

April 2, 2024

The Honorable Dawn O'Connell
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary O'Connell:

We, the undersigned free-market, consumer, and taxpayer organizations write to urge your utmost commitment to the principles of sound stewardship and prudent prioritization of federal resources connected to Project NextGen. This \$5 billion public-private partnership overseen by the Biomedical Advanced Research and Development Authority (BARDA) could, with proper diligence, develop cost-effective responses to future pandemics, thereby avoiding potentially trillions of dollars in economic losses and federal deficit spending.

The federal government has provided [in excess of \\$4.5 trillion](#) for various responses to the COVID-19 pandemic. On its own, this amount would be the equivalent of more than half the national debt increase between March 2020 and March 2023 alone, establishing an unenviable trend that has yet to significantly abate. Other Biden administration activities and actions, like the Inflation Reduction Act, have added trillions more to that debt, even as the Congressional Budget Office recently warned that federal borrowing from the public will exceed the nation's Gross Domestic Product by next year. Governments should never waste resources, but in this fiscal environment, intelligent budgeting and grant spending are even more imperative. NextGen is one program at the intersection of all these events, and, depending on decisions leaders make, can serve as a success story – or a cautionary tale – for the challenges ahead.

Each of the signatories below would have preferred different grant structures, funding amounts offset by reductions in other wasteful programs, and tighter managerial processes embedded in statutory law for many post-COVID federal pandemic preparedness initiatives such as NextGen. Congress may be able to provide such legislative clarity going forward. In the case of Project NextGen, however, the policy is now in the implementation stage, where administrative approaches are needed now.

Over our respective organizational histories spanning decades, we have encountered common features, and problems with federal grant programs, particularly those involved in funding “urgent” research. Based on this experience, we suggest the following steps to better ensure that American taxpayers receive a solid return on their considerable investment in Project NextGen:

- **Maintain proper balance in the grant portfolio.** An age-old question in federal advanced research grant programs is whether funding should be directed to initiatives with elevated risk and high payoff that the private sector will not fund, or lesser risk near-term projects the private sector is close to completing but needs a financial boost to reach fruition. The answer is to maintain a balance that is calibrated toward the underlying goals of the given program. With Project NextGen, the aim is clear: “to advance the pipeline of new, innovative vaccines and therapeutics from labs to clinical trials to potential FDA authorization, approval, and commercial availability for people nationwide.” Given this mandate, grants should not be biased toward specific therapies or treatments with marginal or negligible impacts. Remedies within our grasp, e.g., advanced antivirals and monoclonal antibody-based treatments for millions of immunocompromised populations, and other therapies that could provide near-term benefit in our fight against COVID, could be the most value-based focus of NexGen.

More than almost any other proactive or protective measure, the quick development and ramped-up availability of effective COVID vaccines delivered dividends for taxpayers during the pandemic. By the Center for Medicare and Medicaid Services' [own calculations](#), Medicare saved some \$2.6 billion in hospitalization expenses in the first five months of 2021 due to the availability and use of such vaccines in elderly populations. NextGen can make gains such as these with properly balanced prioritization of research.

- **Keep merit-based criteria as high as possible and keep bureaucratic barriers to entry as low as possible.** From alternative energy, to housing, to national defense, taxpayers have been shortchanged by federal research and development grants awarded with inadequate information and unrealistic expectations. On the other hand, excessive red tape has hindered grant applicants with cost-effective ideas from providing taxpayers with novel solutions. Contractors with significant capital and government connections are often the ones best able to navigate the complex maze of grant criteria. BARDA should conduct quarterly evaluations of its grant awards to monitor and act, if necessary, to keep the critical balance between innovation and accessibility among grantees. Whether large or small contractors win NextGen grants is immaterial – what matters is that the most practical and most promising ideas for the largest segment

of patients rise to the top of the creative list. In public-private partnerships, the government entity involved must take care not to send conflicting or counterproductive signals to potential grantees.

- **Learn from the danger signs in other preparedness programs.** The Government Accountability Office (GAO) has made [386 recommendations](#) – only 45 percent of which had been fully or partially addressed as of April 2023 – regarding the federal government’s response to COVID-19 and to probable future pandemics. These include specific suggestions for Department of Health and Human Services grants, such as learning from BARDA’s managerial approach in the Centers for Innovation in Advanced Development and Manufacturing (CIADM) program that included vaccine countermeasures. [According to GAO](#), underuse of the CIADM facilities, deficient oversight, and inconsistent guidance prior to COVID-19 reduced the program’s effectiveness. Overall, auditors called for an “approach to systematically assess, and respond to, known challenges and risks associated with advanced development and manufacturing of medical countermeasures.” In other programs, insufficient transparency in grant and contract databases, weak anti-fraud measures, and inconsistent data feedback loops were identified. We believe that a sizable portion of this guidance is relevant to your program integrity efforts.

BARDA cannot, on its own, implement these maxims government-wide, but can embrace them in its own program execution with Project NextGen.

Taxpayers are now full partners in the NextGen program which, with sufficient effort, can become a model of excellence – one that develops public health responses with potential to conserve billions, even trillions, in their hard-earned money that might otherwise be spent on reactive (rather than proactive) measures. This means BARDA has a special responsibility to ensure that the best possible value for the 20 projects funded with \$5 billion of federal resources is achieved. To this end, we urge you to keep the preceding guidance in mind. Thank you for your consideration.

Sincerely,



National Taxpayers Union



American Consumer Institute



Center of the American Experiment



Pioneer Institute

cc: The Honorable Xavier Becerra, Secretary of Health and Human Services
The Honorable Robert Johnson, Director, NextGen Program