Dear Secretary Bessent:

We write today regarding the Department of the Treasury's proposed rule implementing the Comprehensive Outbound Investment National Security Act of 2025, or COINS Act. We strongly support the COINS Act and ensuring U.S. capital and expertise do not advance the military, intelligence, surveillance, or cyber-enabled capabilities of the People's Republic of China and the Chinese Communist Party. That goal is the foundation of the statute. However, in the proposed regulations, we are concerned that ordinary biopharmaceutical research, development, co-development arrangements, and ordinary business activities abroad that benefit the United States, merger and acquisitions and American patients will be unnecessarily restricted. We urge Treasury to focus its final rule on transactions that present identifiable threats to the United States and ensure that it does not unnecessarily restrict biopharmaceutical activities that strengthen American innovation and benefit American patients.

The COINS Act was not intended to require a wholesale separation of the American and Chinese economies and consequently does not provide the authority to effectuate one. Nor was it intended to prevent American companies from bringing promising science developed abroad into the U.S. research, development, and regulatory system or from selling American medicines abroad. Rather, the law as written authorizes Treasury to address sectors and transactions that contribute to or enable the military, intelligence, surveillance, or cyber-enabled capabilities of a country of concern. The final rule should remain firmly tethered to that explicit national security nexus.

We are concerned that the biotechnology provisions, as proposed, extend considerably beyond the national security objective of the law and put the United States at a competitive disadvantage to China in the race to develop the next generation of medicines. That would be exactly the wrong result. American policy should strengthen American innovation, American companies, and American patients—not inadvertently hand Beijing another strategic advantage. In particular, the proposed rule would prohibit a broad range of biotechnology transactions without providing either a lower-risk notification pathway or appropriate exceptions for ordinary commercial activity, which are permitted in every other sector in the law. Despite our shared understanding that licensing and co-development agreements are outside the scope of the law, the proposal would also sweep many of these arrangements into the rule through an undefined and potentially expansive interpretation of "joint venture." Under such an approach, even arrangements that do not establish a new entity could potentially become

subject to restrictions because the parties contribute assets or capital and share costs, profits, or losses.

The Administration is right to put American national and economic security first. But overly broad and severe restrictions could undermine that objective by weakening U.S. competitiveness while creating openings for Chinese companies to gain ground. The consequences could be significant. Restrictions on legitimate commercial activities involving China could delay clinical trials, increase development costs, disrupt established development and manufacturing arrangements, reduce the number of promising drug candidates advanced through development, and ultimately delay American patients' access to new medicines. The United States should never adopt a regulatory structure that inadvertently creates a world in which American patients must look to Communist China for innovative treatments that could have been developed and approved here at home.

Real-world biotechnology collaborations illustrate this concern.

Ocugen and CanSinoBIO. Ocugen, a U.S. biotechnology company, partnered with China's CanSinoBIO in connection with OCU400, an experimental gene therapy for retinitis pigmentosa, an inherited disease that can result in progressive vision loss. Under the arrangement described to us, CanSinoBIO performs manufacturing development and supplies therapy for clinical trials, while receiving commercial rights in Greater China and Ocugen retains rights elsewhere. OCU400 has completed enrollment in its Phase 3 trial, with results expected in early 2027.

Coherus and Junshi. Coherus BioSciences, a California company, entered into an arrangement with China's Junshi Biosciences to develop toripalimab for the United States and Canada. The companies established a joint development committee to make development decisions. In 2023, the Food and Drug Administration approved toripalimab as LOQTORZI for the treatment of nasopharyngeal carcinoma.

These examples underscore the importance of distinguishing between transactions that enable the national security capabilities of an adversary and transactions through which an American company gains access to promising science and brings it into the U.S. development, regulatory, and commercial ecosystem. Treating these fundamentally different transactions alike could strand promising medicines abroad, strengthen foreign companies' control over their global development, and disadvantage American patients and innovators.

America cannot strengthen its national security by weakening the industries where we must continue to lead. A carefully tailored outbound investment regime can deny our adversaries access to sensitive American capital and capabilities without isolating American researchers, companies, and patients from scientific advances developed abroad. We can be tough on China without hurting American patients.

We respectfully request that Treasury revise the proposed biotechnology provisions consistent with these principles and continue engaging with Congress, patient organizations, researchers, and the innovative biopharmaceutical sector before issuing a final rule. We stand ready to work with you and the Administration to ensure the COINS Act is implemented in a manner that is tough on genuine threats from the Chinese Communist Party, faithful to congressional intent, and firmly in the interests of American innovation.