



James C. Greenwood
President & CEO

December 18, 2018

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

We were encouraged to learn of the results of your recent meeting with President Xi of the People's Republic of China. The Biotechnology Innovation Organization (BIO) represents a broad swath of American companies that are globally competitive, but are denied a level playing field in China, and thus we welcome the news that the two sides have begun talks to address important structural issues, including forced technology transfer, intellectual property protection, and agriculture. These issues are of prime importance to BIO's members and the future of the U.S. economy. As the negotiations commence, resolving systemic barriers to timely approvals of new agricultural biotechnology products, the approval of all pending products that have languished for years, and intellectual property rights protection of U.S. biomedical products are paramount to continued U.S. innovation, competitiveness, and export growth.

Biotechnology is an increasingly important economic sector, contributing to improvements in human, plant and animal health, and greater economic and environmental sustainability. The U.S. biotechnology sector as a whole is responsible for the employment of approximately eight million people, contributing \$558 billion in wages and benefits and \$2 trillion in economic output.

Each of BIO's member companies – whether manufacturing innovative agricultural production technologies, biopharmaceuticals, or bio-based products – owes its existence to strong intellectual property protections, market access, and a pro-innovation, pro-growth policy environment. Global markets must also conduct predictable, transparent regulatory reviews based on sound science and be free from political influence yet, the biosciences industry continues to be treated unfairly and experience barriers in China.

U.S. farmers, who rely heavily on continuing access to innovative biotech seeds to improve the health and productivity of plants, need fair treatment with respect to tariffs and non-tariff trade barriers in order to increase exports to China. Chief amongst our concerns remains the opaque and increasingly lengthy approval process for new agricultural biotechnology products, where 10 products are waiting final approval after an average of six years under review. Over the past few years, the U.S. government has prioritized approval of delayed agricultural biotechnology applications, and so far, the Chinese government has failed to uphold its commitments to your Administration, including those made as part of the 100-day plan. Addressing systemic challenges as well as securing the approval of all pending products is critical for enabling and sustaining increased sales of U.S. farm exports and closing the trade deficit. Delays in biotechnology availability have caused the United States approximately \$5 billion in lost farm income over the past five years and \$7 billion in reduced economic output, preventing the creation and support of nearly 34,000 jobs. The 90-day negotiations are a critical opportunity to secure the



necessary changes so that this valuable technology can further contribute to the U.S. economy. We urge you to ensure that a systemic solution to these longstanding problems are a core part of any agreement reached with China.

In addition to the regulatory issues affecting agricultural biotechnology, there are constraints in China that undermine the competitiveness of the innovative U.S. biopharmaceutical sector. The U.S. biopharmaceutical industry leads the world in biomedical innovation and is responsible for over 55 percent of the world's new drugs and therapies. Despite policy proposals by China to strengthen intellectual property (IP) protection and enforcement for innovative drugs, the lack of implementation and progress in reforming China's drug IP rights system continues to threaten the competitiveness of American inventions in China – resulting in lower U.S. exports and a market that provides unfair advantages to local Chinese companies at the expense of U.S. innovators. Securing actionable IP commitments from Beijing in the biopharmaceutical sector – particularly on regulatory data protection and patent linkage – would help level the playing field for U.S. companies in China and boost U.S. biopharmaceutical exports. We are concerned also about other policies in China designed to favor the localization of production and technology in-country and that disadvantage foreign developers of innovative medicines, which have an especially large impact on our smaller biotech companies. We likewise urge that effective solutions to these issues affecting the U.S. biopharmaceutical sector are part of any agreement with China.

Thank you for considering our concerns and thoughts on how to successfully support the biotechnology industry and the workers and families that it supports. We will work with your trade and economic team as the negotiations proceed.

Most Respectfully,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is fluid and cursive, with a large loop at the beginning.

Jim Greenwood
President and CEO

Cc: The Honorable Mike Pompeo, Secretary of State
The Honorable Steven Mnuchin, Secretary of the Treasury
The Honorable John Kelly, Assistant to the President and Chief of Staff
The Honorable Sonny Perdue, Secretary of Agriculture
The Honorable Wilbur Ross, Secretary of Commerce
The Honorable Robert Lighthizer, The United States Trade Representative
The Honorable Peter Navarro, Assistant to the President for Trade and
Manufacturing Policy
The Honorable Larry Kudlow, Assistant to the President for Economic Policy