-therapeutic access, and further fossil fuel independent industrial manufacturing. Specifically, the nation requires higher fidelity analytical capabilities and more productive manufacturing technologies to revolutionize both bio-therapeutic (e.g., gene & cell therapies) discovery and manufacturing while enabling petrochemical feedstock substitution (e.g., agricultural chemicals, flavors and fragrances) in industrial production.

2. PROBLEM

Despite the great advances in synthetic biology (e.g., monoclonal antibodies or GMO crops) have brought to our society, insufficient analytical and manufacturing technology capabilities coupled with antiquated regulatory requirements, disjointed supply chains and misaligned economic incentives result in low innovation pipeline and manufacturing yields for both therapeutic and industrial applications. The resultant exorbitant costs hamper adoption, reaching scale and bringing the flywheel of improved population level health outcomes, environmentally sustainable industrial production and scaled high value job creation into motion. Competing nations with more focused industrial policies are quickly catching up to U.S. capabilities and see the opportunity to leap-frog.

3. BACKGROUND

The current lack of a focused, national synthetic bio-economy initiative has resulted in a patchwork of global research and manufacturing processes and disjointed supply chains. This suboptimal research and manufacturing situation has been extended and amplified in next generation bio-therapeutics (e.g. gene/cells/mRNA therapeutics). Developing, manufacturing and regulating these types of medicines has never been reimaged, rationalized and redesigned, rather incremental improvements to existing suboptimal development and manufacturing methods hamper innovation and leave the country with a precarious biotherapeutic supply chain.

In industrial biology applications, the substitution of petrochemical fertilizers, crop protection chemicals, flavors and fragrances and myriad other applications through biological alternatives offer practical alternatives to reducing the environmental impact (GHG reduction, ground water contamination etc.) of hundreds of product categories. However, misaligned financial and regulatory incentives hinder broad based adoption and scale.

Deployment at scale of efficacious, accessible medicines and industrial product substitutes will not be possible to populations in need because of significant development and manufacturing challenges, overcomplicated supply chains and the resultant exorbitant costs.

4. IMPLEMENTATION SUGGESTIONS

Create working group of academia, pharma, industrial synthetic bio and regulatory stakeholders to develop a national synthetic bio-economy strategy and ecosystem with the specific intent of strengthening national competitiveness in the development and manufacture of therapeutic and industrial-use biomolecules. The target should be a 50% cost reduction to drive accessibility/adoption, scale and the achievement of improved population health and environmental sustainability.

Methods to achieve our goals would include:

- A. **Communicate Compelling Objectives and Intent:** – Develop a U.S. National Engineering Biology focused biomedicine and industrial manufacturing and supply chain strategy to reduce cost and environmental impact of bio-therapeutics and industrial chemicals.
- B. **Strengthen the Engineering Biology Ecosystem - Support talent and expertise**
 - a. Set high standards for rigor and depth of engineering training in undergraduate biomedical engineering programs
 - b. Create academic competition with incentives to create centers of excellence to solve vexing challenges in synthetic biology.
 - c. Fund challenge grants to for interdisciplinary approaches to address key challenges in Engineering Biology and Supply Chain for Biomedical Engineering
 - d. Create consultative body joining regulatory, research and private industry with the objective of reducing cost, environmental impact, and create material levels of new employment and national competitive advantage.
 - e. Bring the best U.S. and international expertise together to support the initiative and sustain in country R&D through supportive visa policies.
 - f. Support industry efforts to educate and train research and manufacturing labor through public private apprenticeships, community colleges, and advanced degree programs.
- C. **Deliver incentives** – Create tax incentives and direct cash grants to support research to accelerate synthetic biology molecule development and preferential tax and re-imburement treatment for locally manufactured biomolecules:
 - a. **Improved analytics**, including biosimulation to improve development pipeline yields by 100% (currently at <5%).
 - b. **Scale and on-shore** advanced cellular, metabolic, and genetic engineering to produce more affordable therapeutics.
 - i. Producing mRNA for vaccines and disease therapies
 - ii. Developing NextGen manufacturing for cell therapy
 - c. **Develop prioritized list** of high value petrochemical inputs to reduce environmental impact and incentivize substitution with synthetic biology molecules (e.g, agricultural chemicals, solvents for use in semiconductor manufacturing, etc.)