

## Genetic Innovation in Animals Can Help Prevent and Respond to Infectious Diseases such as Coronavirus

Animal biotechnology has enormous potential to address numerous agricultural, environmental, humanitarian, and public health challenges. The U.S. must act now and develop a sensible, science-based regulatory approval process that provides these technologies with a viable path to market.

### Connection Between Animal and Human Health

- Like the current coronavirus, six out of every 10 infectious diseases found in humans first appear in animals.
- While we won't know the true economic impact for some time, the coronavirus pandemic has made clear when zoonotic diseases impact the human population, there are often enormous health and economic costs:
  - The World Bank estimates that, between 1997 and 2009, the global costs from six zoonotic outbreaks exceeded \$80 billion.
  - The Centers for Disease Control and Prevention estimates that there are annually 2.5 billion cases of zoonotic infections globally, resulting in 2.7 million deaths.

### Policy Position

Both the FDA and USDA have existing legal authority that enables them to regulate animal biotechnology and the products derived from this innovation.

Producers, academics, and BIO support creating a joint agreement between the agencies whereby the USDA leads regulatory oversight of biotechnology-derived *food* animals and the FDA leads oversight of non-food & biomedical animals.

These agencies have entered joint regulatory arrangements before (e.g. cell-based meat) and should do so again here. BIO remains concerned with the U.S. government's current approach to regulating animal biotechnology as a "new animal drug," which has strongly disincentivized investment and blocked market access for a host of products beneficial to society.

### Technology as a Solution

Innovation in animal biotechnology may be able prevent, prepare for, and respond to outbreaks of infectious diseases such as coronavirus, Ebola, Zika, avian influenza (HPAI), and MERS, by creating more disease-resistant animals and supporting the development of disease treatments for humans. However, due to a lack of a viable regulatory path to market, many solutions, including those listed below, have languished:



Genetically designed cattle produce fully human polyclonal antibodies to provide **treatments for infectious diseases** such as COVID-19.



A gene edited pig has been developed that is immune to **African Swine Fever**.



Scientists have developed a chicken that is genetically resistant to contracting and transmitting **avian influenza**.