Emerging Pathogen Preparedness Program Authorization Act
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The Problem

During the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) faced a significant strain on its resources as it worked diligently to review and grant Emergency Use Authorizations (EUAs) for medical countermeasures (MCMs). The unprecedented global health crisis necessitated an urgent response, leading to an overwhelming demand for evaluations. The influx of EUA candidates, each requiring careful scrutiny of clinical trial data, manufacturing processes, and safety profiles, placed immense pressure on the FDA's regulatory infrastructure and impacted the FDA's other review work.

Policy Solution

To address these challenges the *Emerging Pathogen Preparedness Program Authorization Act* would establish a specialized program within the FDA Center for Biologics Evaluation and Research (CBER) to defend against emerging pathogens. The Emerging Pathogen Preparedness Program will allow the FDA to respond to identified threats of concern and focus experienced resources to work quickly on MCM development and review.

The Emerging Pathogen Preparedness Program Authorization Act would:

- Establish a dedicated team of MCM subject experts to conduct regulatory reviews and outreach to developers and manufacturers.
- Support scientific research within CBER that contributes to development and review of biological products to counter biological incidents and emerging pathogens.
- Maintain and build on enhancements to FDA's post-marketing active and passive safety and effectiveness surveillance programs.
- Ensure blood safety and availability.
- Prioritize research and development efforts related to platform vaccine technologies, such as mRNA, because of their exceptional ability to be modified quickly to address new pathogens.