Request for Comment: Healthy Future Task Force Security Subcommittee
Infectious Diseases Society of America

January 31, 2022

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide feedback to the Healthy Future Task Force Security Subcommittee. IDSA represents more than 12,000 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 the Subcommittee's leadership in developing policies to manage future public health threats. The COVID-19 pandemic has demonstrated the need to improve our public health and supply chain infrastructure and bolster our 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 the Healthy Future Task Force Security Subcommittee in addressing the need for robust action on these topics. We would be happy to work with you as you further explore these issues and develop legislative proposals.

Pandemic Preparedness

The Department of Health and Human Services acknowledged the Strategic National Stockpile (SNS) "faces the challenge of maintaining a stockpile of [medical countermeasures] against a plethora of low-probability, high-consequence threats, while continuing to develop important countermeasures against other threats, and maintaining the capacity to rapidly respond to novel threats like emerging or re-emerging infectious diseases." What steps can Congress take to ensure the sustainability of our medical countermeasure (MCM) response capabilities?

IDSA recommends that the federal government develop preemptive federal contracts with private suppliers of essential materials to improve the SNS well in advance of future emergencies. We further recommend that additional federal contracts be provided to academic research centers and laboratories to support the rapid research and development of medical countermeasures for pathogens with pandemic potential.

What challenges does the SNS face when distributing MCMs to State and local partners? What steps can Congress take to fix these challenges?

State and local partners are especially challenged, as they typically have far fewer resources than the federal government, and many individuals in state and local health departments and health care facilities are not familiar with the mechanisms or processes through which they can request supplies from the SNS. IDSA recommends that federal funds be provided to support state and local efforts to develop appropriate supply reserves. We further recommend that the federal government provide routine, simple and clearly communicated mechanisms for states (with input from local governments and health care facilities) to request essential supplies. This will allow

the individuals "on the ground" with the closest view of their community and facility needs to rapidly identify those needs for the SNS.

There is a need for the SNS to better prioritize vulnerable populations (e.g., people with disabilities, people in congregate settings, children, etc.) during public health emergencies to ensure equitable distribution. Planning for pandemic preparedness should identify and designate priority populations to receive SNS materials and MCMs in public health emergencies and develop easily deployable distribution systems that can be readily utilized in public health crises.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act explicitly required the SNS to maintain, in addition to already enumerated items, supplies of "personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile." Are there other products and MCMs Congress should explicitly require the SNS to stock?

Many products that fall under the general categories outlined in the CARES Act are critical for public health emergency responses yet often are subject to shortages. As such, it may be prudent to explicitly require the SNS to stock essential antibiotics, diagnostic testing supplies (e.g., swabs, reagents), ventilators and portable isolation enclosures that can be readily deployed to hospitals and other emergency treatment venues.

What challenges might the Federal government encounter to maintaining this stockpile? Are the SNS's current annual review procedures sufficient for evaluating inventory needs and manufacturing, procurement, and deployment challenges?

The expiration and stocking of inventory in the SNS continues to be a problem for antivirals like Tamiflu. Routine reviews of the SNS to identify products that can be easily put into health care use before their expiration date instead of being automatically discarded would prevent large amounts of medical waste. IDSA recommends that the federal government establish a process to facilitate the dispersal of products into the health care system before their expiration and to replenish the SNS as products are dispersed.

Should additional Federal (or even non-Federal) entities be included in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which provides input on SNS stockpiling decisions? Are there shortcomings in the SNS's coordination with current PHEMCE members? If so, how best can these shortcomings be fixed?

IDSA recommends that PHEMCE include entities that represent frontline clinicians, health care facilities and state and local health departments to provide input on stockpiling decisions. Because these entities are directly serving patients and communities and planning for future public health emergencies, they are best positioned to identify, forecast and communicate on-the-ground needs for SNS supplies.

Much of Operation Warp Speed's success is due to accelerated pathways for development, testing, and approval of vaccine candidates. What changes to the vaccine development and approval process proved most beneficial to the timely development of COVID-19 vaccine, and what changes may still be useful? How might Congress codify what worked during the COVID-19 pandemic for future pandemics?

Operation Warp Speed significantly reduced the delay in moving from one phase of clinical development to the next, allowing COVID-19 vaccines to come to market in record time while still undergoing rigorous evaluation. Large investments of federal funding made this possible, and this approach should be applied more broadly to the development of novel vaccines and non-vaccine therapeutics.

Independent review of the COVID-19 vaccines by the Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) in advance of FDA authorization was crucial to build public confidence in the vaccines. Preserving VRBPAC review of future vaccine candidates will remain important.

Supplemental appropriations for the United States' early pandemic response and proposed transfers of funds illustrated the need for the Department of Health and Human Services (HHS) to act quickly and draw upon all available funding, despite the existence of the Infectious Disease Rapid Response Reserve Fund and the Public Health Emergency Fund. How can Congress better equip these funds, and other resources, to provide HHS with the support it needs to act nimbly with dedicated funding, and without waiting for Congressional action?

While resources for the rapid reserve fund and the public health emergency fund are important, they cannot take the place of sustained, robust funding for our federal, state and local public health infrastructure. For several years preceding the pandemic, state and local health departments (who receive a significant portion of their funding from the Centers for Disease Control and Prevention [CDC]) were operating on very limited budgets while facing a plethora of growing needs. State and local health departments had already been facing years of workforce attrition and outdated technology, and as a result, were already operating well over capacity when COVID-19 struck. We greatly appreciate that COVID-19 relief packages have provided significant resources for public health, but that funding must be sustained over time to allow our public health system to keep pace with emerging threats and scientific and technological advancements.

Additionally, many aspects of a response cannot be scaled up quickly and must therefore already be in place and ready to mobilize before a crisis. For example, training physicians, epidemiologists, laboratory scientists and other medical, public health and scientific professionals necessary for a successful response can take years. Investments in training and recruitment, including incentives for the pursuit of careers in infectious diseases, must be made now and sustained over time.

The COVID-19 pandemic highlighted the efficacy of removing inefficient regulatory barriers that may stall public health and recovery responses. While many federal barriers to the immediate risk were addressed, long-term impediments remain that could discourage State, local, and private sector investment in pandemic preparedness.

During the pandemic, many barriers to the provision of telehealth services have been temporarily removed, which allows a crucial expansion of access to care, particularly for rural communities, elderly individuals and other underserved populations. For example, removing geographic requirements and allowing reimbursement for audio-only visits have been extremely useful. We appreciate that considerable interest exists in making telehealth flexibilities permanent and support these efforts to sustain improved access to medical care in these populations.

What regulatory barriers could be modified to better ensure Federal and State public health agencies are better situated to quickly adapt and efficaciously respond to protect public health in a future PHE?

IDSA recommends that Congress direct HHS to develop and communicate a more clear and rapid process to obtain regulatory flexibility waivers for issues including health care professional licensure requirements, survey certifications, the Emergency Medical Treatment and Active Labor Act, out-of-network payments and inpatient beds to limit paperwork burdens and allow more rapid and seamless responses, and improved coordination across health departments, health care facilities, cities and states. The introduction of central reimbursement standards subsidized by the federal government that can be employed in pandemic and public health emergency medicine can be used to supplement larger hospital bills and ensure insurance premiums do not increase.

What barriers exist that impede private sector investment in resources and capabilities – such as early warning systems, vaccine development, and domestic manufacturing – which could prove beneficial in future pandemics and public health emergencies? What regulatory barriers and burdens could be modified that would better situate local communities to remain economically viable and resilient in the face of future public health emergencies?

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 U.S. exposed to antibiotic shortages that have become routine and harm patients.

What revisions and updates to public health and communicable disease law may be required in light of issues raised during the public health response to the COVID-19 pandemic? Provide feedback on the four priority areas of improvement for a re-envisioned Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) as identified by a recent NASEM paper: (1) articulating PHEMCE's mission and role and explicating the principles guiding PHEMCE's operating principles and processes, (2) revising PHEMCE operations and processes, (3) collaborating more effectively with external public and private partners, and (4) navigating legal and policy issues.

With regards to public-private partnership, there is potential for federal science organizations like the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) to partner with large private sector entities like Apple, Google, etc., to fill current gaps in data-driven infectious diseases (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 clinicians.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has historically focused on and invested in strong public-private partnerships, and during COVID-19, have relied on the success of public-private partnerships such as Operation Warp Speed and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV). What regulatory barriers could be modified to ensure these public-private partnerships continue to be supported and utilized to both prepare for and respond to future pandemic and public health emergencies? Are there other barriers that exist that impede private sector interest and investment in public-private partnerships? Please identify any specific gaps in issue areas or programs that would benefit from additional support and promotion of public-private partnerships.

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 (R&D) and has pushed two of the few small biotech firms conducting antibiotic R&D into bankruptcy since 2019. 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. IDSA strongly supports the bipartisan Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act by Reps. Doyle (D-PA) and Ferguson (R-GA), H.R. 3932, which would provide the innovative approach necessary to solve the financial barriers to private investment in antibiotic R&D. The bill 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 into 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 life-saving drugs.

What other policy considerations should Congress examine concerning reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act?

IDSA recommends that Congress strengthen One Health approaches to pandemic preparedness, including improving coordination of disease surveillance systems across human, animal and environmental health. Zoonotic diseases represent a key source of pandemic threats. In addition, efforts to improve communication across partners at the federal, state and local levels would reduce confusion and improve the efficacy of public health preparedness and response efforts.

Please share any brief additional comments or recommendations that were not properly addressed with the above prompted questions.

Many of our shared goals regarding pandemic preparedness and public health hinge upon the availability and equitable distribution of an expert workforce — including infectious diseases physicians (ID). ID physicians play a wide variety of key roles in hospitals, clinics and communities — caring for patients; developing infection prevention, diagnostic and treatment protocols; advising state and local leaders; serving as trusted health messengers to the public; and leading clinical trials and enrolling patients.

Unfortunately, the workforce is facing serious shortages and recruitment and retention challenges. With regards to ID physicians in particular, we faced an over 20% decline in applicants to ID specialty training in 2011-2016. Despite our recruitment and mentorship efforts, we have made minimal progress in reversing this trend. 2020 saw a large increase in interest in medical careers overall, but only 75% of ID training programs filled their slots, compared with other internal medicine subspecialties that filled 96% to 100% of their training programs. Other health care professionals critical to preparedness — such as infection preventionists and clinical microbiologists — face similar challenges. In surveys and focus groups with medical residents, we have consistently found that financial challenges — specifically high medical student debt and low compensation relative to other medical specialties — as a key barrier to entering the field of ID. These challenges must be addressed to ensure we have the workforce we need to prepare for and respond to the next public health emergency and to address routine ID needs, including infections associated with cancer chemotherapy, organ transplantation and the opioid epidemic; HIV; viral hepatitis; and antimicrobial resistance.

IDSA strongly supports the bipartisan Bolstering Infectious Outbreaks (BIO) Preparedness Workforce Act by Reps. Trahan (D-MA) and McKinley (R-WV), H.R. 5602, which would help expand this workforce and help ensure these experts are located in areas where they are most needed. The bill would establish a new federal loan repayment program for health care professionals who spend the majority of their time working in bio-preparedness in a health care facility or providing ID care in an underserved or health professional shortage area.

Public Health

Community Health Centers (CHCs) play an essential role in the provision of health services to disadvantaged and low-income populations, regardless of their ability to pay. How can Congress better utilize CHCs to deliver high-quality, low-cost to Americans? What temporary flexibilities provided to CHCs during the COVID-19 pandemic merit permanent extension? How can Congress assist CHCs in providing improved care coordination services to patients, and what programmatic changes might CHCs be able to pursue with more robust funding?

We recommend that Congress direct increased funding to CHCs explicitly to support staffing, which will expand CHCs' ability to deliver care. In addition, staff at CHCs serve as important public health messengers and partners with state and local health departments to support pandemic preparedness, communication and responses.

CDC's Public Health Emergency Preparedness (PHEP) Program is comprised of several subprograms, among which are the PHEP cooperative agreement program and CDC Preparedness and Response Capability. Funding for the PHEP Program has been reduced 48% since FY2003. What level of funding is advisable for PHEP? Are there specific program components that should be prioritized for increases? What additional activities would increased funding permit CDC and State, territory, and local grantees to pursue, and how might a revitalization of PHEP enable the United States to better respond to public health threats and emergencies?

The PHEP program has been underfunded, contributing to a lack of public health capacity. While PHEP has six priority areas that all warrant increased funding, Congress could prioritize 1) resources for biosurveillance efforts to support harmonization of state and local surveillance systems and expand surveillance capacities to provide accurate, actionable public health data; and 2) resources to support mental health services for public health professionals responding to emergencies.

Social determinants of health are another key driver of healthcare spending. To what extent do federal health programs already address social determinants of health? How can Congress best address the factors that influence overall health outcomes in rural, Tribal, and other underserved areas to improve health outcomes in these communities? What flexibilities and/or innovative programs/ practices, whether operated by non-governmental entities or local, State, or Tribal governments, might Congress examine for implementation on a national scale?
The COVID-19 pandemic has called attention to some populations' distrust of public health departments and officials, whether through historical wrongs or because of skepticism of more recent public health measures. How can Congress work to bolster Americans' confidence in public health institutions?

Transparency must be at the forefront of promoting trust in public health efforts at the federal and local level. This means that scientific data and information should be released regularly and

be easily accessible so the public can stay informed. This increases trust in public health and fosters meaningful public engagement.

Additionally, IDSA recommends that federal efforts be directed at developing effective strategies to disseminate public health information to communities most prone to distrust and misinformation. This may include:

- Directing resources to improving and supporting health literacy in K-12 programs. Distrust of public health has been fueled by a lack of fundamental understanding of public health principles and practices. Strong health literacy starting in early education can help counteract this distrust. Health literacy education should build an understanding of relevant topics like primary sources, public health practice and basic statistics.
- Establishing and funding scientific communication training programs for frontline health care professionals, including infectious diseases physicians, as many individuals trust their own providers more than the medical or public health establishment.
- Funding and developing mechanisms which enhance scientific communication by utilizing social media and other digital platforms. This will allow for scientific messaging that is more easily accessible and disseminatable.
- Authorizing and appropriating funds to agencies explicitly to help researchers and personnel understand effective strategies in communicating science. Resources like the National Institutes of Health (NIH) Science, Health, and Public Trust should be supported in working to increase effective communication of scientific research.
- Expanding funding for school and employee health programs as well as health programs embedded in child care centers and senior centers. These permanent settings can build local trust and be utilized during emergencies to share public health information.
- Acknowledging historical wrongs perpetuated against historically medically underserved communities by federal science in outreach materials and building off this acknowledgement to establish trust in these communities. Lay out clear strategies that show improvements in transparency and medical ethics.

The COVID-19 pandemic demonstrated how widespread vaccine hesitancy is nationwide, fueled by misinformation campaigns or Americans' lack of knowledge about the importance and efficacy of vaccines. How can the federal government work to reverse both short- and long-term declines in vaccination against vaccine preventable diseases, and better support State and local partners in educating Americans on the efficacy and safety of vaccines and combating misinformation?

Federal efforts should be directed at addressing the root causes of vaccine hesitancy, including vaccine misinformation and distrust in health care systems. This may include:

- Combating vaccine misinformation through targeted outreach to communities with low vaccine rates by utilizing community leaders and local health care personnel. Additionally, ensuring informational materials are culturally competent and reflect the diversity of the communities they target. This can be achieved by ensuring diversity in the teams developing and reviewing the materials.

- Providing federal funding to create a public health ambassadors corps composed of "vaccine ambassadors" recruited from different underserved communities, vulnerable populations and communities with low vaccine uptake. Ambassadors should be compensated with adequate resources to do their job.
- Continuing to fund ongoing community outreach programs through federal agencies like HHS to increase vaccine uptake and trust in medical personnel, building off relevant efforts made to support COVID-19 vaccination.
- Directing federal support to strengthen Immunization Information Systems (IIS). The Adult Vaccine and Access Coalition (AVAC) has raised concern that IIS capabilities differ drastically across states and systems. Funding can help standardize and strengthen IIS systems. This would also support uptake of demographic data that could increase the effectiveness of targeted vaccination initiatives.
- Many populations, often those most vulnerable to COVID-19, have been hesitant to be vaccinated due to concerns about missing work due to routine vaccine side effects. It is essential to incentivize businesses to provide paid time off for COVID-19 vaccination. Additionally, these considerations should be expanded to include incentivizing paid time off for other vaccinations, annual physicals and preventive health care, as well as paid sick leave so individuals can stay home when unwell instead of reporting to work and spreading infectious diseases.

The beginning of the COVID-19 pandemic illustrated the insufficiency of States' public health laboratory testing capacity and surveillance activities. What specific problems contributed to the challenges many States encountered? Which problems remain to be addressed by Congress, and what solutions might Congress pursue to enhance public health laboratory testing capacity and surveillance?

Surveillance capacities remain underdeveloped, especially at the local and state level. Additional resources are needed to develop surveillance capacity to detect and respond to future public health threats. Considerations for developing surveillance capacity include:

- Strengthening collaboration between federal public health agencies like the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) on surveillance and testing standards to support a robust, rapid response to outbreaks. Pandemics are global by nature and necessitate increased collaboration to conduct accurate surveillance.
- Directing federal funding to a national laboratory framework for predicting and detecting emerging pathogens.
- Fully funding human-animal quarantine stations at U.S. borders to detect imported threats as well as an integrated system housed at CDC to gather nationwide data.
- Increasing infrastructure for surveillance that is not dependent on accessing the health care system: wastewater surveillance (currently used for polio, SARS-CoV-2), pharmacy surveillance, school absenteeism, Google searches (Google Flu) and animal surveillance. Support and expand on similar initiatives that already exist in other parts of the world with funding and expertise (e.g., Africa CDC, Nigeria CDC).
- Directing funding to training in genomic sequencing efforts.

In addition to surveillance capacity, the diagnostics capacity of the United States is also lacking, contributing to limited ability for laboratories to effectively carry out testing. The diagnostics supply chain faltered, causing many laboratories to face shortages of necessary supplies like pipette tips, swabs and viral transport media. Substantial action needs to be taken to strengthen the supply chain. Recommendations include:

- Working to establish private laboratories preauthorized by the Food and Drug Administration (FDA) to develop infectious diseases diagnostics in public health emergencies.
- Increasing regulatory capacity to facilitate review of diagnostics tests in emergency conditions, including expanding oversight of testing to credentialed third party reviewers, such as the College of American Pathologists.
- Ensuring laboratories have easy access to biological samples and quantitative assay standards so they can develop and utilize diagnostic tests efficiently. Develop these pathways to access samples and standards in advance of a public health emergency so that testing facilities may easily do diagnostic work.
- Developing centralized databases intended to disseminate successful diagnostic testing protocols for use by other laboratories.
- Surveying capacity for development of diagnostics supplies to identify potential chokepoints in the supply chain. Many constraints were at the level of supplies necessary to collect samples.
- Supporting maintenance of existing biosafety level 3 facilities (BSL3) at public and private institutions, including providing funding for renovations and streamlining certification processes.
- Establishing and funding additional biosafety level 4 (BSL4) laboratories to facilitate additional safe research on the most dangerous pathogens — the ones that can cause serious disease and for which no treatment or vaccines exist — to increase our readiness to combat these pathogens when needed. Support advanced training for laboratory personnel needed to staff these laboratories.
- Promoting the evaluation of novel diagnostics across the lifespan (pediatrics to geriatrics) and across the health lifespan (healthy to medically fragile).
- Deploying nucleic acid amplification tests (NAAT) and sequencing technology to community hospitals for use in day-to-day infection control, to ensure these technologies can be seamlessly and rapidly utilized during an emergency. Additionally, ensure these tests and necessary supplies like culture are reimbursed.
- Engaging academic medical centers, community hospitals and other health care facilities in the development of new diagnostics technologies. Provide funds to support personnel training on new technologies as well as the necessary equipment and reagents to facilitate rapid adoption of new technologies.

How can the federal government improve its efforts to provide quality health care services and support in accordance with its legal obligations?

Ensuring the availability of a health care workforce in rural and other underserved areas is a critical component of improving health outcomes. Unfortunately, nearly 80% of counties in the U.S. lack an infectious diseases physician, with the shortage particularly acute in rural

areas. Evidence demonstrates that patients with various serious infections have better health outcomes, shorter hospital stays and lower health care costs when they have early intervention from an infectious diseases physician, highlighting the need to expand this workforce and ensure a more equitable distribution of these experts. The BIO Preparedness Workforce Act, H.R. 5602, discussed above, would provide important support to strengthen this workforce and ensure infectious diseases experts are located in all communities.

How can Congress better utilize existing programs to address the maternal health crisis?

IDSA recommends that federal efforts be directed at boosting vaccination during pregnancy, including through outreach programs with local health care providers, community health centers (CHCs), and the development of educational programs and materials. These efforts should include a focus on boosting COVID-19 vaccination among pregnant and lactating people. A recent study showed that while pregnant people were not at higher risk of contracting COVID-19, they had a much greater risk of adverse outcomes than nonpregnant people. Further, federal efforts to increase vaccination rates should include midwives, doulas and other home birth specialists in appropriate adult and childhood vaccination so these professionals are empowered to communicate to their patients.

What other policy considerations should Congress examine concerning improving public health and public health infrastructure?

Increased funding for the Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) is important to boost preparedness efforts in health care systems, which are critical partners for state and local public health departments.

Supply Chains and Medical Independence from China

What policies, both foreign and domestic, have resulted in our diminished ability to produce our own active pharmaceutical ingredients, and what policy changes might the federal government implement to encourage domestic investment in the APIs production? What regulatory barriers could be modified to better ensure the U.S. is best positioned to improve our domestic production of APIs? What current barriers exist that impede private sector investment in the resources and capabilities that would support a more robust investment in domestic production and manufacturing?

The COVID-19 pandemic has highlighted the need for robust supply chains able to function effectively during public health emergencies. Supply chain vulnerability stems from a lack of domestic development infrastructure and capacity, in addition to lack of adequate federal leadership across multiple Administrations. Additionally, 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. Novel strategies are needed. Recommendations include:

- Investing in diverse manufacturing sites for medical and pharmaceutical supplies to encourage supply chain redundancy, including onshore manufacturing when possible. This should include working with U.S. hospitals and health care systems to identify medical supplies most affected by supply chain shortages during the pandemic so redundant production of these supplies can be incentivized.
- Investing in electronic inventory technology programs like cloud-based radio-frequency identification (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 U.S. are capable of producing 10 or more APIs.

Where are the greatest vulnerabilities in the drug and medical supply chains, and what steps can the United States take to diversify its supply chains? What policies have resulted in our diminished supply chain and reliance on international partners? How can the United States work with international partners to ensure the reliability of supply chains during public health emergencies? What regulatory barriers could be modified to better ensure the U.S. is best positioned to improve our supply chain issues? What current barriers exist that impede private sector investment in domestic production and manufacturing?

Generic antibiotics commonly used to treat serious infections have been in short supply for several years due to supply chain challenges. Many have a single manufacturer and rely on ingredients with limited availability. There is very little profit opportunity in this field, making it difficult to attract private investment. Many private companies hoping to bring new antibiotics to market go bankrupt before they can. In a 2016 survey of infectious diseases physicians, 70% reported modifying their antimicrobial of choice in the previous 2 years due to an antimicrobial drug shortage. This resulted in the use of broader-spectrum agents (75% of respondents), more costly agents (58%), less effective second-line agents (45%) and more toxic agents (37%). Widespread antibiotic shortages negatively impact patient outcomes and are likely contributing to the development of antibiotic resistance. IDSA supports the bipartisan Onshoring Essential Antibiotics Act (S. 1176, introduced by Sens. Tina Smith (D-MN) and Bill Cassidy (R-LA)) which would direct HHS to provide grants to up to three manufacturers of essential generic antibiotic drugs (or of the active pharmaceutical ingredient or key starting material for such a drug).

How might the federal government identify and implement public-private manufacturing models to improve and maintain domestic manufacturing capacity for drugs, vaccines, and medical countermeasures? What regulatory barriers could be modified, consolidated, harmonized, or repealed to ensure the federal government is supporting public-private partnerships to both prepare for and respond to future pandemic and public health emergencies? How can the U.S. federal government better support, encourage, and invest in promoting and advancing public-private partnerships with the private sector?

In times of public health crises, there is a need for aggregate designs and options for medical supplies like personal protective equipment (PPE) and medical devices. One solution to this is supporting repositories of medical supply designs vetted by health care personnel that can quickly be produced. Open Source Medical Supplies is an example of a private initiative developed by doctors and makers of medical equipment. 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.

Thank you for your leadership on these important topics. IDSA welcomes continued collaboration with you. If you have questions or if we can assist in your efforts, please contact Amanda Jezek, IDSA Senior VP, Public Policy and Government Relations, at ajezek@idsociety.org.