August 1, 2024

The Honorable Diana DeGette
2111 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Larry Bucshon
2313 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Bucshon:

On behalf of the Alliance for mRNA Medicines (AMM) (mrnamedicines.org), we commend your leadership and submit this response to your Request for Information on what Congress can do to further accelerate the discovery, development, and delivery of the next generation of treatments and cures for patients.

About AMM

The Alliance for mRNA Medicines (AMM) is an organization dedicated to advancing and advocating for mRNA and next-generation encoding RNA therapeutics and vaccines for the benefit of patients, public health, and society. Our mission is to propel the future of mRNA medicine, improve patients' lives, and advance scientific knowledge by convening and empowering mRNA industry leaders, innovators, scientists, and other key stakeholders.

AMM officially launched in November 2023 and has become the leading voice of the mRNA community, representing more than 55 members from North America, Europe, Asia, and Oceania. Our members demonstrate the diversity of the mRNA community, which includes biotechnology companies, pharmaceutical companies, academic institutions, service providers, contract

development and manufacturing organizations (CDMOs), and the patients who have and will benefit from mRNA vaccines and therapeutics.

How Cures Propelled mRNA Research Forward

The goal of the original 21st Century Cures Act and Cures 2.0 was to catalyze new therapies and cures for patients, and the remarkable progress and promise of messenger RNA (mRNA) products will play a major part in achieving this goal. mRNA products have the potential to treat a wide range of diseases as prophylactic vaccines, personalized cancer vaccines, protein replacement therapies, therapeutic proteins, and/or as a critical technology enabling gene-editing (*e.g.*, CRISPR). These products could protect the world from malaria, HIV, and other deadly pathogens, and provide treatments and cures for cancer, rare diseases, and other diseases/conditions where there is a significant unmet need.[1]

The 21st Century Cures Act helped propel mRNA in numerous ways. One relates to the mRNA COVID vaccines that saved hundreds of millions of lives across the world. As former Energy & Commerce Committee Chair Fred Upton commented, "the timely approval of the first COVID vaccine can also be traced back to my landmark 21st Century Cures Act, which I spearheaded with my colleague Rep. Diana DeGette (D-CO), and was signed into law by President Obama in 2016."[2] Other provisions of 21st Century Cures enabled critical funding for NIH and FDA as well as hiring authority for FDA. The provisions helped strengthen the scientific foundation for mRNA as well as continue to build the expertise at FDA and NIH. Another important element of the 21st Century Cures law included funding for the Cancer Moonshot initiative. Development of mRNA-based therapeutics offers hope for pancreatic cancer patients and other cancers where treatments have been difficult to find.

Cures 2.0 furthered the work of the original law in promoting mRNA innovation. The provision on ARPA-H has already yielded additional help for mRNA products,[3] and the provisions on vaccine education and pandemic preparedness remain critical to public health and, as we discuss below, should be expanded and enacted.

AMM's Recommendations to Congress

As you consider additional reforms, support mechanisms, or incentives needed to enhance or improve the effectiveness of 21st Century Cures and Cures 2.0, we recommend the following policies to build on the important policies in 21st Century Cures and Cures 2.0:

[1] mRNA The Fourth Pillar Of Pharmaceutical Innovation And Intervention (advancingrna.com)
[2] How the 21st Century Cures Act Paved the Way for the COVID-19 Vaccine | The Ripon Society
[3] https://arpa-h.gov/news-and-events/arpa-h-announces-project-develop-new-tools-strengthen-immune-system

- **Enhance FDA's Regulatory Capacity for mRNA Products**
    - Congress should provide FDA with additional resources to scale up the Center for Biologics Evaluation and Research (CBER)'s and Center for Drug Evaluation and Research (CDER)'s mRNA capacities. This would enable FDA to hire additional review staff, further utilize enhanced review, issue mRNA-specific guidance documents, and hold additional meetings with product sponsors, contract development and manufacturing organizations, and other vital actors in the mRNA innovation ecosystem.

- **Increase Support for Pandemic Preparedness**
    - Congress should increase its support for pandemic preparedness, including these activities specifically included in Cures 2.0 (Section 102 of H.R. 6000, 117th Congress):
        - Developing and administering vaccines, therapeutics, and other medical supplies, including for children, racial and ethnic minorities, and people with disabilities.
        - Modernizing and expanding domestic drug manufacturing, including through continuous manufacturing.
    - Further, Congress should provide additional funding for the Biomedical Advanced Research and Development Authority (BARDA) to support the activities mentioned above as well as for workforce development.

- **Provide Additional Cancer Moonshot Funding**
    - Congress should provide additional resources to the Cancer Moonshot to further enable research and development, including for mRNA products.

- **Support Vaccine Education**
    - Similar to what was included in Cure 2.0, Congress should provide funds to carry out an awareness campaign to educate the public with respect to the safety and importance of vaccines, including mRNA vaccines.

We appreciate your consideration of our input and look forward to working with you throughout the legislative process.

Sincerely,

Clay Alspach, Executive Director

Sara Singleton, Managing Director