DAY ONE PROJECT

Building Medical Supply Chain Resilience through a U.S. Manufacturing Reserve and Digital Stockpile

Sabrina Merlo

November 2020

Summary

To prevent another medical supply chain breakdown like the one experienced during the COVID-19 pandemic, the Federal Government must create an emergency response plan to activate domestic, local medical supply manufacturing. A national network of small-to-mid-size manufacturers and prototyping labs—a **U.S. Prototyping and Manufacturing Reserve**—should be formalized and incentivized to act as first responders for emergency innovation and medical supply manufacturing needs.

To properly equip the Reserve, the Federal Government should build a comprehensive library of open source medical and emergency supply "blueprints"—a **U.S. Digital Stockpile**—that consists of manufacturing requirements to enable distributed local emergency production. Combined, these new national security resources will facilitate rapid local response to both regional disasters and international supply chain disruptions.

Challenge and Opportunity

COVID-19 exposed global medical supply chains to be vulnerable to disruption and domestic medical supply manufacturing to be insufficient to meet our country's needs during crises. The lack of availability of personal protective equipment (PPE) for medical workers during the peak of the COVID-19 crisis received mainstream media attention. Costs for PPE have skyrocketed, with price increases from 100% to 1000% above pre-pandemic pricing.[1] The challenge has not gone unnoticed by lawmakers: currently there are over 40 pieces of proposed legislation[2] in the Congressional database that address the security of our medical supply chain. The August 6, 2020 Executive Order 13944[3] (*Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States*) is also meant to address national medical supply chain insecurities.

However, none of these initiatives effectively leverage our greatest resiliency asset revealed by the COVID-19 crisis: the nation's prototyping and digital fabrication facilities in small businesses,

[1] Dow, William, Lee, Kevin and Lucia, Laurel. 2020. "Economic and Health Benefits of a PPE Stockpile." University of California Berkeley Center for Labor Research and Education and University of California Berkeley School of Public Health.. https://laborcenter.berkeley.edu/economic-and-health-benefits-of-a-ppe-stockpile/.

[2] Legislative Search Results," Congress.gov, accessed October 16, 2020, https://www.congress.gov/search?q=%7B%22source%22%3A%22legislation%22%2C%22search%22%3A%22medical+supply+chain%22%7D.

[3] "Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States," Federal Register, August 14, 2020, https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies-and-strengthening-national-security-by-ensuring-essential.

universities, community colleges, K-12 schools, and community makerspace[4] and FabLab[5] environments. Because these facilities are oriented towards rapid prototyping, as opposed to large scale production, this network of talent and tools—over 600 groups across every state in the U.S.[6]—was able to leverage cloud platforms and distributed networks of fabricators. These efforts delivered more than 8 million units[7] of PPE, supplies and medical devices to U.S. hospitals, social services, and essential workers in need during March through August 2020—at least 2.3 million were reported as manufactured and delivered *before April 10, 2020*, less than 6 weeks after U.S. PPE shortages received first public awareness.[8]

Supplies such as face shields and cloth masks have made up the highest volume of products produced through these local efforts. Disposable stethoscopes (Food and Drug Administration (FDA) Device Class I) with 3D printed parts, while produced in significantly lower quantities, became important to response efforts by providing new solutions for patient care[9] and clinician safety.[10] Intubation boxes, nasal test swabs, and surgical gowns are additional examples demonstrating the range of sorely needed medical supplies and devices developed and produced by makers and local manufacturers that have been used by clinicians during the crisis. As the COVID-19 pandemic continues to evolve, independent rapid prototyping teams are making significant progress on open source designs for more complex devices (typically Class II) such as pulse oximeters (used for diagnostic and monitoring), oxygen concentrators, and ventilators.

Millions of units of product were fabricated and distributed (mostly as donations) by this ad-hoc network since March 2020, despite numerous difficulties:

- No access to COVID-19 government emergency funding. Teams spent valuable time raising private donations to fund their efforts, and most production networks were impeded by a lack of funding to purchase supplies.

---

[4] "Makerspace." Dictionary.com. Dictionary.com. Accessed November 10, 2020. https://www.dictionary.com/browse/makerspace?s=ts. "A collaborative workshop that supplies equipment and technology," commonly outfitted with digital fabrication tools like 3D printers, CNC routers—but also often woodshops, textile studios, electronics workshops, and metal fabrication facilities.

[5] Getting Started with Fab Labs (Fab Foundation), accessed November 10, 2020, https://fabfoundation.org/getting-started/. A FabLab is brand of makerspace developed by the Massachusetts Institute of Technology (MIT) that focuses on the digital fabrication toolset.

[6] "Local Response World Map," Open Source Medical Supplies, August 27, 2020, https://opensourcemedicalsupplies.org/local-response/map/.

[7] "Collective Impact." Open Source Medical Supplies, October 15, 2020. https://opensourcemedicalsupplies.org/impact/.

[8] "Seriously People—Stop Buying Masks!" Twitter. U.S. Surgeon General, February 29, 2020. https://twitter.com/Surgeon_General/status/1233725785283932160?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1233725785283932160%7Ctwgr%5Eshare_3.

[9] "Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States," Federal Register, August 14, 2020, https://www.federalregister.gov/documents/2020/08/14/2020-18012/combating-public-health-emergencies-and-strengthening-national-security-by-ensuring-essential.

[10] "AANP Member Spotlight: Facing COVID-19 With Cutting-Edge Health Care Technology," American Association of Nurse Practitioners, August 19, 2020, https://www.aanp.org/news-feed/aanp-member-spotlight-facing-covid-19-with-cutting-edge-health-care-technology.

- No availability of medically-vetted open source designs. Designs were developed from scratch, delaying delivery of locally-produced supplies to essential and medical workers by weeks.
- Inconsistent response from hospital leadership around acceptability of locally-produced products, as well as confusion from local manufacturers around **regulatory** requirements.

The COVID-19 supply chain crisis has demonstrated that rapid prototyping facilities, makerspaces, and small to medium-scale manufacturers represent a national security asset akin to the Civil Air Patrol[11] and the Civil Reserve Air Fleet (CRAF)[12]—both of which have marshalled the capabilities of the country's private sector aviation resources in times of need since the mid-20th century. As we plan for greater national resilience and future disaster response, designers, prototypers, engineers, makers, local manufacturers and their facilities should be formalized, supported and leveraged as a distributed emergency innovation and manufacturing response network.

Plan of Action

Proposed Action: U.S. Prototyping and Manufacturing Reserve (USPMR)

The next administration should formalize and support the ad hoc domestic manufacturing ecosystem that provided the most expeditious and localized emergency response to COVID-19 through creation of a **U.S. Prototyping and Manufacturing Reserve (USPMR).** This federally-defined but state-activated network of facilities and volunteers would be utilized to solve for breakdowns in traditional supply chain channels and to augment traditional emergency response services by ensuring the availability of local rapid prototyping and production facilities in times of crisis.

A federal interagency task force with members from the Department of Defense (DOD), Small Business Administration (SBA) and Federal Emergency Management Agency (FEMA) should determine standards for tiered certification, with levels indicating facility capabilities. This task force should also determine the lead administrative agency, which will develop and host a USPMR membership database and platform for inter-state communications. State offices of emergency management should coordinate operations and deployment, and liaison with FEMA operation centers in times of emergency.

[11] "Who We Are," Civil Air Patrol National Headquarters, accessed October 16, 2020, https://www.gocivilairpatrol.com/about/who-we-are. The Civil Air Patrol has assembled and trained a reserve force of civilian aviators since 1941.

[12] "Civil Reserve Air Fleet," U.S. Air Force, July 28, 2014, https://www.af.mil/About-Us/Fact-Sheets/Display/Article/104583/civil-reserve-air-fleet/. CRAF has organized private aviation resources for deployment in times of emergency since 1951.

USPMR members should reflect the range of responders critical to addressing the COVID-19 medical supply chain emergency, from independent designers to community makerspaces to medium-scale manufacturers. Incentives to participate could include:

1. Certification that enables faster access to state-allocated emergency funds during disasters.
2. Streamlined registration with the FDA as a Current Good Manufacturing Practice (CGMP) facility; with FEMA as well as clearly defined pathways for ISO 9001 certification[15] of appropriate and effective Quality Management Systems.
3. Training programs and USPMR reserve corps status available for individuals (analogous to the Air Force's Civil Air Patrol).
4. Access to a federally-funded / local-match revolving, forgivable loan fund, and/or New Markets Tax Credits[16] that offer resources for USPMR facility capital improvements and capacity building.
5. Opportunities to compete for grants to serve as a premium-tier USPMR workforce development and regional emergency response training and surge production center (a paid reserve function, similar to the Civil Reserve Air Fleet (CRAF)).
6. Opportunity to participate in a USPMR aggregator program or cooperative which could market USPMR products and offer preferred contracting opportunities with state and national stockpiles, Department of Veterans Affairs (VA), etc. (akin to the Civil Air Fleet participant benefit structure[17]).

The challenge of any surge capacity endeavor lies in the cost of ongoing maintenance. To address this, existing manufacturing workforce development facilities and corresponding investments (e.g. SBA MaTCH[18] and the Department of Education's OCTAE[19]) should be expanded to serve as USPMR premium tier network hubs. Community colleges, in particular, were active medical supply contributors during this crisis, and could logically serve as dual-purpose regional USPMR hubs and workforce development centers.

The rapid prototyping orientation of USPMR members and facilities is well suited for first responder, extremely local emergency innovation and manufacturing needs—including but not limited to PPE and medical supplies. It is worth noting that the 15 public-private U.S. Manufacturing Institutes[20] dedicated to U.S. competitiveness in advanced manufacturing are currently proposing a new Manufacturing National Guard.[21] While similarly focused on national resilience through manufacturing, their focus is on larger-scale manufacturing and national

[15] "ISO 9000 Family - Quality Management." ISO, March 11, 2020. https://www.iso.org/iso-9001-quality-management.html.
[16] "What Is the New Markets Tax Credit, and How Does It Work?" Tax Policy Center (Urban Institute/Brookings Institution), accessed October 16, 2020, https://www.taxpolicycenter.org/briefing-book/what-new-markets-tax-credit-and-how-does-it-work.
[17] "Civil Reserve Airfleet Allocations," U.S. Department of Transportation, accessed October 20, 2020, https://www.transportation.gov/mission/administrations/intelligence-security-emergency-response/civil-reserve-airfleet-allocations.
[18] The Makerspace Training, Collaboration, and Hiring (MaTCH) Pilot Competition, accessed October 16, 2020, https://www.sba.gov/match.
[19] Office of Career, Technical, and Adult Education (OCTAE) - Home page (US Department of Education (ED), April 23, 2020), https://www2.ed.gov/about/offices/list/ovae/index.html.
[20] "Institutes," Manufacturing USA, accessed October 16, 2020, https://www.manufacturingusa.com/institutes.
[21] "About," Manufacturing Guard, accessed October 16, 2020, https://www.mfgguard.com/.

supply chain management. Thus, USPMR should be considered a complementary initiative to the proposed Manufacturing National Guard.

Proposed Action: U.S. Digital Stockpile

Central to the success of the USPMR will be access to a comprehensive library of open source medical supply "blueprints"—a **U.S. Digital Stockpile.** Its initial scope could be limited to medical supplies and devices, and later become a full repository of disaster response designs, such as for water filters or emergency shelters. Citizen manufacturers, USPMR locations, and even larger-scale manufacturers could freely access the Digital Stockpile designs in future medical and PPE supply chain breakdowns.

The National Institutes of Health (NIH) 3D Print Exchange[22] is an existing example of such a government-held open repository. However, its scope is limited to designs for additive manufacturing, thus missing critical medical supplies such as designs for protective gowns, which are still in short supply. The U.S. Digital Stockpile should be manufacturing-agnostic, include designs for low-resource environments, offer plain-language user guidance, and provide complete manufacturing requirements and testing guidance.

For medical designs specifically, FDA participation in the Digital Stockpile should include dedicated staff to develop approval pathways for open source supplies and devices, and provide advance coordination of Emergency Use Authorizations aligned with Digital Stockpile designs and USPRM facilities. This new type of certification would reflect an understanding of the rigor of USPRM certification and be available to this trusted manufacturing network in times of crisis.

Establishing the USPMR and U.S. Digital Stockpile would require leadership from the White House to drive cross-agency cooperation and actions such as the following:

- To facilitate the creation of an infrastructure to support these efforts, the White House Office of Science and Technology Policy (OSTP) should reinstate a Senior Advisor for Making, as well as restore the Maker Interagency Working Group. The Group should retain original members[23] and be expanded to include National Institute for Occupational Safety and Health (NIOSH) and Federal Emergency Management Authority (FEMA), and be again formalized through a National Science and Technology Council (NSTC) charter.
- The DOD should partner with the VA, the FDA, National Institute of Standards and Technology (NIST) and the NIH to evolve the NIH 3D Print Exchange library beyond

[22] "NIH 3D Print Exchange," National Institutes of Health (U.S. Department of Health and Human Services), accessed October 16, 2020, https://3dprint.nih.gov/.

[23] The Maker Interagency Working Group included representatives from the Department of Defense (DOD), Health and Human Services (HHS), Veterans Administration (VA), Small Business Administration (SBA), Department of Commerce (DOC), National Science Foundation (NSF), Department of Education, Institute of Museum and Library Services (IMLS), State Department, National Aeronautics and Space Administration (NASA), Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Department of Energy (DOE), National Institute of Standards and Technology (NIST), and United States Agency for International Development (USAID).

additive manufacturing (3D printing) into a Digital Stockpile that encompasses a full range of medical and emergency supply designs.

- The Department of Education Office of Career, Technical, and Adult Education (OCTAE), SBA, and FEMA should establish an interagency partnership for USPMR emergency/workforce training elements.
- The White House should announce a call for relevant potential responders to join the USPMR.
- The White House should formally recognize and celebrate outstanding demonstrations of commitment to USPMR akin to the Obama Administration's Champions of Change program.

What could be a minimum viable product for the U.S. Digital Stockpile?

Ten key items were responsible for 80% of the PPE shortage during COVID-19, and could be the focus of an initial effort to stockpile designs. Get Us PPE[30], one of the most active PPE "needs" database and supply matching programs during COVID-19, has shared summary information on the top ten most requested types of PPE over the course of the pandemic. (Note this cumulative data is not yet published, but their monthly "shortage index"[31] reports do provide time-centric updates on current demand.) As a byproduct of the CARES Act Section 506J, the FDA also now publishes a list of supplies in limited supply. However, there is no indication of level of need, so there is no way to understand "most needed" or priorities from that list.

Listed are Get Us PPE's top 10 most requested PPE items since March 2020, with footnotes to available open source designs and/or explanatory notes:

1. Filtering facepiece respirators (N95 and KN95)[32]
2. Disinfecting wipes (hospital grade)[33]
3. Surgical/procedure masks[34]
4. Gowns[35]
5. Hand sanitizer[36]
6. Face shields[37]
7. Nitrile gloves[38]
8. Thermometers[39]
9. Handmade cloth masks[40]
10. Safety goggles[41]

[30] "Personal Protective Equipment to Those Who Need It Most," Get Us PPE, October 13, 2020, https://getusppe.org/.
[31] "PPE Shortage Data Index Compiled by Get Us PPE." Get Us PPE, 13 Oct. 2020, https://getusppe.org/data.
[32] "Project Library." Open Source Medical Supplies, October 15, 2020. https://opensourcemedicalsupplies.org/library/?library=category, category=N95-respirators. Distributed N95 mask manufacturing is not currently possible due to sophisticated meltblown plastic manufacturing equipment requirements. However, alternative product designs have been manufactured (e.g., flexible 3D printed silicone masks that use a smaller amount of the meltblown fabric as a filter, and powered air purifier respirators [PAPR]). Testing is needed for both categories of designs before they may be considered alternatives to certified respirators with N95-level filtration, but there is significant opportunity for the advancement of these designs.
[33] Ibid, category=hand sanitizer. Open source design for hospital-grade wipes needs development.
[34] Ibid, category=cloth masks
[35] Ibid, category=gowns
[36] Ibid, category=hand sanitizer
[37] Ibid, category=face shields
[38] Ibid, category=examination gloves. Open source design needs development.
[39] Ibid, category=non-contact thermometers. Open source design needs development.
[40] Ibid, category=cloth masks
[41] Ibid, category=goggles

Other in-demand items with open source designs and produced in large quantities include ear savers and mask hooks, test swabs, booties, and hair caps.[42]

For medical supplies, local manufacturing and design solutions for N95/KN95 masks offer an opportunity for collaboration between the U.S. Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) and the U.S. Digital Stockpile. BARDA can galvanize industry and designers and issue challenges to come up with the best design possible for the U.S. Digital Stockpile repository.

What pending legislation are these proposals most aligned with? Who are their sponsors?

H.R.7853 Resilient Manufacturing Task Force Act of 2020[43] by Rep. Haley Stevens (D-MI-11) with Chris Coons (D-Del.), Marco Rubio (R-Fl.), Troy Balderson (R-Ohio), and cosponsored by U.S. Senators Maggie Hassan (D-N.H.) and John Cornyn (R-Texas), is the piece of legislation we have identified that most closely aligns with this proposal. This bill includes a number of overlaps to the concepts of the USPMR, but as it stands, it misses the opportunity to incorporate the network of prototyping labs and distributed civilian fabrication efforts.

Section 2(b)(i) of H.R.7853 specifies, "(i) The formation of a National Manufacturing Guard, which shall be a reserve of industry volunteers who are trained and empowered to, in times of crisis, help manage manufacturing supply chains, logistics infrastructure, and workforce resources." And Section 2(b)(iii) specifies "the formation of a Technology Corps to serve as a workforce pipeline that prioritizes manufacturing skills that the Task Force and the National Manufacturing Guard described in clause (i) determine to be essential to the economic security of the United States." These descriptions have the potential to be inclusive of the prototyping, designer, student and citizen-driven efforts that produced so much value in 2020, but given the larger scale and business orientation of the Manufacturing Institutes' membership, it would be an uphill battle to ensure alignment.

H.R.7853 does not include any elements of the U.S. Digital Stockpile concept.

Another bill, H.R. 7574—Strengthening America's Strategic National Stockpile Act of 2020 Section 4(a)(L)(ii)[44] by Rep. Elissa Slotikin (D-MI-8), suggests "(ii) geographically diversifying domestic production of such medical supplies, as appropriate." This plan's emphasis on distributed and regionally-focused manufacturing as emergency response is aligned with the general principles of this proposal. However, the bill does not elaborate further nor provide for any specific actions or structures to be created.

---

[42] "COLLECTIVE IMPACT." Open Source Medical Supplies, October 15, 2020. https://opensourcemedicalsupplies.org/impact/.
[43] Stevens, Haley M. "Text - H.R.7853 - 116th Congress (2019-2020): Resilient Manufacturing Task Force Act of 2020," Congress.gov, July 29, 2020, https://www.congress.gov/bill/116th-congress/house-bill/7853/text?q=%7B%22search%22%3A%5B%22Resilient+Manufacturing%22%5D%7D.
[44] Slotkin, Elissa. "Text - H.R.7574 - 116th Congress (2019-2020): Strengthening America's Strategic National Stockpile Act of 2020," Congress.gov, September 22, 2020, https://www.congress.gov/bill/116th-congress/house-bill/7574/text?q=%7B%22search%22%3A%5B%22medical+supply+chain%22%5D%7D.

What other models for this kind of USPMR reserve force are there and how are they funded?

The Civil Air Patrol is a nonprofit organization that receives funds from the U.S. Air Force to conduct aerospace education, cadet programs and emergency services. In 2000, Congress allocated $26.6 million of the Air Force's appropriation for the Civil Air Patrol, and states contributed another $2.9 million.[45]

The Civil Reserve Air Fleet (CRAF) is a model to reference when considering the creation of new and dedicated USPMR facilities to serve as regional training and manufacturing centers. According to the Department of Transportation (DOT) website, "The Civil Reserve Air Fleet is a cooperative, voluntary program involving the DOT, DOD and the U.S. civil air carrier industry in a partnership to augment DOD aircraft capability during a national defense related crisis, air carriers volunteer their aircraft to the CRAF program through contractual agreements ... In return, the participating carriers are given preference in carrying commercial peacetime cargo and passenger traffic for DOD."[46] The CRAF is also funded by Congress through contracts: "For FY2005, the guaranteed portion of the CRAF contract was $418 million. AMC estimates that throughout fiscal 2005 it would also award more than $1.5 billion in additional business that is not guaranteed."[47] Using this CRAF model of reserve payment plus priority contracting, USPRM locations could regularly manufacture products that are purchased by federal and state strategic stockpiles.

Volunteer firefighters are another example of an enormous emergency response asset that state and local officials manage and employ in times of emergency. This largely unpaid labor force is motivated by the extended community of service and dedicated training programs, but the broader firefighting infrastructure leverages state and local investments.

What is the "trigger" mechanism for activating a USPMR reserve?

Established channels for the declaration of a State of Emergency—through state governors—would be appropriate to activate USPMR disaster response, and coordinate the response with other emergency efforts.

How would the U.S. Digital Stockpile address the divergent manufacturing realities of large, small, and under-resourced manufacturers?

[45] "Report to Congressional Requesters - CIVIL AIR PATROL." United States General Accounting Office, 2000.
[46] "Civil Reserve Airfleet Allocations." U.S. Department of Transportation. Accessed October 19, 2020. https://www.transportation.gov/mission/administrations/intelligence-security-emergency-response/civil-reserve-airfleet-allocations.
[47] Bolkcom, Christopher. "CRS Report for Congress - Civil Reserve Air Fleet (CRAF)S," October 18, 2006.

The Digital Stockpile designs should include designs with and for a variety of manufacturing specifications, along with an interface that helps users sort available data. A face shield design, for example, could contain designs and requirements for 3D printing, which can be done by very small manufacturers, but also manufacturing guidance for injection molding, which requires more capital-intensive equipment likely to be owned by larger operations.

What do these USPMR facilities look like? Who runs them? Where are they? How many are there?

These "local response" organizations are comprised of established prototyping education and community development facilities (makerspaces or FabLabs); small and medium digital fabrication manufacturers; and internet- and social media-enabled distributed networks of individuals who produce at home but aggregate production through organized collection and distribution methods. The OSMS Local Response Map[48] is the most thorough inventory of this citizen-driven medical supply prototyping and manufacturing movement, listing over 600 such organizations in the U.S. with contact information, production status, type of items produced, and location.

Facilities most likely to participate as physical locations in a USPMR are the shop spaces with established organizational identities and legal status, such as independent 501(c)(3) makerspaces and FabLabs in communities as well as those located in libraries, universities, community colleges, and K-12 schools. Depending on their legal status and whether they are hosted by an educational institution (e.g., UC Berkeley or Case Western University), these labs are generally run by a combination of paid staff and volunteers. For-profit and non-profit community spaces are both supported most often through paid membership and educational programming, with non-profits also funding programs through foundation, local government, and private sector grants.

Independent prototypers and fabricators would likely also participate in the USPMR if it offered a program for individual membership (akin to the Civil Air Patrol Cadet[49] or local volunteer firefighter programs).

Is there a precedent for a government agency to hold a repository of open source designs? How would the intellectual property of these designs be managed?

[48] "LOCAL RESPONSE WORLD MAP," Open Source Medical Supplies (Open Source Medical Supplies, August 27, 2020), https://opensourcemedicalsupplies.org/local-response/map/.
[49] "Cadet Programs," Civil Air Patrol National Headquarters, accessed October 19, 2020, https://www.gocivilairpatrol.com/programs/cadets.

The NIH's 3DPrint Exchange[50] is a close example of a government-administered, open source design repository. There are a variety of open source license conventions for hardware that enable free access to design and manufacturing instructions, but with different restrictions on how users can share, remix, market, or modify the information. Recommended open source licenses for this shared information repository for disaster relief supplies would be either the Creative Commons 0[51] license or the CERN open hardware license version 2 Type P.[52]

What other methods or approaches exist to implement strategies like those laid out in this proposal, and why is this the path we should follow?

It is conceivable that a private-sector, volunteer, local prototyping and manufacturing response would emerge organically again in response to the next major crisis. Unfortunately, without policy improvements, effectiveness will (again) be hindered by lack of resources, quality information, and confusion.

Or it is possible that existing (yet financially vulnerable) non-governmental initiatives like Open Source Medical Supplies might be relied upon to maintain and expand their current equivalents of the U.S. Digital Stockpile and USPMR. Even if that is a preferred option, without consistent government-defined standards and visibility, the programs are subject to the survival challenges of non-profits and unlikely to gain sufficient integration and acceptance by the FDA, FEMA, and state emergency management services.

States could define standards and invest in these networks without federal guidance or funding as extensions of state emergency management offices. However, lack of federal involvement in standards and deployment risks the same problems of integration and adoption as in the NGO model.

Proven models for implementation exist for both the USPMR and the U.S. Digital Stockpile:

- For the USPMR, reference public-private partnership service organizations such as the Civil Air Patrol. Given the mission of ensuring adequate prototyping and manufacturers as first responders, a national program with state and NGO partnership would provide for clear and consistent membership requirements; regional relevance and intelligence in the case of emergency; and the opportunity for private sector cooperation.
- The U.S. Digital Stockpile is more akin to the NIH 3D Printer Exchange in mission and in administration. Given software's ability to scale, federal funding and a federal agency ownership is a more suitable model.

[50] "NIH 3D Print Exchange," National Institutes of Health (U.S. Department of Health and Human Services), accessed October 20, 2020, https://3dprint.nih.gov/.
[51] "CC0," Creative Commons, June 22, 2017, https://creativecommons.org/share-your-work/public-domain/cc0/.
[52] "Software Package Data Exchange (SPDX)," CERN Open Hardware License Version 2 - Permissive | Software Package Data Exchange (SPDX), accessed October 20, 2020, https://spdx.org/licenses/CERN-OHL-P-2.0.html.

About the Author

Sabrina Merlo serves as Head of Local Response at Open Source Medical Supplies (OSMS), building an international community of practice across engineers, manufacturers, designers, crafters, and medical professionals around the world working in their communities to fill medical supply shortages stemming from the COVID-19 pandemic. Prior to OSMS, Sabrina was one of the creators of Maker Faire, the internationally recognized festival brand celebrating makers and the culture of innovation.

About the Day One Project

The Day One Project is dedicated to democratizing the policymaking process by working with new and expert voices across the science and technology community, helping to develop actionable policies that can improve the lives of all Americans, and readying them for Day One of a future presidential term. For more about the Day One Project, visit dayoneproject.org.