IDSA
Infectious Diseases Society of America

IDSA Headquarters
4040 Wilson Boulevard
Suite 300
Arlington, VA 22203
Tel: (703) 299-0200
Email: Info@idsociety.org
Website: www.idsociety.org

October 4, 2024

The Honorable Brad R. Wenstrup
2335 Rayburn House Office Building
Washington, DC 20515

The Honorable Mark Green
2446 Rayburn House Office Building
Washington, DC 20515

The Honorable Blake D. Moore
1131 Longworth House Office Building
Washington, DC 20515

The Honorable August Pfluger
1124 Longworth House Office Building
Washington, DC 20515

RE: RFI on Policy Solutions to Secure and Enhance Domestic Medical Supply Chains

Dear Representatives Wenstrup, Green, Moore and Pfluger,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide feedback to Representatives Wenstrup, Moore, Pfluger, and Green regarding the medical supply chains. IDSA represents more than 13,000 infectious diseases physicians, scientists and other health care and public health professionals who specialize in infectious diseases. Our members work across a variety of settings, including hospitals, academic medical centers, long term care facilities, public health departments, publicly funded clinics and private practice.

We appreciate your leadership in developing policies to strengthen medical supply chains and improve domestic pandemic preparedness. Below, we offer recommendations and responses to the questions and priority areas indicated in your RFI. We welcome continued dialogue and collaboration with you in addressing the need for robust action on these topics.

2. Lessons learned, challenges, and opportunities with respect to efforts to diversify supply chains, address potential global vulnerabilities, and onshore key operations.

The COVID-19 pandemic highlighted the need for robust supply chains and domestic production capability to bolster pandemic preparedness. Recent shortages of critical medical supplies, such as BD Bactec blood cultures and bicillin antibiotics for syphilis treatment, highlight the ongoing nature of supply chain failures. Supply chain vulnerability stems from a lack of domestic development infrastructure and capacity. Reliance on foreign entities for medical supplies like pharmaceuticals, drug components, and personal protective equipment (PPE) poses a risk to the health of the American people, as these supply chains are prone to break down during public health emergencies (PHEs), especially those with a global impact. Novel strategies are needed to be prepared to protect the public. Recommendations include:

- Federal investment in diverse manufacturing sites for medical and pharmaceutical supplies to encourage supply chain redundancy, including onshore

manufacturing when possible. This should include working with US hospitals and healthcare systems to identify medical supplies most affected by supply chain shortages so redundant production of these supplies can be incentivized.

- Private-public partnerships supporting electronic inventory technology programs like cloud-based RFID technology that can better catalog and ensure accurate reflections of available products.
- Funding large-scale manufacturing sites capable of producing large volumes of active pharmaceutical ingredients (APIs) and investing in technology that increases production capacity. A study found only 15 sites in the US are capable of producing 10 or more APIs.
- Exemplified by the recent Bicillin shortage, if FDA allows importation of alternative drugs there should be consideration of 340B pricing or other federal rebates to cover costs. If alternatives are too expensive for locations like FQHCs or public health clinics, those alternatives remain functionally unavailable.
- Ensuring standardization of bottling and containment for specific medical supplies, such as BD BACTEC blood cultures, so they can be used in all medical systems, even if it comes from a different supplier than normal due to supply chain shortages.

3. Feedback on the scope and priority level of medical products and services in need of onshoring, friendshoring, or increased diversification (ex. PPE, generics, devices, ingredients, pre-clinical or clinical services, etc.)

In public health crises, there is a need for aggregate designs and options for critical medical supplies like PPE and medical devices. One solution to this is supporting repositories of medical supply designs vetted by healthcare personnel that can quickly be produced. Open Source Medical Supplies is an example of a private initiative developed by makers of medical equipment and doctors. More robust repositories could be supported by federal-private partnerships in this area, ensuring that designs for medical equipment are easily available to be quickly produced in PHEs, and can be designed to incorporate necessary diversification of products and services.

Antimicrobials also require increased manufacturing diversification, as many antimicrobials in use are produced by a single manufacturer, and often rely on ingredients not readily available. Persistent antimicrobial drug shortages are already a serious problem and are poised to worsen during public health emergencies due to potential bottlenecks and supply interruptions.

In addition, increased research is needed to discover, develop and manufacture novel antimicrobials. The bipartisan PASTEUR Act is an essential step forward that Congress can take now to ensure a steady supply of novel antimicrobials.

6. Insight into the main barriers to domestic production (ex. environmental or FDA regulations, permitting barriers, workforce challenges, etc.) and what policy options Congress has to alleviate them.

Antimicrobials are a critical medical supply and are crucial for pandemic preparedness, as any event involving high levels of hospitalization is likely to cause an increase in hospital associated multidrug resistant infections, as exemplified by COVID-19. As discussed above, we face serious shortages of existing antimicrobials as well as a dearth of innovation of new antimicrobials.

High research and development costs and limitations on use to prevent the development of antimicrobial resistance have led to an extremely weak antimicrobial pipeline, underscoring the need for incentives to promote sustainable antimicrobial innovation and production. The bipartisan Pioneering Antimicrobial

Subscriptions to End Upsurging Resistance (PASTEUR) Act provides the innovative approach necessary to solve the financial barriers to private investment in antimicrobial R&D and ensure a reliably manufactured supply of novel antimicrobials. The bill would change the way the federal government pays for novel antimicrobials that address unmet needs by paying for value instead of volume. Specifically, the bill would establish a subscription model to allow the federal government to enter into contracts with novel antibiotic developers to pay a set amount for a supply of a novel antimicrobial, regardless of the volume used. This provides a predictable return on investment that is delinked from use—exactly the approach needed to ensure a strong supply of effective, novel antimicrobials in the domestic medical supply chain through incentivizing domestic production of antimicrobials.

We thank Representatives Wenstrup and Green for their cosponsorship of the PASTEUR Act. To best position PASTEUR to advance this year and ensure respect for regular order, the bill sponsors have removed the $6 billion authorization language from the bill and are seeking to only authorize the subscription model. We urge you to please encourage congressional leadership to pass this zero-dollar version of PASTEUR this year.

There is a continued need for a strong, diverse biomanufacturing and biomedical workforce in this country. To achieve this goal, federal support is needed to incentivize interest in the field. This is especially true for trainees in medical technology and medical laboratory services, who contribute to the biomanufacturing workforce and provide laboratory capacity. Tuition reimbursement and loan subsidization targeted at trainees in laboratory sciences can be effective means of growing the workforce. Other incentives include tax credits to employers for costs of training biotechnology workers, state level grants for biotechnology and biomanufacturing training, and development of biotechnology curricula and training for community colleges.

Programs in medical technology and medical laboratory services are limited, as the number of programs has decreased drastically across the country. This limits the pipeline of trainees, decreases equitable geographic distribution of laboratory workers and stifles the biomanufacturing as a whole. Federal support for training programs and to incentivize careers in health technology are needed to address workforce gaps. Attention should be paid to ensuring regional equity in federal identification, support, and/or creation of training programs.

The Bio-Preparedness Workforce Pilot Program, authorized by the *Consolidated Appropriations Act of 2023* is an example of the type of program that can help to address workforce shortages in biotechnology professionals. The pilot would help address significant infectious diseases workforce challenges by providing loan repayment for health care professionals with expertise in infectious diseases and emergency preparedness—including laboratory professionals—who work in federal facilities, health professional shortage areas and medically underserved communities. It is critical that Congress appropriate funding to launch this pilot in order to build the biosecurity workforce.

8. Current programs that can be utilized to assist in catalyzing new innovative technologies for advanced manufacturing.

Several existing federal programs should be supported so they can be utilized in technological and biomedical innovation. Advanced Research Projects Agency for Health (ARPA-H) serves a critical role of spearheading novel platforms, resources, and technology that cannot be readily accomplished through traditional research or commercial activity. Research programs within ARPA-H include focus areas like novel biomedical data fabric toolboxes, digital health security, and performance evaluations of useability of AI. The research ARPA-H conducts is critical to creating novel, scalable innovations that can innovate the advanced manufacturing, and medical development space. Because of ARPA-H's critical nature, IDSA is concerned with proposals to

consolidate ARPA-H into the NIH structure. This may stifle the innovative nature of ARPA-H's research, as ARPA-H was specifically kept separate from other institutes and centers to ensure that its key goals of advanced research with innovative concepts were able to be conducted in a timely and nimble manner. IDSA also supports the work of the Biomedical Advanced Research and Development Authority (BARDA), specifically for the role of their Broad-Spectrum Antimicrobials and CARB-X program developing novel antibiotics to meet patient needs. To this end, IDSA continues to advocate for $330M to support the key role the program plays in strengthening the supply of antimicrobials in the US medical supply chain. BARDA also funds and supports a wide array of advanced biomedical research that can strengthen the medical manufacturing infrastructure in the United States. BARDA plays a unique role in the manufacturing process by helping obtain US FDA approvals for products, developing and stockpiling medical countermeasures, and assisting the medical supply chain during PHEs. These activities should continue to be supported for their role in the manufacturing and medical supply chain landscape.

9. What types of public-private partnerships could be most effective in accelerating the onshoring of pharmaceutical manufacturing?

With regard to public-private partnership, there is potential for federal science organizations like the NIH and NIAID to partner with large private sector entities like Apple, Google, etc. to fill current gaps in data driven ID work that could be critical in preventing the next pandemic. Public-private partnerships in this area could further harmonize data systems, prevent essential data from being siloed, and encourage data standardization. These partnerships can support ID data science research that enhance pandemic preparedness. Federal science should also prioritize public-private partnerships in the ID research space that incorporate frontline physicians.

The federal government should also develop preemptive federal contracts with private suppliers of essential materials to improve the Strategic National Stockpile (SNS) well in advance of future emergencies. A key area that should be targeted is vaccine development. In many instances, investments in vaccine development and domestic manufacturing may be too risky and offer too little promise of return on investment to be feasible for the private sector. Development of a vaccine that does not currently have a reliable, adequately sized market is unlikely to receive sufficient private investment.

Additionally, antimicrobial development should be targeted with public-private partnerships as discussed above. Domestic manufacturing of generic antibiotics—which are essential to treat the hospital associated infections that spiked during COVID-19 surges as hospitals were overwhelmed—has been significantly challenged for years. Generic antibiotics are available at very low cost, making it extremely difficult for a company to currently justify investments in their manufacturing and leaving the US exposed to antibiotic shortages that have become routine and harm patients. Private-public partnerships can incentivize production of antimicrobials and bolster domestic medical countermeasures.

11. What long-term strategies should Congress consider to ensure the sustainability and competitiveness of domestic pharmaceutical manufacturing over the next 10-20 years?

Dedicated, sustained federal funding is needed to ensure medical supply chains in the United States are maintained, and readily able to handle PHEs. Lawmakers should ensure that domestic programs dedicated to medical supply chains, such as those outlined above, are fully funded, and have the resources needed to take sustainable action geared toward preparedness and readiness. As experts predict an increased likelihood of new PHEs over the next decades, manufacturing and supply chains must build in preparedness planning to ensure they can handle surge manufacturing. Many aspects of an emergency response for the medical supply chain cannot be scaled up quickly and must therefore already be in place and ready to mobilize before a crisis.

Thank you for your leadership on these important topics. IDSA welcomes continued collaboration on the topics outlined above. If you have questions about these comments or would like to connect, please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org.

Sincerely,

Steven K. Schmitt, MD, FIDSA, FACP
President, IDSA