



COVID-19 Proposal:

FUNDING FOR NEW INITIATIVES AT HHS AND DOD TO RAPIDLY DEVELOP MEDICAL COUNTERMEASURES FOR NOVEL INFECTIOUS DISEASES IN MONTHS, NOT YEARS

PROBLEM

Today's COVID-19 pandemic is an undeniable example of an increasing global trend of deadly infectious disease outbreaks. More than 200,000 people are dead, communities are shut down, and huge economic losses are occurring around the world. The profound effects of this pandemic must galvanize the US government to do everything in its power to prevent this from happening again. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner.

Our best defense is safe and effective medical countermeasures: drugs, vaccines, and diagnostics. However, the development of these life-saving products still takes years.

When the next deadly pathogen emerges, the United States needs to move much faster to develop and deploy medical countermeasures. Existing programs at HHS and DOD are primarily directed toward specific known, high-priority health security threats (including chemical, biological, radiological, and nuclear threats, and pandemic influenza). There is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats, referred to here as Virus 201.

PROPOSAL

The United States must set an ambitious goal of rapidly developing medical countermeasures for novel or unknown threats in months, not years. Innovative technologies, outside-the-box thinking, and game-changing science must be harnessed to meet this goal.

A new dedicated Virus 201 strategy, program, and funding must be created to achieve this goal through the HHS Biomedical Advanced Research and Development Authority (BARDA) and the DOD Joint Program Executive Office for Chemical and Biological Defense (JPEO). This strategy should not compete with or cannibalize other important medical countermeasure development efforts focused on specific known threats, and it should involve other innovative agencies like DARPA and In-Q-Tel.

Therefore, a new congressional appropriation of \$1 billion, divided equally between HHS and DOD, should be provided to enable these agencies to initiate a robust and coordinated strategy to accomplish this goal before the next virus threatens the globe. Specifically, an additional \$500 million should be provided to BARDA and \$500 million to JPEO to implement these initiatives.



The Virus 201 Medical Countermeasure Strategy should be coordinated through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by HHS ASPR and DOD JPEO, with each agency supporting product candidates that best meet the needs of the populations they serve. PHEMCE must ensure collaboration with DARPA and In-Q-Tel.

VIRUS 201 MEDICAL COUNTERMEASURES STRATEGY

Virus 201 means a previously unidentified viral threat, whether naturally occurring or man-made. These pathogens can affect both military personnel and the American public. DOD and HHS investment strategies should be coordinated through PHEMCE, with DOD taking the lead on products targeted to protect young, healthy military personnel, and HHS leading on other products needed to protect the diverse American public, including children and other vulnerable populations.

Since Virus 201 medical countermeasures may not have a commercial market that drives private sector investment, it is essential that a sustainable public-private partnership model and dedicated funding be created to share the development risk, incentivize development of new medical countermeasures, and invest in faster capabilities to respond to potential pandemics. Such countermeasures may include:

- **Antivirals:** In the time before a vaccine is available, antiviral treatments must be developed and deployed to decrease complications, hospitalizations, contagiousness, and mortality. Novel antiviral therapies range from small molecules to monoclonal antibody-based products. Under this proposed Virus 201 Medical Countermeasure Strategy, several kinds of antiviral therapies should simultaneously be supported.
- **Vaccines:** Vaccines are the best solution to protecting Americans from novel viruses, but they usually take the longest to develop. Vaccine technologies have progressed in recent years to include several promising platform technologies that can be more quickly leveraged once a threat has been characterized. More can be done to develop better and faster vaccine platform technologies as well as next-generation manufacturing capabilities that enable faster response.
- **Diagnostics:** Diagnostics are critical to identifying people who have been exposed to a virus. In recent years, rapid diagnostic testing technology has become more robust. Diagnostic challenges experienced during the COVID pandemic involve engaging the private sector to scale up these new technologies into wider commercial use. Additionally, new artificial intelligence and machine learning tools can be leveraged to respond faster and more precisely.

VIRUS 201 ANTIVIRAL THERAPIES

The most promising area for a Virus 201 Medical Countermeasures Program is antiviral therapies. Several initiatives should be implemented to enable more rapid response. They can be divided into several functional components.



1. Repurposing of existing antivirals: Take high-risk viral families (eg, paramyxoviruses) and screen existing and newly developed antiviral compounds against these viral family members. Artificial intelligence and machine learning tools can make this process faster.
2. Broad-spectrum antiviral development: Design antiviral compounds that may have an effect against high-risk viral families. Such antivirals may target a specific pathway shared by all family members in designated viral families. These compounds could then form the basis of a more specific product once a threat materializes.
3. Monoclonal antibody development: Assess high-risk viral families for their susceptibility to neutralization by monoclonal antibodies that could potentially be used for pre-exposure prophylaxis, treatment, and post-exposure prophylaxis. Characterize the requisite antibody target and develop the appropriate monoclonal antibody. Such antibodies would be trialed in animal models, with promising candidates advancing through existing development programs.
4. Immune modulation: Many immunomodulatory products are available that may have nonspecific effects that ameliorate common pathways that lead to host damage. Fund research to understand the inflammatory cascade brought on by high-risk viral families (in animals and humans) and assess existing and potential immunomodulatory compounds for their ability to interdict these processes. Such nonspecific measures may be able to decrease the morbidity and mortality of infection. In addition to immunomodulatory compounds, develop nonspecific procedures or devices such as aphaeresis for cytokines or akin to LPS hemoperfusion (used for bacterial septic shock) for similar use.

VIRUS 201 VACCINES

New vaccine platform technologies (such as messenger RNA, DNA, modified vaccinia ankara, adenoviral vectors) have advanced in recent years and are expected to enable more rapid response to a new virus. Platform technologies are a sustainable pluripotent infrastructure that can be applied to vaccines with minimal added financial risk, thereby diminishing costs and time of vaccine development. These platforms are being leveraged to develop COVID-19 vaccines.

Despite the economies of scale achievable via platform-based approaches, Virus 201 will never represent a major market with large financial rewards and minimal opportunity costs. Therefore, a dedicated Virus 201 program funded by governments, nongovernment organizations, and philanthropies is required to identify and fund promising ideas to make these vaccine platforms even faster and better for future pandemics. In addition, next-generation manufacturing technologies that can quickly scale up to produce millions of doses of vaccine within weeks must be supported.

VIRUS 201 DIAGNOSTICS

Pathogen-agnostic diagnostics are now available through next-generation sequencing providers. These products can test blood samples for hundreds of pathogens. However, these technologies are not being applied in a systematic manner for Virus 201 readiness. The new Virus 201



Medical Countermeasures Strategy must leverage these technologies and work with manufacturers to ensure their capability to respond to new viral threats. Additionally, innovative artificial intelligence technologies and machine learning tools should be evaluated.

CONCLUSION

As COVID-19 has demonstrated, new deadly viruses can spread quickly and easily around the globe, causing significant loss of life and economic downturn. With nearly 200 epidemics occurring each year, the next fast-moving, novel infectious disease pandemic—Virus 201—could be right around the corner. It still takes too long to develop novel antivirals, vaccines, and diagnostics through existing programs at HHS and DOD, which are primarily directed toward specific known, high-priority health security threats. The United States must set an ambitious goal of rapidly developing and deploying medical countermeasures for novel or unknown infectious disease threats in months, not years. Therefore, Congress should fund a new dedicated Virus 201 Medical Countermeasures Strategy and programs at BARDA and JPEO, coordinated through PHEMCE.

The Johns Hopkins Center for Health Security's mission is to protect people's health from epidemics and disasters and ensure that communities are resilient to major challenges.

Six months ago, the Center hosted Event 201, a high-level pandemic exercise with private sector and international leaders that illustrated areas where public-private partnerships are necessary during the response to a severe pandemic in order to diminish large-scale economic and societal consequences. <http://www.centerforhealthsecurity.org/event201/>

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