January 20, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Richard Neal
Chairman
Committee on Ways & Means
U.S. House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris-Rodgers
Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
Committee on Ways & Means
U.S. House of Representatives
Washington, DC 20515

The Honorable Patty Murray
Chairwoman
Committee on Health, Education, Labor & Pensions
U.S. Senate
Washington, DC 20510

The Honorable Ron Wyden
Chairman
Committee on Finance
U.S. Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor & Pensions
U.S. Senate
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
U.S. Senate
Washington, DC 20510

Dear Chairman Pallone, Ranking Member McMorris-Rodgers, Chairman Neal, Ranking Member Brady, Chairwoman Murray, Ranking Member Burr, Chairman Wyden, and Ranking Member Crapo:

We write to express our strong support for the *Manufacturing API, Drugs, and Excipients (MADE) in America Act* (H.R. 3927/S. 2082). This legislation contains several key provisions that will improve the manufacturing ecosystem for branded drugs, generics and biosimilars, active pharmaceutical ingredients (API), diagnostics, durable medical equipment, and personal protective equipment (PPE); encourage a competitive, 21st century domestic supply chain that will bolster our nation's pandemic preparedness; reduce shortages; and accelerate the adoption of innovative manufacturing technologies.

For years, the FDA, industry, and healthcare thought leaders have warned that the supply chain for these medical products is fragile. High-profile shortages caused by outdated facilities, reliance on foreign manufacturers, hurricanes, and most recently, the COVID-19 pandemic, have further highlighted the need for more robust and redundant infrastructure. The *MADE in America Act* would bolster the U.S. supply chain in two distinct ways.

First, it would encourage the domestic production of these products through a new thirty-percent tax credit that would apply to manufacturers operating in certain Opportunity Zones across the country. U.S. territories, like Puerto Rico, would also be eligible for this credit. Opportunity Zones have spurred billions in investment in and transformed once depressed communities across the country. This legislation

would build on that success, further uplifting communities while simultaneously strengthening our supply chain and national security.

Second, it would empower the FDA to better enforce our stringent safety measures abroad and to adapt new technologies at home. It would do this by—

- Requiring greater coordination between the Office of Drug Shortage and FDA inspection and compliance staff after inspections of facilities that produce drugs in shortage or that are at potential for shortage. While FDA currently balances benefit and risk in the context of its regulatory actions, these have not resulted in a true collaborative framework under which manufacturers of life supporting or life sustaining products in shortage or at risk of shortage can work with FDA to resolve manufacturing risk without increasing risks to public health.

- Requiring a comprehensive public report on FDA's utilization of Mutual Reliance Agreements, which can help FDA spread scarce foreign inspection resources by coordinating and partnering with other nations with analogous cGMP standards;

- Building upon FDA's annual facilities inspection reports, which reflect the timeliness of inspections necessary to approve products, by requiring the agency to apply the current drug reporting requirements specifically to generic drugs, drugs with three or fewer manufacturers, drugs in shortage, and life sustaining or life supporting drugs, to provide the granular detail necessary to understand if there are certain types of products that are subject to greater delay, or if the Agency is using the resources necessary to expedite the inspections of facilities critical to pressing public health needs; and

- Establishing a product-agnostic review pathway for advanced drug manufacturing technologies to incentivize their adoption in both new and currently marketed products. Currently, the use of a new advanced manufacturing technology only adds to the overall development risk of the drug product. Making in-house investments in manufacturing, or taking a risk on a new manufacturing technology offered by a contract manufacturer, is often not tenable, especially for smaller companies. This new pathway would allow FDA to evaluate and designate technologies for specific context of use, similar to the congressionally created pathways for the review of biomarkers and the use of master files for medical countermeasure platforms. The concept of such a product-agnostic pathway to assess manufacturing technologies is supported by the National Academies of Medicine (including committee members from the Department of Defense, the Biomedical Advanced Research and Development Authority, and the National Institute of Allergy and Infectious Diseases at the National Institutes of Health) and other scholars.[1,2,3]

[1] W. N. Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C.L. Rev. 491 (2014), http://lawdigitalcommons.bc.edu/bclr/vol55/iss2/5.
[2] *FDA in the Twenty-First Century: The Challenges of Regulating Drugs and New Technologies, chapter - Innovation Policy Failures in the Manufacturing of Drugs, 2015*
[3] National Academies of Sciences, Engineering, and Medicine. 2021. *Innovations in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations*. Washington, DC: The National Academies Press. https://doi.org/10.17226/26009.

Acting FDA Commissioner Janet Woodcock acknowledges that "(i)ndustry's reluctance to embrace new technologies… is probably related to expected regulatory obstacles with FDA and other regulators, and promotion of broad adoption of advanced manufacturing will likely require incentives.[4]"

If the U.S. is to continue to lead the world in healthcare innovation, it is critical that Congress take concrete action to streamline our regulatory system, encourage the adoption of new manufacturing technologies, and reshore our domestic supply chain for branded drugs, generics and biosimilars, API, PPE, durable medical equipment, and diagnostics. With bipartisan support in both the House and Senate, the *MADE in America Act* can provide the blueprint for a stronger, safer, and healthier America. We strongly urge Congress to take action to enact this common sense, bipartisan legislation.

Sincerely,

American Mask Manufacturer's Association (AMMA)
American Surgical Mask Company LLC
AmerisourceBergen
Blue Star NBR, LLC
Buy Ohio PPE Manufacturers' Network
Coherus BioSciences
Dedicare
Health Supply US
Heartland Health
iRemedy
National Resilience, Inc.
Pfizer
Phoenix Quality Manufacturing
Premium PPE
Renco Corporation
SafeSource Direct
Securing America's Medicines and Supply (SAMS) Coalition
Showa Best Glove Inc.
Skalar Pharma
Texas Medplast LLC
Teva Pharmaceuticals
Tradepoint Atlantic
United Safety Technology
US Biologic
US Glove Supply
Viatris

cc: The Honorable Darren Soto, U.S. House of Representatives
The Honorable Buddy Carter, U.S. House of Representatives
The Honorable Jacky Rosen, U.S. Senate
The Honorable Tim Scott, U.S. Senate

[4] National Academies of Sciences, Engineering, and Medicine. 2020. *Innovations in Pharmaceutical Manufacturing: Proceedings of a Workshop—in Brief*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25814.