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The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to provide feedback to the Office of Science and Technology Policy (OSTP) on biomanufacturing and biosecurity.

IDSAs represents more than 12,000 infectious disease physicians, scientists, public health practitioners and other health care professionals specializing in infectious diseases. IDSAs members focus on the investigation, diagnosis, prevention and treatment of infectious diseases. We are pleased to offer recommendations to strengthen national biotechnology and biomanufacturing infrastructure and domestic biosecurity efforts to help ensure health care facilities and personnel have the tools they need to provide optimal patient care and prevent the spread of infectious diseases.

Building a Vibrant Domestic Biomanufacturing Ecosystem

What is the current state of U.S. and global biomanufacturing capacity for health and industrial sectors and what are the limits of current practice?

While great promise exists for our biomanufacturing, current capacity contains significant gaps that should be addressed prior to the next public health emergency.

Over the course of the COVID-19 pandemic, laboratories experienced critical shortages of essential supplies, including nasal swabs, viral transport media and PCR reagents that could have been averted. Because of the global scope of the pandemic, the lack of domestic manufacturing of diagnostics materials became a severe limitation to protecting the public in the U.S. It is critical to identify diagnostics supply chain and logistical bottlenecks and ensure that backups and alternatives are in place. This includes the deployment of general-purpose Nucleic Acid Amplification and Nucleic Acid Sequencing devices in clinical settings for ordinary use so that they will be ready and available when the next new pathogen hits. The early deployment of these technologies could feed data directly into the appropriate CDC database for real-time analysis.

In addition, during the early phases of the pandemic, shortages of personal protective equipment (PPE) and other medical supplies highlighted urgent needs to build redundancies in our supply chains and improve practices to regularly review

and replenish the Strategic National Stockpile (SNS) as well as clarify procedures for states and health care facilities to request supplies from the SNS.

US capacity for developing novel antibiotics and manufacturing generic antibiotics is also insufficient. There are few incentives to develop low-cost antibiotics despite the rising threat of antimicrobial resistance. The dearth of novel antibiotics leaves growing numbers of patients with multidrug resistant infections few to no safe and effective treatment options. Even prior to the pandemic, shortages of generic antibiotics have hampered patient care, requiring clinicians to select therapies that may be less effective, more toxic or broader spectrum—contributing to the growth of antimicrobial resistance.

What can the Federal Government do to expand and scale domestic biomanufacturing capacity and infrastructure? What level of investment would be meaningful and what incentive structures could be employed?

Federal investment in diverse manufacturing sites for medical and pharmaceutical supplies is essential 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 during the pandemic as preparation to incentivize redundant production of these supplies.

The federal government should develop preemptive federal contracts with private suppliers of essential materials to improve the Strategic National Stockpile well in advance of future emergencies. Additional federal contracts should also be provided to academic research centers and laboratories to support the rapid research and development of biological products (i.e. vaccines and other medical countermeasures) to support emergency preparedness infrastructure in biomanufacturing.

Additional recommendations are listed below:

- Require manufacturers to validate diagnostic products on at least two alternative devices so that laboratories that lack the budget and space to purchase additional instruments or platforms are able to run tests on existing devices. Vendors have an incentive not to do this currently, and laboratory use of unvalidated alternatives can void the device warranty.
- Initiate a national inventory of diagnostic equipment. The federal government should identify choke points and establish and fund a plan to address them, including through backup plans and redundancies to avoid breakdowns in access to testing supplies.
 - Include research labs in this inventory, including labs with smaller machines (e.g., thermocyclers).
- Invest in [electronic inventory technology programs](#) like cloud-based RFID technology that can better catalog and ensure accurate reflections of available products.
- Fund large-scale manufacturing sites capable of producing large volumes of active pharmaceutical ingredients (APIs) and invest in technology that increases production capacity. [A study](#) conducted in 2021 found only 15 sites in the US can produce 10 or more APIs.

What are barriers that must be addressed in order to better enable domestic supply chains for biomanufacturing?

- 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.

- 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.
- Medical products for small patient populations pose a key barrier for private sector investment, as a small market can diminish the opportunity to earn a return on investment. This is exactly the challenge that has caused nearly all large pharmaceutical companies to halt antibiotic research and development and has caused two of the few small biotech firms conducting antibiotic R&D to declare bankruptcy since 2019 and another to announce it will cease operations this year. Antibiotics are typically prescribed for a short duration, and new antibiotics must be held in reserve and used only when needed to preserve their utility. Antibiotics are crucial for pandemic preparedness and response, as any event involving high levels of hospitalization is likely to cause a significant increase in hospital associated multidrug resistant infections, as we have seen with COVID-19. The bipartisan Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act introduced in the 117th Congress provides the innovative approach necessary to solve the financial barriers to private investment in antibiotic R&D. The bill, soon to be reintroduced in the 118th Congress, would change the way the federal government pays for novel antibiotics that address unmet needs by paying for value instead of volume. Specifically, the bill would allow the federal government to enter contracts with novel antibiotic developers to pay a set amount for a supply of a novel antibiotic, regardless of the volume used. This provides a predictable return on investment that is delinked from use—exactly the approach needed to revitalize antibiotic R&D and promote appropriate antibiotic use to protect the utility of these lifesaving drugs. This concept was endorsed in the President’s Budget Request for FY2023.
- During a PHE, there is a need for aggregate designs and options for medical supplies like personal protective equipment and medical devices. During the first phase of the COVID-19 pandemic, innovative solutions were developed without efficient ways to share them with others who may be able to benefit from them and scale up production to reach more communities. 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 physicians. 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 public health emergencies.

Biotechnology and Biomanufacturing Workforce

How can the U.S. strengthen and expand the biotechnology and biomanufacturing workforce to meet the needs of industry today and in the future? What role can government play at the local, state, and/or Federal level?

To grow the biotechnology and biomanufacturing workforce, federal support is needed to incentivize interest in the field. Clinical trials for antimicrobial drugs, vaccines and diagnostic tests are often led by infectious diseases (ID) physicians, and ID physicians also play critical roles enrolling patients in trials and ensuring these products once approved are used optimally for maximum benefit of patients and public health. Yet the ID physician workforce is in crisis. Nearly 80% of counties lack a single ID physician. In 2022 only 56% of ID physician training programs filled their slots. ID is the fifth lowest compensated medical specialty, and significant medical student debt drives many physicians to more lucrative fields. The US must address these financial barriers to incentivize more people to enter the

field of ID. Unlike many other specialists, ID physicians do not perform procedures, and the Medicare reimbursement system persistently devalues the cognitive work performed by ID physicians. This paradigm must change to ensure we have the supply of ID physicians necessary to support innovation in biotechnology.

IDSA recommends that the Centers for Medicare and Medicaid Services update inpatient evaluation/management (E/M) value codes so they maintain historic relativity with outpatient E/M codes, reflect the complexity of care provided and support patient access to ID physicians. The American College of Emergency Physicians and the Society for Hospital Medicine also support this approach. More detailed information is available in IDSA's comment letter to CMS: https://www.idsociety.org/globalassets/google-ad/2022-09-06-idsa_cy-2023-pfs-comments_final.pdf. IDSA recommends that the federal government establish a mechanism to provide enhanced payment to providers when a PHE related to an infectious disease is declared and establish a payment modifier that would allow clinicians to receive enhanced Medicare reimbursement during an outbreak.

Trainees in medical technology and medical laboratory services also contribute to the biomanufacturing workforce and provide laboratory capacity, and these fields are also facing significant shortages. 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 health care workforce 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 who work in federal facilities, health professional shortage areas and medically underserved communities. It is critical that the federal government fund and implement this program right away to begin impacting career choices in upcoming educational, training and recruitment processes.

Reducing Risk by Advancing Biosafety and Biosecurity

What can the Federal Government do to support applied biosafety research and biosecurity innovation to reduce risk while maximizing benefit throughout the biotechnology and biomanufacturing lifecycles?

Access to BSL-4 facilities for research purposes can facilitate biosecurity research efforts, as these are essential to research. Despite the need for BSL4 labs demonstrated by recent outbreaks, the number of laboratories in the US is limited, and not equitably distributed across the country. The current facilities are located in Atlanta, GA; Fort Detrick in Frederick, MD; and San Antonio and Galveston, TX. Adding new facilities with BSL-3/4 capabilities with biosafety and biosecurity at the forefront of deliberations would increase research capacity and strengthen outbreak and pandemic preparedness in the US. New

labs should be positioned strategically throughout the country based on safety assessments and geographic equity to prepare for and respond to novel agents quickly and safely. Biosafety practice considerations should be at the forefront of the creation of new labs. When locations for new laboratories are identified, CDC and local experts should communicate clearly with the surrounding community to build trust, provide education about the planned laboratory and its work, answer questions and alleviate potential concerns.

Additionally, the federal government should support empirical research on biosafety efforts. Important research topics include reasons why laboratory accidents happen, the frequency of these accidents and other data needed to create and update evidence-based mitigation measures. Biotechnology and biomanufacturing are constantly evolving, and practice guidelines on biosafety need to be as up to date and backed by data as possible. In addition, [studies](#) have indicated this research can help inform where new laboratories of different safety levels can be built safely.

How can Federal agencies that fund, conduct, or sponsor life sciences research incentivize and enhance biosafety and biosecurity practices throughout the United States and international research enterprises?

Growing the laboratory workforce and infectious diseases (ID) workforce is crucial to ensure adequate staffing for current and future facilities and improving overall biosecurity efforts. ID researchers with a specific interest in BSL3/4 laboratories face challenges in securing funding for training and research. Dedicated funding for students interested in pursuing a career in BSL3/4 facilities will help grow the workforce, combined with broader policy efforts to address student loan burden and inequitable compensation to help make the ID specialty for researchers and physician-scientists financially feasible. This also ensures that workers engaging in these fields have adequate training in biosafety practices.

IDSA also believes there is a need for stronger engagement of clinical laboratorians in biosafety and work at the federal level. Staff working in clinical laboratories who deal with biosafety should be better integrated into biosafety discussions and activities. Often, discussions most pertinent to clinical laboratory staff at the federal level do not include all relevant stakeholders; specifically, those working at the local level in clinical laboratories. Involving these stakeholders more closely and intentionally can facilitate stronger biosafety efforts and help inform biosafety practice. The federal government should aim to foster more clear and consistent communication on biosafety issues to clinical laboratory staff. As novel threats and agents emerge, federal guidance needs to be clear and unified so that the biosafety workforce can follow it easily and work to combat emerging public health threats through safe research practices.

IDSA appreciates the opportunity to comment on improving biomanufacturing infrastructure and strengthening biosecurity and biosafety efforts. If you have questions about these comments, please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org.