Congress of the United States
Washington, DC 20515

[[DATE]]

The Honorable Scott Bessent
Secretary of the Treasury
U.S. Department of the Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

Re: Proposed Rule implementing the Comprehensive Outbound Investment National Security Act:

Dear Secretary Bessent:

We write with serious concerns about the biotechnology provisions in the proposed rule implementing the *Comprehensive Outbound Investment National Security (COINS) Act*.[1] We strongly support the Act's national-security objective: preventing American capital from advancing the military, intelligence, and surveillance capabilities in countries of concern. However, the proposed restrictions appear broader than necessary to address those risks for the biotechnology sector and could create serious unintended consequences for American patients, workers, and scientific leadership.

The United States can protect its national security and maintain its biotechnology leadership without subjecting the biopharmaceutical industry to broad outbound investment restrictions intended to address discrete national security threats. The proposed rule may inadvertently create sweeping restrictions on biotechnology investment and collaboration, which would risk weakening America's leadership in science and innovation.[2]

We appreciate that the Treasury Department, in soliciting comments, acknowledged that its proposed restrictions could pose public health risks and harm U.S. competitiveness. These are our fundamental concerns as well. As it stands now, the definition of prohibited biotechnology in the proposed rule is incredibly broad. For example, the proposal classifies everyday pharmaceutical compounds and common production methods --such as small molecules, polymers, vaccines, blood products, and monoclonal antibodies-- as prohibited technology rather than limiting the scope to pathogens or dual-use bioweapons technology.[3] The proposal also leaves the term "biological system" undefined, potentially capturing routine research tools and development processes, as well as promising advances in science. Meanwhile, other sectors impacted by COINS include a notification tier for lower-risk transactions, but biotechnology

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[1] 91 FR 67396
[2] Incubate Coalition. "https://www.incubatecoalition.org/post/incubate-responds-to-treasury-s-proposed-regulations-implementing-the-coins-act." *Incubate*, 22 October 2026, https://www.incubatecoalition.org/post/incubate-responds-to-treasury-s-proposed-regulations-implementing-the-coins-act. Accessed 9 November 2026.
[3] Alliance for Aging Research. "Alliance for Aging Research Questions Treasury's Proposed COINS Act Rule and Raises Concerns." *Alliance for Aging Research*, 26 October 2026, https://www.agingresearch.org/news/alliance-for-aging-research-opposes-treasurys-proposed-coins-act-rule/. Accessed 9 November 2026.

does not - thereby making a categorical prohibition that extends past original congressional intent.

While licensing agreements generally would not be prohibited under the proposed rule, many biotechnology partnerships combine licensing with equity investment, joint development, financing, or operational expansion.[4] These allow a U.S. company to obtain the rights to bring a promising drug to the United States for further development, regulatory approval, and clinical trial activities. Importantly, when these agreements result in successful FDA approval and commercialization, these agreements can also generate revenue that enables U.S. companies to invest in further R&D. Without clearer guidance, companies may decide these partnerships are too risky, even when they would support research and development in the U.S. That uncertainty could have real consequences for patients and the U.S. innovation ecosystem.

Carefully structured international partnerships can complement U.S. biotechnology leadership by allowing U.S. companies to identify promising research abroad and bring it to American patients. This exchange of scientific information does not displace investment in U.S. innovation, and instead allows for the faster discovery and availability of innovative medicines.

We urge you to focus on making the United States a more competitive place to develop and manufacture medicines. That means speeding up clinical trials through efforts like Operation TrialBlazer and the *Faster Clinical Trials Act*, supporting domestic manufacturing, and investing in developing and retaining the biotechnology workforce. "Preserving the ability to develop breakthrough innovations from our own world-leading domestic pipeline while also identifying promising innovations from elsewhere is essential to maintaining America's competitive advantage and access for U.S. patients."[5]

We share the Department's interest in keeping American capital out of China's military buildup and ensuring a U.S. competitive advantage, but believe that absent change, the proposed rule will result in consequences that inadvertently harm patients' access to medicines and limit U.S. biotechnology companies' ability to form smart global partnerships that advance science.[6] We stand ready to work with you to ensure that the proposed rule addresses true security risks without harming the ecosystem that makes the United States the best place in the world to create vital new treatments for our patients.

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[[SIGNATURES]]

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[4] Gormley, Brian. "Treasury to Limit Chinese Biotech Deals, But Still Allow Licensing." *The Wall Street Journal*, 26 October 2026, https://www.wsj.com/pro/venture-capital/treasury-to-limit-chinese-biotech-deals-but-still-allow-licensing-36a38e48. Accessed 9 November 2026.

[5] MassBio. "MassBio Statement on release of proposed COINS Act rules." *MassBio*, 22 October 2026, https://www.massbio.org/news/recent-news/massbio-statement-on-release-of-proposed-coins-act-rules/. Accessed 9 November 2026.

[6] No Patient Left Behind (NPLB). "Statement from No Patient Left Behind on the Treasury's Proposed Rule to Implement the COINS Act — No Patient Left Behind." NPLB, 22 October 2026, https://www.nopatientleftbehind.org/press-releases-1/nplb-statement-on-the-proposed-treasury-rule-to-implement-the-coins-act. Accessed 9 November 2026.