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PRATT'S  
**GOVERNMENT  
CONTRACTING  
LAW**  
REPORT



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**EDITOR'S NOTE: THE NDA**

Victoria Prussen Spears

**THE FY 2020 NATIONAL DEFENSE  
AUTHORIZATION ACT: WHAT  
GOVERNMENT CONTRACTORS SHOULD  
WATCH FOR**

Alexander O. Canizares and Julia M. Fox

**DOJ GUIDELINES INCENTIVIZE  
COMPANIES TO SELF-DISCLOSE AND  
COOPERATE IN FALSE CLAIMS ACT  
CASES**

Maurice Bellan, William Devaney,  
Marilyn Batonga, Daniel Fiedler, and  
Courtney Giles

**SUPREME COURT EXTENDS FALSE CLAIMS  
ACT *QUI TAM* LIMITATIONS PERIOD**

Michael J. Navarre, Patrick F. Linehan, and  
Paul R. Hurst

**PAHPAI REAUTHORIZES KEY  
BIODEFENSE INITIATIVES AND PROVIDES  
OPPORTUNITIES FOR INDUSTRY  
PARTNERS**

Jennifer Plitsch and Brooke Stanley

**IN THE COURTS**

Steven A. Meyerowitz

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**Editor's Note: The NDAA**

Victoria Prussen Spears 309

**The FY 2020 National Defense Authorization Act: What  
Government Contractors Should Watch For**

Alexander O. Canizares and Julia M. Fox 311

**DOJ Guidelines Incentivize Companies to Self-Disclose and  
Cooperate in False Claims Act Cases**

Maurice Bellan, William Devaney, Marilyn Batonga, Daniel Fiedler, and  
Courtney Giles 318

**Supreme Court Extends False Claims Act *Qui Tam* Limitations  
Period**

Michael J. Navarre, Patrick F. Linehan, and Paul R. Hurst 322

**PAHPAI Reauthorizes Key Biodefense Initiatives and Provides  
Opportunities for Industry Partners**

Jennifer Plitsch and Brooke Stanley 326

**In the Courts**

Steven A. Meyerowitz 330

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# PAHPAI Reauthorizes Key Biodefense Initiatives and Provides Opportunities for Industry Partners

*By Jennifer Plitsch and Brooke Stanley\**

*This article explains the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 that was recently signed into law. The legislation is a key development in strengthening the country's ability to respond to bio-threats, disasters, and other national emergencies by defining federal program initiatives and funding states and private researchers.*

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 ("PAHPAI") recently was signed into law.<sup>1</sup> The Act is a much anticipated reauthorization of the Pandemic and All-Hazards Preparedness Act, originally passed in 2006.<sup>2</sup> The legislation is a key development in strengthening the country's ability to respond to bio-threats, disasters, and other national emergencies by defining federal program initiatives and funding states and private researchers. PAHPAI-authorized grants allow for the research and development of biodefense measures and the stockpiling of preparedness supplies.

## THE PAHPAI

PAHPAI continues several initiatives and implements new programs and priorities, reflecting that countermeasure development and procurement and emergency response programs remain critical components of public health preparedness. Perhaps most importantly, PAHPAI includes significant appropriations for these initiatives. The key appropriations implemented in the 2019 legislation include:

- *Public Health Security Grants.* PAHPAI authorizes the Secretary of Health and Human Services to award grants to states, consortiums of states, or other public entities to conduct activities to achieve the

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\* Jennifer L. Plitsch is a partner at Covington & Burling LLP and co-chair of the firm's Government Contracts practice group, where her practice includes a wide range of contracting issues for large and small businesses in both defense and civilian contracting. Brooke Stanley is an associate at the firm, where she is a member of the Government Contracts Practice Group. The authors may be reached at [jplitsch@cov.com](mailto:jplitsch@cov.com) and [bstanley@cov.com](mailto:bstanley@cov.com), respectively.

<sup>1</sup> Pub. L. No. 116-22, \_\_\_ Stat. \_\_\_ (June 24, 2019) (to be codified in scattered sections of 42 U.S.C.), <https://www.congress.gov/116/bills/s1379/BILLS-116s1379enr.pdf>.

<sup>2</sup> Pub. L. No. 109-417, 120 Stat. 2831 (2006).

preparedness goals described by the National Health Security Strategy.<sup>3</sup> These activities can include research, development, and planning, related to a series of strategic goals, including the integration of private and public medical capabilities, development of public health security strategies and medical response strategies, maintaining coordination and continuity of operations in the event of a national emergency, and the creation of resiliency strategies for public health crises. In particular, the 2019 National Health Security Strategy includes two new preparedness goals: (1) response to zoonotic diseases in plants or animals; and (2) domestic response to global health threats originating abroad, such as the recent Zika or Ebola outbreaks. PAHPAI appropriates \$685 million per year for these grants through 2023.<sup>4</sup>

- *Biomedical Advanced Research and Development Authority* (“BARDA”). This authority, housed in the Department of Health and Human Services, is tasked with awarding and administering contracts, grants and cooperative agreements and entering into other transactions (“OTAs”) to produce, through advanced research and development or procurement, measures to counteract threats from three particular sources: (1) chemical, biological, radiological, or nuclear (“CBRN”) and infectious disease-related threats; (2) threats that will or may potentially become a pandemic; and (3) threats that may present treatment complications, such as resistance to current treatments. BARDA is funded by the Biodefense Medical Countermeasure Development Fund, and PAHPAI appropriates \$611.7 million per year for this fund through 2023.<sup>5</sup> In addition to this funding, PAHPAI increases the threshold for OTA approvals to \$100 million.<sup>6</sup>
- *The Strategic National Stockpile* (“SNS”). PAHPAI once again authorizes the Secretary of Health and Human Services to work with the Director of the Centers for Disease Control and the Secretary of Homeland Security to maintain a stockpile of biodefense instruments, including drugs, vaccines, and medical devices to combat potential emergencies. In addition to creating and maintaining the stockpile, the Department of Health and Human Services is tasked with conducting an annual threat-based review of the SNS, including an evaluation of

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<sup>3</sup> See Pub. L. No. 116-22, § 101.

<sup>4</sup> See *id.* § 202.

<sup>5</sup> See *id.* § 504.

<sup>6</sup> See *id.* § 602.

CBRN threats and the adequacy of planned countermeasures. These reviews must be conducted on an “ongoing basis.” The Act appropriates \$610 million per year through 2023 for the preservation of the stockpile.<sup>7</sup>

- *BioShield Special Reserve Fund.* This Fund allows for the procurement of countermeasures intended to combat CBRN threats. PAHPAI appropriates \$7.1 billion for this fund through fiscal year 2028.<sup>8</sup> The Secretary of Health and Human Services is authorized to use this fund in two restricted circumstances: (1) payment to a vendor for advanced development of a CBRN countermeasure; or (2) payment to a vendor for a direct procurement of such a countermeasure.
- *Funding for the Assistant Secretary for Preparedness and Response.* First established in PAHPA, the Assistant Secretary for Preparedness and Response (“ASPR”) within the Department of Health and Human Services is tasked with leading all matters related to public health and medical preparedness and public health emergency response at the federal level. PAHPAI assigns the ASPR new duties as well—to address threats that pose a significant risk to public health and national security, particularly strains of pandemic influenza. PAHPAI appropriates \$250 million per year through 2023, intended specifically to fund the confrontation of this threat.<sup>9</sup>

The legislation also includes appropriations for additional initiatives to facilitate military and civilian preparedness, including the National Disaster Medical System,<sup>10</sup> the Military and Civilian Partnership for Trauma Readiness Grant Program,<sup>11</sup> and Hospital Preparedness Program.<sup>12</sup>

## CONCLUSION

PAHPAI is but one signal of continuing congressional emphasis on biodefense and preparedness measures. On June 26, 2019, the Subcommittee on National Security of the House Committee on Oversight and Reform held

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<sup>7</sup> See *id.* § 403.

<sup>8</sup> See *id.* § 504.

<sup>9</sup> See *id.* § 404.

<sup>10</sup> See *id.* § 301.

<sup>11</sup> See *id.* § 204.

<sup>12</sup> See *id.* § 202.

a hearing<sup>13</sup> to discuss U.S. government and healthcare system readiness to respond to naturally occurring pandemics and biological attacks, as well as the increasing threat of antimicrobial-resistant diseases. Together, these developments reflect a need for, and commitment to, increased preparedness planning and countermeasure development, as well as continuing opportunities for industry members in this area.

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<sup>13</sup> <https://oversight.house.gov/legislation/hearings/us-biodefense-preparedness-and-implications-of-antimicrobial-resistance-for>.