



June 2, 2020

The Honorable Nancy Pelosi  
Speaker  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
Washington, DC 20510

The Honorable Kevin McCarthy  
Republican Leader  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Chuck Schumer  
Democratic Leader  
U.S. Senate  
Washington, DC 20510

Dear Speaker Pelosi, Leader McConnell, Leader McCarthy, and Leader Schumer:

We the following 27 members of the Council of State Bioscience Associations (CSBA), along with the Biotechnology Innovation Organization (BIO), urge Congress to support the *Advancing Emergency Preparedness Through One Health Act* and advance legislation directing the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to develop a Memorandum of Understanding (MOU) to streamline the regulatory oversight of animal biotechnology.

CSBA represents state and regional life science organizations across the country, and our members are dedicated to supporting the development and delivery of innovative life-enhancing and life-saving products. Our organizations represent the broad cross-section of the biotechnology ecosystem developing technologies benefitting agriculture, the environment, public health, and our national economy.

The outbreak of coronavirus pandemic (COVID-19) has brought to light the interconnectedness between human and animal health. As Congress works in responding to the current crisis and ensuring that our country is better prepared for the next pandemic, we request Congress advance two policies that will help our nation recover from COVID-19 and make us more resilient to future zoonotic diseases. Namely, the establishment of a national One Health Framework to coordinate federal activities around zoonotic diseases and modernizing America's animal biotechnology<sup>1</sup> regulatory approach.

Like the current coronavirus, scientists estimate that more than 6 out of every 10 known infectious diseases in people can be spread from animals, and 3 out of every 4 new or emerging infectious diseases in people come from animals.<sup>2</sup> In addition to the dreadful health implications, the resulting economic costs of a

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<sup>1</sup> [https://archive.bio.org/sites/default/files/Animal%20Genome%20Editing\\_FINAL\\_0.pdf](https://archive.bio.org/sites/default/files/Animal%20Genome%20Editing_FINAL_0.pdf)

<sup>2</sup> <https://www.cdc.gov/onehealth/basics/zoonotic-diseases.html>

pandemic are profound. The World Bank estimates that, between 1997 and 2009, the global costs from six zoonotic outbreaks exceeded \$80 billion.<sup>3</sup> While COVID-19 has already produced one of the sharpest economic downturns in U.S. history and is costing the U.S. treasury alone trillions of dollars.

The U.S. was woefully unprepared for this pandemic. We must employ modern approaches to be ready for future outbreaks. One Health collaboration eliminates barriers that often exist between human health, animal health, and environmental health strategies to create smarter, multi-faceted and coordinated efforts. The bipartisan, *Advancing Emergency Preparedness Through One Health Act of 2019*<sup>4</sup>, (H.R. 3771/S. 1903) would direct the U.S. Department of Health and Human Services and USDA to coordinate with other agencies and state and local leaders to advance a national One Health<sup>5</sup> framework to better prevent, prepare for, and respond to zoonotic disease outbreaks like COVID-19.

Animal health and wellness is a critical component of One Health strategy. Animal biotechnology<sup>6</sup> has enormous potential to address numerous agricultural, environmental, humanitarian, and public health challenges. Genetic innovation in animals can help prevent and respond to future infectious diseases.

For example, biotechnology could arm pigs with resistance to African Swine Fever (ASF)<sup>7</sup>, which has been devastating herds throughout Asia<sup>8</sup>. Researchers at Iowa State University estimate an outbreak in the U.S. could cost up to \$50 billion<sup>9</sup>. Similarly, scientists have developed a chicken that is resistant to contracting and transmitting avian influenza<sup>10</sup>. Other innovations in animal biotechnology may be able prevent, prepare for, and respond to outbreaks of infectious diseases by providing prevention strategies and treatments for humans<sup>11</sup>.

Since the mid-1990s, the FDA has applied its “new animal drug” regulatory paradigm to these products in a manner that is not appropriate for the product, which has stymied the use of the technology. This puts at risk an entirely new generation of technology and threatens to drive research, jobs, and innovation overseas. Similar concerns were raised by a bipartisan group of Representatives in a letter to FDA last year<sup>12</sup>.

The current crisis underscores the urgent need to break down roadblocks to progress. To overcome these barriers and foster innovation in these critically-needed areas Congress should advance legislation directing FDA and USDA to

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<sup>3</sup><http://documents.worldbank.org/curated/en/612341468147856529/pdf/691450ESW0whit0D0ESW120PPPvol120web.pdf>

<sup>4</sup> <https://www.congress.gov/bill/116th-congress/house-bill/3771>

<sup>5</sup> [https://archive.bio.org/sites/default/files/OneHealth\\_Final.pdf](https://archive.bio.org/sites/default/files/OneHealth_Final.pdf)

<sup>6</sup> [https://archive.bio.org/sites/default/files/Animal\\_Innovation\\_and\\_Covid\\_Relief\\_0.pdf](https://archive.bio.org/sites/default/files/Animal_Innovation_and_Covid_Relief_0.pdf)

<sup>7</sup> <https://innovature.com/article/gene-editing-could-protect-pigs-diseases>

<sup>8</sup> [http://www.fao.org/ag/againfo/programmes/en/empres/ASF/situation\\_update.html](http://www.fao.org/ag/againfo/programmes/en/empres/ASF/situation_update.html)

<sup>9</sup> <https://www.card.iastate.edu/products/publications/synopsis/?p=1300>

<sup>10</sup> <https://www.fooddive.com/news/gene-edited-chicken-cells-may-stop-the-spread-of-bird-flu/556976/>

<sup>11</sup> <https://www.sdnewswatch.org/stories/sioux-falls-biotech-firm-rushing-to-develop-coronavirus-treatment/>

<sup>12</sup> <https://www.bio.org/sites/default/files/2020-05/190726%20-%20EC%20Letter%20to%20FDA%20re%20Gene%20Editing.pdf>

develop a Memorandum of Understanding (MOU) to streamline oversight of animal biotechnology. A MOU between both agencies will help farmers, innovators, and consumers realize the benefits that modern technology can bring to the United States and the world.

Elevating and prioritizing the relationship of living things through One Health strategies and modernizing America's animal biotechnology regulatory approach are two policies Congress must address in any future COVID-19 legislation. Doing so will ensure we are ready for the next potential animal to human disease outbreak.

Thank you for your consideration.

Sincerely,

Council of State Bioscience Associations (CSBA)  
Biotechnology Innovation Organization (BIO)  
BIO Alabama  
Arizona Bioindustry Association, Inc (AZBio)  
BIOCOM  
California Life Sciences Association (CLSA)  
Colorado BioScience Association (CBSA)  
Delaware BioScience Association (Delaware Bio)  
Georgia BIO  
iBIO  
Indiana Health Industry Forum (IHIF)  
Iowa Bio  
BioKansas  
Kentucky Life Sciences Council (KLSC)  
MassBio  
Medical Alley  
Michigan Biosciences Industry Association (MichBio)  
Missouri Biotechnology Association (MOBIO)  
Montana Bioscience Association  
Bio Nebraska  
BioNJ  
Bioscience Association of North Dakota (BioND)  
Industry-University Research Center, Inc./BIO Alliance Puerto Rico  
RI Bio  
South Dakota Biotech  
Southern California Biomedical Council (SoCalBio)  
Texas Healthcare and Bioscience Institute (THBI)  
BioUtah  
BioForward Wisconsin