INSTITUTE FOR PROGRESS

# Preparing for Pandemic Preparedness Legislation:

*Nine legislative ideas to improve our biosecurity response*

*IFP submitted a letter with the following recommendations to the Senate HELP Committee on March 29, 2023*

Over the past few years it has become increasingly clear that strong and agile preparedness and response capabilities for biological threats are crucial for the safety and security of our nation. In response to this pressing need, the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) presents a timely opportunity to reassess and fortify our national biosecurity apparatus. The evolving nature of biological threats, which now encompass not only known pathogens but also unknown, accidental, engineered, and natural hazards, necessitates a comprehensive and flexible approach to preparedness and response.

To address these challenges, we have identified nine core recommendations aimed at enhancing the United States' ability to prevent, detect, and respond to biological threats. These recommendations focus on broadening the scope of key agencies and initiatives, such as the Biomedical Advanced Research and Development Authority (BARDA) and the Strategic National Stockpile (SNS), as well as increasing transparency in the decision-making processes of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). In the face of an ever-changing biothreat landscape, these recommendations seek to ensure that the United States remains at the forefront of pandemic preparedness and innovation.

## 1. Congress should expand BARDA's mandate to include threat-agnostic (Disease X) rather than solely threat-specific approaches.

*Context*

- Today, the Biomedical Advanced Research and Development Authority's mandate limits its responses to specific chemical, biological, radiological, and nuclear threats. This approach was designed in 2006 when the biological threat landscape consisted of mostly known pathogens (e.g., Anthrax). Unfortunately, this mandate is no longer sufficient in a world where BARDA must respond to a rapidly evolving biological threat landscape that includes known, unknown, accidental, engineered, and natural biological threats.

- It is crucial to broaden BARDA's mandate to allow the agency to work on broad-spectrum or pathogen-agnostic prevention techniques. These approaches are both practical and cost effective. Furthermore, broadening BARDA's mandate is aligned with Objective 1.1. of the BARDA Strategic Plan 2022-2026, which emphasizes the need to "accelerate the development of agile MCMs that can pivot and be brought to scale in response to new threats."
- These changes to BARDA will result in the development of agile and resilient medical countermeasures and prevention capabilities that can respond to current and future biological incidents.

*Recommendations*

- Congress should modify BARDA's mandate to give it the responsibility to provide basic response and prevention tools for all accidental, engineered, and natural biological incidents. This modification corresponds to the ASPR Strategic Plan 2022-2026 Objective 1.2, which calls for addressing an evolving threat landscape where novel and engineered threats require investments in broad-spectrum and pathogen-agnostic approaches.
- Congress should add threat-agnostic measures to the (F) Strategic initiatives clause of the current statute. This approach could be modeled on S.2640 Disease X Act, which calls for the establishment of a pan-viral family medical countermeasure program within the U.S. Department of Health and Human Services.
- BARDA should lead the development of next-generation medical countermeasures such as ultraviolet-C (UVC) systems for preventing disease transmission and metagenomic diagnostic systems with integrated reporting for the detection of novel pathogens. These tools should be deployed before a disease outbreak to enable early detection and mitigate potentially serious consequences. See suggested bill text in **Appendix A**.

## 2. Congress should modify the Project BioShield mandate to include threat-agnostic (Disease X) rather than threat-specific approaches. This ensures that funds can be used to invest in capabilities that respond to multiple material threats.

*Context*

- Project BioShield funding is based on a list of material threats determined by the U.S. Department of Homeland Security's Material Threat Assessment. HHS conducts its own assessment to determine which countermeasures should be prioritized based on the DHS material threats list,

- The focus on individual material threats was a response to the biothreat landscape of 2006, which mostly consisted of known pathogens. Unfortunately, this narrow focus prevents Project BioShield from using its funds to respond to a modern biothreat landscape that includes combinations of known, unknown, and/or engineered biological threats.
- Given changes in the threat landscape, Congress should allow HHS to increase investment in threat-agnostic approaches. This would provide the flexibility to target multiple material threats with one capability, and address material threats in the context of more broadly applicable countermeasures and capabilities.

*Recommendations*

- In order for the HHS to use Project BioShield funding to develop multi-threat capabilities or countermeasures, Congress should modify Clause (B) Determination of Material Threats in BARDA's mandate. See suggested bill text in **Appendix B.**

## 3. Congress should move toward a "reconfigurable" Strategic National Stockpile model. This would increase SNS agility by incorporating innovative platform-based technologies to create, store, and administer next-generation countermeasures and capabilities.

*Context*

- Reconfigurable and rapidly deployable platform-based technologies would complement existing SNS products and countermeasures for known biological threats (e.g., smallpox or anthrax) by increasing the SNS's responsiveness to unknown biological threats with Disease X products.
- Reconfigurable platform-based technologies can be used to create targeted diagnostic tests, vaccines, and therapeutics. A reconfigurable SNS model will require stockpiling limiting components that can be used to respond to a variety of critical biothreats.
    - For instance, once a particular threat is identified, platform-based technologies like mRNA can be reconfigured to produce a range of more potent and targeted medical countermeasures, such as incorporating specific mRNA sequences for different protein targets. In addition, flexible and rapid advanced manufacturing can quickly make new products available on a wide scale.

- A “reconfigurable” SNS model would be more agile and would keep industry partners primed for developing medical countermeasures and capabilities during non-public health emergencies.
    - Rapid tests using innovative CRISPR-based platform-based technologies are multipurpose. They can be stockpiled for threat response but can also be commercialized for a variety of endemic diseases such as sexually transmitted infections.
- Stockpiling otherwise limiting components for mRNA-based vaccine platforms enables the rapid deployment of targeted vaccines in a public health emergency. The SNS already stockpiles components for vaccine administration. Including upstream components would complement this approach.
- A “reconfigurable” SNS and the resulting commercial market is aligned with the warm-base manufacturing provisions in the 2023 Consolidated Appropriations Act. It would foster regional bioindustrial manufacturing hubs and drive biotechnology investment to under-resourced areas of the country.

*Recommendations*

- Modify the definition of products in the SNS to explicitly include platform-based technologies. See suggested bill text in **Appendix C.**
- Congress should require the U.S. Food and Drug Administration to create a path for platform-based in-vitro diagnostics in the SNS. This would be similar to the path that was recently created for platform-based therapeutics. Further information is available in **Appendix D.**
    - Congress should authorize the FDA to conduct a risk-benefit analysis during the Emergency Use Authorization review process, taking into account the full range of an EUA’s potential benefits and harms to individual *and* public health. This would capture many of the unique strengths of at-home rapid diagnostics that are not currently reflected in FDA’s standard decisionmaking (e.g., immediate results, low cost, and potential over-the-counter uses) and reduce the burden on healthcare systems during emergencies.
        - Past action includes the FDA Risk Analysis to assess the safety and effectiveness of the rapid HIV test OraQuick in 2012 to support its approval for over-the-counter use. This was the first and only rapid test to receive such an approval prior to the COVID-19 pandemic.
- Congress should designate BARDA, in coordination with FDA, as the USG lead for independent test validation. Further information is available in **Appendix E**.
- The SNS should include reconfigurable platforms for rapid diagnostic tests, vaccines, and therapeutics to address a range of known and unknown

pathogens. In non-public health emergencies, these platforms can be cycled through other public health settings to address endemic diseases.

## 4. Congress should establish a Public Health Emergency Medical Countermeasures Enterprise external advisory committee to increase the transparency of PHEMCE decision-making processes.

*Context*

- The 2019 PAHPAIA reauthorization formalized PHEMCE roles and responsibilities, but ambiguities persist in decision-making processes.
- In 2021, both the U.S. Government Accountability Office and National Academies of Science, Engineering and Medicine provided recommendations on restructuring the PHEMCE to clarify SNS decision-making processes.
    - The GAO report recommended ASPR restructure the PHEMCE to increase transparency SNS annual reviews and other decision-making processes. The report emphasizes the need to foster greater interagency collaboration while also making sure proper safeguards protect sensitive information.
    - The NASEM report outlined key problems with PHEMCE decision-making, including ambiguous processes for reviewing, assessing, and procuring SNS products. Additionally, PHEMCE practices were described as not fully scientific, justifiable, transparent, adaptive, or accountable.
- A PHEMCE external advisory committee would also ensure consistency during political transitions, which has impeded PHEMCE effectiveness.

*Recommendations*

- To address transparency problems with PHEMCE decision-making, Congress should authorize an external advisory committee to advise the Secretary of HHS, the Assistant Secretary for Preparedness and Response (ASPR), and the heads of all Federal entities that conduct, support, or have an interest in the medical countermeasure enterprise.
    - This committee would be made up of no more than 20 public and private experts, such as former ASPR and SNS staff, industry representatives, hospital preparedness administrators, end-users, and other SLTT stakeholders. Meetings of the PHEMCE external advisory committee and any subcommittees would be conducted according to the Federal Advisory Committee Act and other Department policies.

- Meetings of the full committee should be held approximately three times within a fiscal year. They may be convened on an as-needed basis as determined by the executive director of the PHEMCE external advisory committee or a designated federal officer. The PHEMCE external advisory committee should also have an annual public meeting.
- The PHEMCE external advisory committee should:
    - Recommend strategies and guidance for enhancing transparency and accountability around the medical countermeasure enterprise.
    - Advise the records management of the SNS annual review and other PHEMCE activities.
    - Review PHEMCE decision-making practices for reviewing, assessing, and procuring SNS products, and recommend practices for securing sensitive documentation.
    - Review PHEMCE priority-setting processes and recommend public communication strategies of priorities for enterprise partners.
    - Recommend multifunctional countermeasure investments and opportunities to leverage private sector and academic innovation to address unmet prevention and medical countermeasure needs.
    - Advise on the creation of a data system to monitor the entire medical countermeasure pipeline (i.e., research, development, and deployment),
    - Address any other issues as directed by the Secretary of HHS.

## 5. Congress should clarify roles and responsibilities between the Assistant Secretary for Preparedness and Response and the US Federal Emergency Management Agency by requiring a joint briefing or hearing.

*Context*

- This reauthorization should reaffirm the role of the ASPR as the “principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies,” especially as ASPR expands its operational capabilities. In particular, this reauthorization should ensure that ASPR is the primary driver of the public health emergency response and is empowered to coordinate effectively with FEMA to provide response resources as detailed in the Stafford Act.

*Recommendation*

- Congress should encourage ASPR and FEMA to conduct joint exercises to ensure clear operational roles and responsibilities during disease outbreaks as

well as public health emergencies. Exercises should adhere to the National Response Framework and the National Incident Management System and should incorporate federal, SLTT, and private sector stakeholders.
- Congress should hold a joint briefing or hearing every five years to ensure ASPR is coordinating effectively with FEMA. This hearing should emphasize that responsibilities during public health emergencies are clearly articulated and executed.

## 6. Congress should increase the level of intelligence provided to ASPR and the PHEMCE.

*Context*

- To adequately prepare for emerging chemical, biological, radiological and nuclear threats, ASPR must have sufficient personnel to receive relevant national security threat intelligence and ensure appropriate readiness and response.
- There should be a cadre of PHEMCE members that can be briefed on relevant national security threat intelligence to ensure SNS readiness and effective response to the CBRN threat landscape.

*Recommendation*

- Increase the number of ASPR personnel with appropriate security clearances.
- Increase the number of PHEMCE members with appropriate security clearances.

## 7. Congress should expand ASPR contracting authorities.

*Context*

- Increasing the contracting authority for ASPR to flexibly procure and acquire products would allow the administration to competitively partner with industry.

*Recommendation*

- As an operating division, ASPR's contracting authority must be increased in order to meet its mission.
- ASPR should have similar authority as the U.S. Department of Defense's general procurement and acquisition authority, outlined by 10 U.S.C. § 4023. See suggested bill text in **Appendix F**.

- ASPR should also have innovative general procurement and acquisition authority similar to DoD's authority outlined in 10 U.S.C § 3458. See suggested bill text in **Appendix G.**
- ASPR should also have authorities, similar to those outlined in the Defense Production Act Title III (50 USC 4531-4534), to enable industrial base expansion and domestic industrial support. In addition to scaling production, these capabilities would allow ASPR to commercialize key R&D investments to prevent and respond to CBRN threats.

## 8. Congress should require the CDC to create a national policy on field biosafety.

*Context*

- The Office of the Director of National Intelligence flagged the lack of field biosafety standards as cause for concern given increased field sampling and advanced research in its 2023 Annual Threat Assessment.
    - For example, improper bat field research for biomedical sampling could result in viral spillover.
- Field biosafety is typically overseen at the institutional level. Federally, there are also no field biosafety standards across different departments and agencies. This results in fractured oversight and a lack of comprehensive federal standardization of field biosafety.

*Recommendation*

- Congress should require the CDC to add a chapter on field biosafety to the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual to provide guidance to field researchers.

## 9. Congress should require ASPR to provide oversight of gene synthesis providers and customers.

*Context*

- Many synthetic DNA providers have implemented voluntary screening systems to mitigate risk. These systems verify customers' identities and monitor orders to ensure harmful sequences are not released to inappropriate parties. Unfortunately, screening is inconsistent across the industry due to lack of federal oversight.

- As the cost of DNA synthesis falls, screening will make up a greater share of the total cost of synthesis. This will make it harder for companies that screen to remain competitive with those who don't.
- The U.S. has long been a biotechnology leader and it should demonstrate its leadership by creating norms that will allow the domestic bioeconomy to safely grow.
    - A 2018 NASEM report highlights biodefense concerns around synthetic pathogen misuse. The report emphasized that synthetic biology increases the range and harmfulness of pathogens that can be produced, decreases the timeframe of engineering pathogens, and broadens the types of actors that manipulate pathogens.
- ASPR should coordinate with the Office of the Director of National Intelligence as well as the Department of Commerce to create a robust regulatory framework on gene synthesis.

*Recommendation*

- We recommend including a gene synthesis screening bill in PAHPA reauthorization.

# Appendix A

## 42 USC 247d-7e: Biomedical Advanced Research and Development Authority

### (F) Strategic initiatives

The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding contracts, grants, and cooperative agreements, or entering into other transactions, to support innovative candidate products in preclinical and clinical development that address priority, naturally occurring and man-made threats or their potential sources that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to or prevent such a threat (including medical response and treatment capabilities, ~~and~~ manufacturing infrastructure, detection systems, and prevention infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of countermeasures and products, as applicable, to address areas including-

(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient developed, approved, licensed, or authorized countermeasures or prevent systems exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

(ii) threats that consistently exist or continually circulate and have a significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material; personal protective equipment; detection systems); and

(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious diseases, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens; and

(iv) potential sources of threats from a chemical, biological, radiological, or nuclear agent, or emerging infectious diseases (including prevention of or early

detection of zoonotic spillover or laboratory accidents, and defensive modifications or additions to existing and emerging technologies).

## Appendix B

### §247d–6b. Strategic National Stockpile and security countermeasure procurements

**(2) Determination of material threats**

**(A) Material threat**

The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis-

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

**(B) Public health impact; necessary countermeasures, prevention, and response capabilities**

The Secretary shall on an ongoing basis-

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures, prevention, or response capabilities that can be applied to any biological threat are necessary to protect the public health.

## Appendix C

42 USC 247d-6b: Strategic National Stockpile and security countermeasure procurements

**(1) In general**

The Secretary, in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration and production of drugs, vaccines and other biological products, medical devices, reconfigurable innovative platform-based technologies, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 300hh–10a of this title, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2).

**3) Procedures**

The Secretary, in managing the stockpile under paragraph (1), shall-

(A) consult with the working group under section 247d–6(a) of this title and the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title;

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events, and the availability, deployment, dispensing, production, and administration of countermeasures;

**(7) Procurement**

(IX) Contract terms

The Secretary, in any contract for procurement under this section-
(aa) may specify-
(AA) the dosing and administration and production requirements for the countermeasure to be developed and procured;
(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

## §300hh–10. Coordination of preparedness for and response to all-hazards public health emergencies

**(7) Countermeasures budget plan**

Develop, and update not later than March 15 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title) for each such threat. Each such plan shall-

(A) include consideration of the entire medical countermeasures enterprise, including-

(i) basic research and advanced research and development;

(ii) approval, clearance, licensure, and authorized uses of products;

(iii) procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile;

(iv) the availability of technologies that may assist in the advanced research and development of countermeasures and opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development; and

(v) potential deployment, distribution, and utilization of medical countermeasures; development of clinical guidance and emergency use instructions for the use of medical countermeasures; and, as applicable, potential postdeployment activities related to medical countermeasures;

(B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

(C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 247d–6b of this title;

(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, production, and administration technologies, and other countermeasure needs as applicable and appropriate;

(E) be made available, not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and

(F) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.

## Appendix D

### Congress should direct the FDA to streamline access to rapid diagnostics for use during public health emergencies.

- FDA approves products, not platforms. When a new pathogen emerges, medical countermeasures are needed as soon as possible. However, when companies submit applications for new products to the FDA, they are only required to consider safety and efficacy information related to the novel pathogen. This information takes multiple months to gather for two primary reasons: (1) a lack of scientific understanding of the novel pathogen; and (2) clinical trials can't begin until the early response has failed and the pathogen becomes widespread.
- Congress and FDA are updating this approach. In Section 2503 of PREVENT Pandemics Act, enacted in the FY23 Omnibus, Congress directed FDA to establish a new approach for evaluating new treatments and vaccines, but not diagnostics, which are considered medical devices. The act instructed the HHS Secretary to establish a pathway for sponsors to reference data from past applications for similar products. This new pathway is applicable for platform technologies — drugs or biologics that share a technical design — and enables earlier and more reliable FDA evaluation.
    - This reauthorization should direct FDA to establish a similar platform technology pathway for in vitro diagnostics. This will enable the rapid deployment of novel tests using a pre-approved platform technology that has already been well characterized across multiple tests.
- The enacted language in the PREVENT Pandemics Act should serve as a template for platform-based in vitro diagnostics. FDA officials are considering ways to leverage platform technologies to aid regulatory decision-making. The FDA's Center for Devices and Radiological Health (CDRH) and its Office of Health Technology 7 (OHT 7): In Vitro Diagnostics, as well as the Office of the Commissioner, have established themselves as leaders on this issue. These offices should participate in developing the novel FDA evaluation pathway given their experience pioneering accelerated approval mechanisms for rapid diagnostics against COVID-19. This will ensure that the new pathway has a clear, actionable design with minimal ambiguity for sponsors or reviewers.

## Appendix E

### Congress should designate BARDA, in coordination with FDA, as the USG lead for independent test validation.

- Tests need to be validated quickly in an emergency. A diagnostic test for a novel pathogen is typically evaluated in two steps:
    1) **Analytical validation**: researchers directly measure the test's ability to detect the presence or absence of a pathogen in samples.
    2) **Clinical testing:** researchers administer the tests to actual patients or have patients self-administer the test in a clinical trial to determine whether it gives accurate results in a real-world setting.
- DIY validation by test developers is slow and unreliable during an emergency, yet there is no USG lead for this process. During the early days of an outbreak, specimens from infected patients are scarce and not readily available to diagnostics developers who need them to conduct analytical validation. FDA leaders have publicly advocated for a USG lead to fill this gap.
- Congress should direct BARDA to develop a standing capacity for rapid distribution of specimens, protocols, and technical support to developers conducting analytical validation. Agile public-private partnerships to facilitate access to specimens and validation tests are critical to improving regulatory decision-making and allowing faster access to diagnostics in future emergencies. These partnerships should be informed by the success of RADx's Independent Test Assessment Program for COVID-19 rapid test validation. BARDA has already articulated plans to fulfill a similar function for all novel threats within its Rapid Response Partnership Vehicle's consortium of medical device developers, with BARDA's Division of Detection, Diagnostics and Devices Infrastructure (DDDI) likely playing a key role in this process.

Congress should ensure that BARDA regularly exercises standing capability for medical countermeasure development and manufacturing by providing adequate authority, funding, and oversight. To ensure the program can partner with developers to meet FDA's needs during an emergency, BARDA must exercise this capability frequently in both emergencies and non-emergency scenarios. This was a key lesson from the failure of other pre-pandemic programs like CIADM, which failed to provide a standing capacity for medical countermeasure development and manufacture during the pandemic. Crucially, BARDA must also remain active against infectious disease threats. Rather than creating a single point of failure in test development, BARDA's work should be one part of a decentralized ecosystem of private developers that are also validating their tests to FDA's satisfaction.

## Appendix F

### §4023. Procurement for experimental purposes

(a) Authority.-The Secretary of Health and Human Services and the Assistant Secretaries of the HHS agencies may each buy medical countermeasures and supplies, prevention and response capabilities, ~~ordnance, signal, chemical activity, transportation, energy, medical, space-flight, telecommunications, and aeronautical supplies,~~ including parts and accessories, and designs thereof, that the Secretary of Health and Human Services or the Assistant Secretaries concerned considers necessary for experimental or test purposes in the development of the best supplies that are needed for the national defense.

(b) Procedures.-Purchases under this section may be made inside or outside the United States and by contract or otherwise.

## Appendix G

**§3458. Authority to acquire innovative commercial products and commercial services using general solicitation competitive procedures**

(a) Authority.-The Secretary of Health and Human Services and the Assistant Secretaries of HHS departments may acquire innovative commercial products and commercial services through a competitive selection of proposals resulting from a general solicitation and the peer review of such proposals.

~~(b) Treatment as Competitive Procedures.-Use of general solicitation competitive procedures under subsection (a) shall be considered to be use of competitive procedures for purposes of chapter 221 of this title.~~

(c) Limitations.-(1) The Secretary may not enter into a contract or agreement in excess of $100,000,000 using the authority under subsection (a) without a written determination from the Assistant Secretary for Financial Resources or the relevant service acquisition executive of the efficacy of the effort to meet mission needs of the Department of Health and Human Services ~~or the relevant military department~~.

(2) Contracts or agreements entered into using the authority under subsection (a) shall be fixed-price, including fixed-price incentive fee contracts.

(3) Notwithstanding section 3451(1) of this title, products and services acquired using the authority under subsection (a) shall be treated as commercial products and commercial services.

(d) Congressional Notification Required.-(1) Not later than 45 days after the award of a contract for an amount exceeding $100,000,000 using the authority in subsection (a), the Secretary shall notify the congressional health committees of such award.

(2) Notice of an award under paragraph (1) shall include the following:

(A) Description of the innovative commercial product or commercial service acquired.

(B) Description of the requirement, capability gap, or potential technological advancement with respect to which the innovative commercial product or commercial service acquired provides a solution or a potential new capability.

(C) Amount of the contract awarded.

(D) Identification of the contractor awarded the contract.

(e) Innovative Defined.-In this section, the term "innovative" means-

(1) any technology, process, or method, including research and development, that is new as of the date of submission of a proposal; or

(2) any application that is new as of the date of submission of a proposal of a technology, process, or method existing as of such date.