Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (Public Law 116-22)

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The Policy

Synopsis

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 [18] (HR 269, 116th Congress) aims to improve national public health security by increasing and reauthorizing funding for programs that are in place to respond to, among other threats, emerging pandemics and antimicrobial resistance. The bill allots resources to various healthcare providers to aid in emergency and disaster situations with an emphasis on the care of children, elder adults, and individuals with disabilities. The legislation also forms councils to evaluate the use of antibiotics and prevention of antimicrobial resistance. Additionally, the bill forms advisory committees comprised of science and health experts to inform preparation guidelines. The bill covers many topics, but this brief will mainly focus on sections involving genetics and genomics specifically.

Section 404: Preparing for pandemic influenza, antimicrobial resistance, and other significant threats

Section 404 provides initiatives and funding for research of influenza and other emerging infectious diseases, as well as the procurement of countermeasures for such pandemics.

Section 504: The Biomedical Advanced Research and Development Authority and the Bioshield Special Reserve Fund

Section 504 renews funding for the Bioshield Special Reserve [19] and the Biomedical Advanced Research and Development Authority [20] (BARDA), which are responsible for both researching and procuring countermeasures to public health threats.

Section 505: Additional strategies for combating antibiotic resistance

Section 505 outlines the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria [21]'s duties, including advising policy and programs that involve antibiotic use and antibiotic resistant infections.

Section 605: Review of the benefits of genomic engineering technologies and their potential role in national security

Section 605 outlines calls for a meeting, and provides recommended attendees for this meeting, to discuss the role of genomic engineering technologies in public health security.

Section 606: Report on vaccines development

Section 606 commissions a report to describe efforts made to advance pandemic and/or epidemic products, such as vaccines. This report is to be compiled by the Department of Health and Human Services (HHS) and submitted to the Committee on Health, Education, Labor, and Pensions of the Senate [22] and the Committee on Energy and Commerce of the House of Representatives [23].

Context
Since 2000, notable traumatic events (e.g., the anthrax attacks of 2001, Hurricane Katrina in 2005, and the Ebola outbreak of 2014) have led to the prioritization of public health emergency preparation in United States governmental policy, emphasizing the importance of a robust federal response to public health emergencies. Public health emergencies include natural disasters, outbreaks of infectious diseases [24], and bioterrorism.

A number of different federal laws address responsiveness to public health emergencies. Among them, the Public Health Service Act [25] (PHS) sets the standard for a federal response to public health emergencies by giving the United States Public Health Service [26] the task of preventing the spread of disease from foreign countries into the United States.

The Public Health Security and Bioterrorism Preparedness Act of 2002 [27] expanded upon the PHS by providing funding to hospital and health system preparations on the state level. Two years later, the Project BioShield Act of 2004 [28] incentivized drug development that would further aid with public health disaster response.

The Pandemic and All-Hazards Preparedness Act of 2006 [29] both reauthorized existing programs under the PHS and funded new preparedness-related plans and offices. These new programs included the BARDA and the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan [30]. These programs involve research of new therapeutics for drug resistant pathogens and research on potential health effects of bioterrorism.

**Policy History**

On May 15, 2018, the Senate referred a draft of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 as S 2852 [31] (115th Congress) to the U.S. Senate Committee on Health, Education, Labor and Pensions [22]. The bill was then introduced in the house on July 16, 2018 as HR 6378 [32] (115th Congress). The House then considered the bill as unfinished business under the title HR 7328 [33] (115th Congress) on December 20, 2018. The current draft of the bill, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPA), then entered the next session of Congress and was then titled HR 269 in the House.

An identical version of the bill, S 1379, was introduced in the Senate on May 8, 2019. This bill has since passed Congress and was signed into law (Public Law 116-22) on June 24, 2019.

**The Science**

**Learn About the Science**

Antimicrobial Resistance [34]
CRISPR-Cas9 and Genome Editing [35]
Science Synopsis

**Antibiotic resistance** [37], mentioned in HR 269 as a public health emergency, involves microbes that have developed a type of resistance that can cause treatment-resistant infections in humans. Typically, these infections are extremely difficult to treat. These germs often result from exposure to an antibiotic that does not completely kill off the group of microbes; thus, survivors adapt to resist the effects of the drug. This is one reason that doctors advise finishing all antibiotics in a prescription, to ensure that all the germs are targeted and therefore prevent adaptation to resist the drug. Infections caused by antibiotic-resistant germs can affect anyone and are often extremely serious, even deadly. The Centers for Disease Control and Prevention (CDC) explains [37] that at least two million individuals are affected by, and 23,000 people die of, antibiotic-resistant infections in the United States every year.

**Bioterrorism** [38] is the deliberate release of germs that cause serious illnesses. Sometimes, as is the case with **anthrax** [39], these germs can go virtually completely undetected due to the microscopic nature of these microbes; our difficulty in detecting these organisms can then lead to **widespread illness** [40]. The CDC cites anthrax as the one of the most likely weapons for bioterrorist attacks because spores of the bacteria that cause this infection are easily obtainable and can live for long periods of time without a host. The spores can be placed in food, water, or even released in the air to quickly infect large numbers of individuals. Once infected, people only have a short window of time to seek treatment in order to survive.

**Genomic engineering** [41] is mentioned in this Act as a new technology with potential implications in national health security. Genomic engineering is the process of editing the DNA sequence of living organisms. One common means of such a technique is **CRISPR-Cas9** [42], a technology developed and repurposed from single celled organisms’ natural antiviral response. The CRISPR portion of the technology is used to recognize a specific sequence of DNA that will be targeted for editing. The Cas-9 portion cuts the DNA sequence that CRISPR identifies and targets. Using these two processes together provides scientists and clinicians a way to edit the genes of a living organism.

Scientific Assumptions

**Certain emerging infectious diseases can become resistant to countermeasures (Section 404):** The concept of pathogens becoming resistant to treatments, such as antibiotics, is widely accepted in the medical field and is agreed upon in various works of literature.

**Antimicrobial resistance is a pressing issue, and therefore new therapies for bacterial infections should be researched (Section 505):** Because microbes that give rise to infectious diseases can become resistant to standard treatments (i.e. antibiotics), new methods of treating these ailments are required to replace those that have ceased to be effective. Scientific researchers and governmental agencies have both recognized the threat of antimicrobial resistance and the need for new therapies to replace antibiotics.

Relevant Experts
Dr. Cameron Robert Wolfe is an associate professor of medicine at Duke who researches various pathogens along with hospital emergency preparedness.

Relevant publications:


The Debate

Scientific Controversies / Uncertainties

In order to combat threats such as an influenza pandemic and antibiotic-resistant germs, the Act recommends, among other measures, research into and development of vaccines. Scientists are currently debating the possibility of creating a universal flu vaccine and novel vaccines for diseases that are not typically preventable by vaccination. There has been some successful animal testing of a universal flu vaccine [44], however scientists remain unsure if or how these vaccines will work in human subjects. On April 3, 2019, the National Institutes of Health announced [45] the first human trial of a universal influenza vaccine (H1ssF_3928 [46]) that targets markers on the influenza virus that remain stable from strain to strain.

With regard to vaccine development [47], there are currently hundreds of new vaccines for infectious diseases in clinical trials or under review by the Food and Drug Administration [48]. There are also vaccines for the prevention of cancer [49], such as a vaccine against the Human Papillomavirus, which was previously believed to be unpreventable by vaccine. There is, however, no predicting if and when these therapies will be approved for market.

Research involving the use of CRISPR-Cas9 for new vaccines [50] is also underway. Scientists aim to use CRISPR-Cas9 to edit immune cells to protect against pathogens that were previously unresponsive to vaccines. Trials [50] with these new technologies have been successful in mice cells and human cells in vitro (i.e., out of body); as of February 2019, there were no human trials of such technology.

There is some additional controversy around the ethics of genomic engineering tools, such as CRISPR-Cas9. Literature on the topic demonstrates [51] that both the public and the scientific community are uncertain about the ethics of genomic engineering tools and how far their usage should go. For example, many debate the distinction between using genetic engineering to heal versus enhance and researchers are unsure of long term effects of genome editing in humans due to the novelty of these technologies. This debate was fueled by an event in November 2018; in China, a scientist utilized CRISPR-CAS9 to edit germline cells of a human fetus [52] without approval. In response, there has been an international effort [53] to strengthen the regulations on human genome editing with hopes to prevent unintended outcomes with this new technology. This response was a testament to the level of uncertainty concerning potential
risks of genome editing, especially in *germline cells* [54] as these mutations will presumably pass to the individual's offspring. Therefore, there is still some controversy within the scientific community regarding if, and to what extent, these technologies should be used on humans.

### Endorsements & Opposition

- Numerous Health Organizations, letter [55], December 5, 2018: “The legislation addresses some gaps we have seen in recent responses, such as the speed of funding for public health emergencies, development and deployment of medical countermeasures for significant threats and preparedness for children in disasters.”
- **Biotechnology Innovation Organization** [56] (BIO) President and CEO Jim Greenwood statement [57], July 20, 2018: “[…] this legislation would provide much needed flexibility and predictability for both government agencies as well as their private sector partners, which play a vital role in discovering and developing the medical countermeasures so desperately needed to protect our nation from these threats.”

### Potential Impacts

This bill will potentially provide “flexibility and predictability” when facing public health emergencies, as explained by Jim Greenwood of BIO. Greenwood also believes that the funding included in the new bill will increase cost efficiency and quality of emergency response efforts.

Senators Alexander's (R-TN), Burr's (R-NC), and Murray's (D-WA) statements [58] second those of Greenwood, predicting a strengthened capability to face public health threats. The **American Health Association** [59], along with other health organizations, predict [55] that the bill will increase the accessibility of funds in times of emergency. These organizations also foresee better preparedness for the care of children in emergencies, given the passage of this bill.

### Status

S 1379 was introduced to the Senate on May 8, 2019. The bill passed the Senate on May 16, 2019. The bill then passed the House of Representatives on June 4, 2019. On June 24, President Trump signed the Act into Public Law 116-22.

### Recommended Citation


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