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November 13, 2026

Department of the Treasury
Director Meena R. Sharma
Office of Investment Security Policy and International Relations
1500 Pennsylvania Avenue NW
Washington, DC 20220

Re: Comment on Proposed Regulations Adding Biotechnology to Prohibited Covered Transactions Under the Comprehensive Outbound Investment National Security (COINS) Act. Docket No. TREAS-DO-2026-0595

The Independent Women's Center for Better Health submits this comment in response to Treasury's proposed rule that would add biotechnology to the list of prohibited covered transactions under the COINS Act.

Who We Are

The Independent Women's Center for Better Health is a nonprofit public education organization committed to expanding patient access to affordable, innovative medical care through market-based solutions. Our concern with this proposed regulation is not with the use of outbound investment controls as a policy instrument to protect national security. It is with the downstream consequences of an overbroad prohibition on the export of technologies that will inadvertently hurt the interests of patients.

We Support the National Security Goal

We do not dispute that the United States has a legitimate interest in preventing American technology and expertise from strengthening strategically sensitive Chinese biotechnology capabilities. The COINS Act's architecture—distinguishing between prohibited transactions and those that just trigger notification to government officials—reflects a sound judgment that different technologies warrant different levels of scrutiny. Our comment concerns where the line between those categories should fall.

The Proposed Rule Captures Ordinary Therapeutics and Medical Devices in the Prohibitions

The proposed rule's definition of covered biotechnology is broad enough to reach pharmaceutical compounds, biologics, vaccines, cell and gene therapies, and the polymers and delivery mechanisms used to administer them, as well as sequencing, bioinformatics, and laboratory technologies. This breadth is appropriate for technologies whose primary value to an adversary is military, surveillance, or intelligence-related. It is not appropriate for products subject to rigorous FDA premarket review, primarily developed for patient care, and whose mechanisms have no meaningful dual-use application.

The definition's reach into polymers, delivery systems, and laboratory technologies is particularly concerning because these categories capture medical devices that bear no resemblance to strategically sensitive biotechnology. A diagnostic platform for endometriosis. A minimally invasive surgical tool for gynecologic procedures. A biomaterial-based device for wound care or vascular repair. These products may incorporate engineered polymers or advanced biomanufacturing processes, but they are regulated by FDA under device authorities—not as weapons-relevant technology—and their patient benefit is direct and well-documented.

The Patient Access Stakes Are Substantial for Pharmaceuticals

Licensing agreements between U.S. pharmaceutical companies and Chinese biotechnology partners announced in the first five months of 2026 alone totaled **$43 billion**. These agreements are the primary mechanism through which Chinese-developed drug candidates reach U.S. clinical development and ultimately American patients. A prohibition that chills these arrangements will reduce therapeutic options, reduce competitive pressure on pricing, and slow development in areas where the existing standard of care is inadequate, and patients can benefit from innovative new therapies, regardless of where they originate.

Women are disproportionately affected by therapeutic gaps in autoimmune disease, oncology, and rare disease—areas where Chinese biotechnology development has been particularly active. The patient access cost of overbroad prohibition is not abstract.

The Stakes Are Different but Equally Serious for Medical Devices

The pharmaceutical and medical device sectors face this rule differently, and the device consequences deserve separate attention.

Unlike pharmaceuticals, where licensing is the dominant commercial structure and equity investment is one mechanism among several, medical device development depends heavily on equity investment during early and mid-stage development. Venture and strategic equity capital funds the iterative clinical testing, design

validation, and regulatory work that moves a device from concept to FDA clearance or approval. A categorical prohibition on equity investment in Chinese-origin device companies does not merely redirect capital—it can defund development programs mid-cycle in ways that cannot easily be replaced through alternative financing.

This matters because device development timelines are long. A Class III device seeking PMA approval may spend **five to seven years** in development before FDA review. A prohibition that cuts off U.S. investment at year three of a seven-year development program can strand a product that would otherwise have reached patients. The cost is borne not by investors—who can redeploy capital—but by patients waiting for therapies that do not yet exist.

Women's health is among the most acutely affected areas. Medical device innovation in women's health has historically been underfunded relative to disease burden. Endometriosis affects an estimated **one in ten women** and takes an average of **seven to ten years to diagnose**; diagnostic device development in this space is active but capital-intensive. **Pelvic floor** disorders, **minimally invasive** approaches to gynecologic oncology, and **fertility**-related diagnostics all represent areas where device innovation pipelines depend on the kind of cross-border capital structures this rule would prohibit.

The dual-use national security argument—already strained when applied to FDA-reviewed pharmaceuticals—is weaker still for therapeutic and diagnostic medical devices. An engineered polymer scaffold for pelvic floor repair does not become a national security concern because it was developed in China. Treating it as one, categorically, imposes real harm on patients while contributing nothing to national security.

FDA Review Is the Appropriate Safety Screen—and Already Exists

Both pharmaceuticals and medical devices subject to FDA premarket review must demonstrate safety and efficacy before reaching U.S. patients. The regulatory scrutiny these products receive is rigorous, well-established, and independent of their geographic origin. For **pharmaceuticals**, this means IND, NDA, or BLA review. For **devices**, it means 510(k) clearance, PMA approval, De Novo authorization, or HDE designation depending on device class and risk profile.

Treasury's proposed prohibition adds no patient safety value beyond what FDA review already provides. What it does do—when applied categorically to FDA-regulated products—is reduce competition in markets where competition is already insufficient.

A Note on Proportionality

We observe that even for categories where prohibition is appropriate, the proposed rule does not close the primary pathway by which Chinese-developed drugs reach the U.S. market. Traditional licensing transactions are largely outside the covered-investment framework. A Chinese company can develop a product without U.S. investment and license it to an American company for commercialization. If the proposed prohibition cannot prevent Chinese-developed therapeutics from reaching U.S. patients through licensing, the case for prohibiting equity investment in therapeutic development is weakened. This is not an argument for expanding the rule to cover licensing. It is an argument for proportionality: The prohibition, as written, imposes real costs on patients while leaving the supply chain exposure it purports to address largely intact.

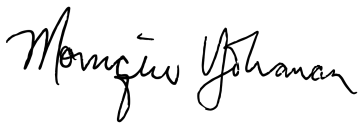
Our Ask

We ask Treasury to amend the final rule to move FDA-regulated pharmaceutical and therapeutic products and FDA-cleared or approved medical devices from the prohibited category to the notifiable category. This covers products subject to IND, NDA, BLA, 510(k), PMA, De Novo, or HDE review. This change would:

- Preserve Treasury's ability to review, condition, or block specific transactions that present genuine security concerns on a case-by-case basis;
- Avoid categorical prohibition of ordinary therapeutic and device development;
- Protect patients' downstream interest in competitive drug and device markets and available therapies;
- Prevent the stranding of long-cycle device development programs mid-development; and
- Draw a principled, administrable line between FDA-regulated medicines and devices and genuinely dual-use biotechnology.

We appreciate Treasury's consideration of this comment.

Respectfully submitted,



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