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November 2, 2026

VIA REGULATIONS.GOV

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

Re: Outbound Investment Security Program Regulations
Docket No. TREAS-DO-2026-0595, RIN 1505-AC94 (91 FR 67396)

Dear Ms. Sharma:

Arcstone Strategy Group LLC ("Arcstone") welcomes the opportunity to comment on the proposed rule implementing Subtitle C of the Comprehensive Outbound Investment National Security Act (the "Proposed Rule"). We support the statute's aim of keeping U.S. capital and expertise from strengthening the military, intelligence and surveillance capabilities of countries of concern. Our comments address the provision with the largest consequences for our sector: the addition of biotechnology as a prohibited technology in § 851.226(r)-(u), and the definitions that decide which life sciences transactions it covers.

Arcstone is an advisory firm based in San Diego. We advise biotechnology and pharmaceutical companies on cross-border licensing, partnerships and business development. Our clients include U.S. companies that license drug candidates from developers in China, Japan and Korea, and companies in those countries that seek U.S. partners to develop and sell their medicines here. No client asked for, reviewed or paid for this comment.

The biotechnology prohibition, as drafted, extends well beyond the risks Treasury describes. Section 851.226(r)(4) would prohibit U.S. investment in any covered foreign person that uses "a biological system" or "any component of a biological system" to produce or modify "[a] pharmaceutical compound, including, small molecules, polymers, vaccines, blood and blood components, allergenics, cell and gene therapies, and monoclonal antibodies or other recombinant therapeutic proteins, as well as their delivery mechanisms". That covers nearly all biologic drug development, and any small molecule work that uses cells or enzymes in production. Treasury itself recognizes that restrictions in this sector "may

potentially have countervailing effects on national security to the extent restrictions lead to significant public health risks or harm U.S. businesses in this sector".[1] We agree, and we propose a rule that keeps the prohibition where Treasury's stated risks lie and uses notification for the development of medicines. Section 2 sets out the evidence on its effect, drawn from 56 recent transactions, clinical trial registrations and company filings. Section 10 describes how we can help Treasury test the proposed provisions against that evidence.

Summary of recommendations

Primary requests

1. Give biotechnology two tiers: keep the prohibition for agents and toxins, energetic materials, biomanufacturing equipment under export control, design platforms and listed entities, and make pharmaceutical compounds (§ 851.226(r)(4)) and bioinformatics tools (§ 851.226(u)(4)) notifiable (Treasury's questions on § 851.226(r) and (u)).[2]
2. State in the rule that a license, an option to license or a product collaboration that forms no jointly owned entity is not a joint venture, and that buying shares in a U.S. company that is not a covered foreign person is not entering a joint venture with its other shareholders.
3. Keep "direction or control" and "principal place of business" from turning companies led from the United States into covered foreign persons because their chief executive is a national of a country of concern living here, their licensor holds a minority stake in them, or they run trials in China.

Additional requests

4. Let U.S. companies upgrade existing operations in countries of concern under the intracompany exception, and confirm that sponsoring clinical trials is not engaging in § 851.226(r)(4).
5. Count under § 851.104(c)(8) only Treasury information given in writing; establish the public database; and make non-binding feedback available on a non-binding term sheet.
6. If any part of § 851.226(r)(4) stays prohibited, create a streamlined national interest exemption, decided within 45 days, for transactions that secure U.S. rights to a medicine.
7. Explain the return to doubling the transaction count, revise the cost estimate for biotechnology, and prepare a regulatory flexibility analysis.
8. Make the biotechnology provisions effective 180 days after the final rule is published, and use § 851.501(k) to encourage allies to act.

[1] 91 FR 67405. Unless another document is named, page references to 91 FR in these notes are to the Proposed Rule.

[2] 91 FR 67405-67406.

1. The biotechnology prohibition should have two tiers

What the text covers. Read as written, § 851.226(r)(4) covers a company developing a cell therapy for lymphoma, a company developing a novel antibody for a U.S. partner, an insulin biosimilar maker and a vaccine producer. Section 851.226(u)(4) adds any company that develops "computational or bioinformatics tools for research, design, optimization, modeling and simulation, discovery, or assessment of biological systems or processes". Paragraph (r)(4), and paragraphs (u)(1), (u)(4) and (u)(5), carry no technical threshold or end use limit. The sector has no notifiable tier, so the $50,000 de minimis exception, which applies only to notifiable transactions, never applies. Elsewhere the Proposed Rule uses end use limits, for example for quantum sensing and hypersonic materials (§ 851.226(k), (o)); in explaining one such limit, Treasury recognized that "similar technologies could have important civilian purposes". Its alternatives analysis rejected broad sectoral definitions because they "would create ambiguity and uncertainty" and "significant compliance costs", yet paragraph (r)(4) is one in all but name.[3]

What the stated risks justify. Treasury's preamble says that "[c]ertain advanced or sensitive biotechnologies" pose an acute risk, and the statute allows technical parameters "as reasonably needed for national security purposes".[4] The National Security Commission on Emerging Biotechnology likewise asked for outbound rules covering "certain biotechnologies that could pose a national security risk".[5] Treasury names four risks: the proliferation of biological weapons, brain-computer interfaces, supply chain security, and the "indigenization" of technologies with military, intelligence and surveillance uses.[6] The first is met by paragraph (r)(1) on agents and toxins, and the second by paragraph (s). The third and fourth are met by paragraph (r)(2) on energetic materials, by paragraph (t) on biomanufacturing equipment already controlled for export and, once part of the sector is notifiable, by § 851.226(v), which would then treat biotechnology activity of an entity on the Entity List, the section 1260H list or the list of biotechnology companies of concern that OMB is to publish under the BIOSECURE Act as prohibited technology.[7] We support each of those prohibitions. Treasury explains why super intelligence and quantum have no notifiable tier, but it gives no such reason for biotechnology.[8]

Recommendation. Keep paragraphs (r)(1), (r)(2), (t) and (v) as prohibited technology. Move paragraphs (r)(4) and (u)(4) into § 851.218 as notifiable technology. We take no position on paragraphs (r)(3), (r)(5), (s), (u)(1) and (u)(5), which lie outside our practice. In answer to Treasury's question whether

[3] 91 FR 67410 (de minimis exception), 67404 (civilian purposes), 67416 (alternatives).

[4] 91 FR 67405 (sensitive biotechnologies), 67403 (technical parameters).

[5] National Security Commission on Emerging Biotechnology, final report (April 2025), Recommendation 3.3a, biotech.senate.gov/final-report/chapters/recommendations.

[6] 91 FR 67405.

[7] 91 FR 67406.

[8] 91 FR 67402.

"pharmaceutical compounds" should be scoped "to focus on advanced or frontier technologies",[9] we suggest drawing the line between platforms and products. Platforms for the de novo design or engineering of organisms, pathogens or agents are frontier work and could stay prohibited. The development and production of a specified medicine for human use should be notifiable. If Treasury keeps any part of (r)(4) prohibited, it should at least treat as notifiable the development or production of a compound that is the subject of an investigational new drug application in effect under 21 CFR part 312, or of an application approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, and of generic and biosimilar versions of such products. We also ask Treasury to confirm that chemical synthesis without a biological system falls outside paragraph (r), and that testing a compound in cells, tissue or animals is not using a biological system to "control" it.

Equipment. Paragraphs (u)(2) and (u)(3) track the parameters of ECCN 3A069, which the Bureau of Industry and Security created in January 2025. But they replace the defined term "specially designed" with "designed", and they omit the BIS exclusion for flow cytometers and mass spectrometers that the FDA has authorized for marketing, or that are exempt from premarket notification and listed with the FDA.[10] The final rule should restore both.

Why notification is the better tool here. Treasury's benefits analysis says that notifications "have increased the U.S. Government's visibility into transactions by U.S. persons".[11] Part 850 never covered biotechnology, so Treasury receives no notifications on U.S. biotechnology investment in China today, and a sector that is prohibited outright will produce almost none. A notifiable tier would give Treasury evidence it has never had on individual transactions, and a basis to extend the prohibition, by rule, through § 851.226(v) or through the public database, to the categories and entities that the evidence shows to carry acute risk. Under an exclusive license of a clinical stage medicine, the licensee takes the rights outside the licensor's home market, with the data and know-how needed to use them, and leads development there, in the United States under FDA oversight, though it may rely on the licensor for clinical supply until manufacturing is transferred. Deals for assets from China accounted for 39% of the in-licensing deals by the largest drug companies with at least $50 million paid upfront in 2025 (19 deals), and 51% in the first nine months of 2026 (18 deals).[12] Of the 56 deals with Chinese licensors that we identified, 43 are cash licenses; section 2 shows which of the other 13, which also carry equity, a NewCo or shared development, could fall under the rule. We recognize the concern that U.S. companies increasingly depend on assets from China. Prohibiting U.S. investment leaves that dependence in place and moves the deals to partners

[9] 91 FR 67406.

[10] Bureau of Industry and Security, *Controls on Certain Laboratory Equipment and Related Technology To Address Dual Use Concerns About Biotechnology*, interim final rule, 90 FR 4612 (January 16, 2025), at 4613-4614 and 4616.

[11] 91 FR 67416.

[12] J.P. Morgan, *Q3 2026 Biopharma Licensing and Venture Report*, slide 14, using DealForma data through September 30, 2026 (jpmorgan.com). The share is deals for assets from China as a percentage of all in-licensing deals by global large cap biopharmaceutical companies carrying at least $50 million in upfront cash and equity, by number of deals.

outside the United States, as Treasury recognized in 2024 when it noted that "investors from specific countries, including those that are not U.S. allies, may replace U.S. investors for prohibited transactions".[13]

2. Which U.S. transactions and companies the prohibition would cover

Treasury asked commenters to "discuss impacts" of the biotechnology provisions.[14] Public data allow a first measurement in three places: recent transactions, U.S. companies' own work in China, and the new U.S. companies formed around licensed medicines.

Transactions. We identified 56 licensing, NewCo and collaboration deals announced between January 1, 2025 and October 31, 2026 in which a developer headquartered in mainland China or Hong Kong licensed a medicine or discovery platform to a company outside Greater China, for at least $50 million in cash and equity agreed at signing.[15] U.S. companies were the licensee in 29. None of the licensors appears on the Consolidated Screening List or the section 1260H list. Our list understates the true number, because the threshold leaves out smaller deals that use the same structures.

Thirteen of the 56 carried a feature beyond a cash license: shares changing hands in either direction, a NewCo in which the Chinese licensor holds or will hold equity, or development costs or profits shared from signing. Nine of the 13 had U.S. licensees. Under the rule, parties to the other 43 would still have to check them for those features, part of the cost that section 8 asks Treasury to estimate.

The rule bears on the nine U.S. deals in different ways. In one, the licensee bought $100 million of newly issued shares in the licensor, which is listed in Hong Kong, alongside a license with $1.25 billion paid upfront.[16] Treasury's existing guidance on follow-on offerings may already except such a purchase, and

[13] Treasury, final rule, 89 FR 90398 (November 15, 2024), at 90458-90459.

[14] 91 FR 67405.

[15] Arcstone dataset, compiled November 2026 from company releases (some read through verbatim reprints), SEC and HKEX filings and counsel announcements. The 56 deals, with a source for each and our method and judgment calls, are filed with this comment as a separate spreadsheet. The threshold counts cash and equity agreed at signing, including a licensee's purchase of the licensor's shares, and excludes milestones, as in the J.P. Morgan series cited in section 1. For large drug companies our count (16 deals in 2025 and 17 in January-September 2026) is close to DealForma's (19 and 18). At least six of the 13 structured deals clear the threshold only because their equity is counted, and in 2025 at least four deals below it, each recorded in an exchange filing, also gave the licensor equity. Licensors were checked on November 2, 2026 against the Consolidated Screening List and the section 1260H list (Department of Defense, 91 FR 35189, June 10, 2026); OMB has not yet published its BIOSECURE list.

[16] Pfizer Inc., Form 10-K for fiscal year 2025, Note 2F ("an upfront payment of $1.25 billion"; "We also made a $100 million equity investment in 3SBio"); 3SBio Inc., HKEX announcement, August 1, 2025 (completion of the subscription by Pfizer of 31,142,500 new shares under general mandate, about 1.28% of the enlarged share capital).

the preamble expects that guidance to be reissued.[17] In a second, the same licensee agreed with another Chinese developer to co-develop four early stage cancer programs, drawn from a portfolio of antibody-drug conjugates and multispecific antibodies, sharing development costs worldwide and profits in the United States and Europe.[18] Under the preamble's reading of "joint venture" and § 851.209(a)(3), that agreement could be a prohibited joint venture, which is why section 3 asks Treasury to draw the line in the rule.[19] In the other seven, the shares, warrants or notes went the other way, to the Chinese licensor.

Companies headquartered elsewhere used the same structures. In October 2025 a Japanese drugmaker agreed to pay $1.2 billion upfront for rights to a Chinese developer's cancer programs, including a $100 million purchase of its shares, and, for the lead program, to share global development costs and U.S. profits or losses 60/40.[20] The Proposed Rule would apply to such a company only through its U.S. persons: a U.S. subsidiary that enters the collaboration, which would face the rule as any U.S. company would, or executives who are U.S. persons and approve the deal, unless they recuse themselves from it under § 851.209(a)(6)(ii). A company headquartered in the United States that signed the same agreement would have no such option. Until allies adopt comparable rules, that difference favors foreign partners, which is why section 9 asks Treasury to use § 851.501(k) to bring them along.

U.S. companies' development work in China. Of the trials that 13 large drugmakers headquartered in the United States first posted on ClinicalTrials.gov in 2025, 152 of 526 (28.9%) listed a site in mainland China, and 129 of those also listed U.S. sites.[21] A trial site is not an investment, and section 5 asks Treasury to confirm that sponsoring trials falls outside § 851.226(r)(4). The rule would apply where a U.S. company works through its own subsidiary in China, as some do; one of the 13 lists China among its "[m]ajor production sites".[22] A subsidiary that makes a biologic for global supply would be limited to maintaining its existing operations unless pharmaceutical compounds become notifiable, as section 1 proposes; section 5 asks Treasury at least to let it upgrade them.

New U.S. companies. In seven of the nine U.S. deals the Chinese licensor took, or will take, shares, warrants or notes in the U.S. licensee. Five of the seven licensees are NewCos built around the licensed

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[17] Treasury, *Outbound Investment Security Program: Frequently Asked Questions* (updated December 23, 2025), question X.1, on securities issued in a follow-on offering that "will be fungible with such publicly traded securities". On reissuing the guidance, 91 FR 67408.

[18] Innovent Biologics, Inc. and Pfizer Inc., joint press release, May 28, 2026: the companies "will co-develop four programs globally and share the development costs", and "the two companies will share the profits in the U.S. and Europe".

[19] 91 FR 67401.

[20] Takeda Pharmaceutical, news release, October 21, 2025 (takeda.com/newsroom/newsreleases/2025/innovent).

[21] Arcstone count from the ClinicalTrials.gov API (version 2), November 2, 2026, site lists as of that date: interventional studies first posted in 2025 whose lead sponsor is Eli Lilly, Pfizer, Merck, Bristol Myers Squibb, Johnson & Johnson, AbbVie, Amgen, Gilead, Regeneron, Biogen, Vertex, Moderna or Alnylam.

[22] Eli Lilly and Company, Form 10-K for fiscal year 2025, Item 2.

medicine, and every NewCo in our data with confirmed licensor equity is based in the United States. Disclosed licensor stakes run from about 9 percent to 60 percent; the largest holder is expected to fall to about 34 percent, with the right to designate two directors, once its NewCo merges with a company listed on Nasdaq.[23] Four of the five NewCos have announced financings: three raised $610 million in their first rounds, and investors, the licensor among them, have agreed to buy $820 million of the fourth's shares in a placement that is to close with its merger.

The licensor's stake is an inbound investment, but it can bring U.S. investors within the rule in two ways. The company becomes a covered foreign person if persons of a country of concern together own 50 percent or more of its votes, board voting power or equity (§ 851.208(a)(5)), or if the licensor has "direction or control" of it (§ 851.208(a)(6)). And under the preamble's reading of "joint venture", investors who form such a company alongside the licensor could be said to enter a joint venture with it (§ 851.209(a)(3)). Either way, the rule applies only if the company's work falls within § 851.226(r)(4). Three of the seven develop a fusion protein or antibodies, which paragraph (r)(4) plainly covers. The other four license small molecules or a peptide, one of them by press report only, so for them the answer turns on whether a biological system is used to make, modify or "control" the medicine, the term section 1 asks Treasury to clarify. The NewCo with the majority holder warns, in an SEC filing, that if Chinese holders together again held half or more of its votes, equity or board voting power, "U.S. investors could be prohibited from acquiring [its] securities in private placements", which "could significantly impair [its] ability to raise capital", though it does not believe the Proposed Rule covers its license.[24] The confirmations we ask for in sections 3 and 4 would settle both questions for most companies of this kind.

3. Licenses and collaborations are not joint ventures

The Proposed Rule does not define "joint venture". Treasury instead relies on "the plain English meaning of the term, i.e., as involving the contribution of capital and/or assets by two parties and the sharing of profits and losses", and states that no new entity is needed.[25] Ordinary biopharmaceutical agreements can fit those words: a co-development agreement in which each party funds part of a trial, or a co-commercialization agreement that splits profits in a territory. A joint venture is covered "wherever

[23] Zenas BioPharma, Form 8-K, October 8, 2025 (about 10.6% at signing, 9.3% after a concurrent placement); NextCure, Inc., Form S-4/A (SEC accession no. 0001104659-26-120808): the licensor's preferred stock, issued "as additional upfront consideration for the license", is 60.00% of Avere Therapeutics as converted at June 30, 2026 and 33.96% of the combined company; two board designees; a $320.0 million placement, increased by $500.0 million on August 10, 2026. First financings: Braveheart Bio $185 million (Goodwin Procter, November 2025), AirNexis Therapeutics $200 million (January 9, 2026), Solstice Oncology $225 million (September 9, 2026).

[24] NextCure, Inc., Form S-4/A (SEC accession no. 0001104659-26-120808), risk factors, describing Avere Therapeutics, which is to merge with NextCure; the same passage says, "Based on our initial review of the proposed regulations, we do not believe they cover Avere's license from Hansoh".

[25] 91 FR 67401.

located" (§ 851.209(a)(3)). If such a collaboration will develop or produce a biologic, and the U.S. company knows it, the agreement could be a prohibited joint venture.

Treasury's fact sheet says that "[c]ontractual arrangements (other than those for technology transfer or technical knowledge transfer) or the procurement of material inputs for any covered national security transactions would be explicitly excepted from coverage", and that activities outside the definition of a covered national security transaction "would not be subject to the program except where they are undertaken to evade or avoid the proposed rule".[26] Neither statement answers whether a collaboration is itself a joint venture, and a fact sheet does not bind Treasury in an enforcement action. The final rule should state that an agreement is not a joint venture where no jointly owned entity is formed, the U.S. person's economic interest is limited to rights in specified products in specified territories, any sharing of development costs or product profits is confined to those products, and the counterparty gains no governance rights over the U.S. person. It should also state that an option to license that conveys no equity, and no right to acquire equity, is not a contingent equity interest under § 851.205; and that an in-license is not "technology transfer or technical knowledge transfer" for the purposes of § 851.501(h)(1), provided that any rights or data flowing back to the licensor are limited to the licensed product in the licensor's retained territory. Nor should buying shares in a U.S. company that is not a covered foreign person be treated as entering a joint venture with its other shareholders, including a licensor that holds a minority stake.

4. Who is a covered foreign person

Foreign nationals who live in the United States. Because § 851.214(b) treats any person as a foreign person for the purposes of § 851.208(a)(5) through (a)(8), a U.S. company is a covered foreign person if an individual described in paragraph (a)(1) "has the power, directly or indirectly, to direct or cause the direction of the management or policies of such entity" (§ 851.208(a)(6), (b)). Paragraph (a)(1) covers any citizen of a country of concern who is not a U.S. citizen or permanent resident. Read literally, a Delaware company with its laboratory in the United States, whose founder and chief executive is a Chinese scientist working here on a visa, is a covered foreign person; if it develops an antibody, U.S. venture investment in it would be prohibited. Title VIII's "direction or control" prong names a country of concern, its government, and the entities and party leaders described in the statute's first two prongs, not ordinary nationals, so applying it to employees is Treasury's choice.[27] We recommend that § 851.208(b) define control by reference to voting interests, board rights or contract, not service as an officer or employee, and that an individual residing in the United States in lawful immigration status not be treated as a person described in paragraph (a)(1) for the purposes of paragraph (a)(6) only. The ownership tests in paragraphs

[26] Treasury, *Public Fact Sheet & FAQs: COINS Act NPRM* (October 22, 2026), p. 9, answer to "Are technology licensing, consulting, or procurement contracts covered?"

[27] 91 FR 67399.

(a)(5) and (a)(7) would still apply to such individuals in full, so Treasury's redomiciliation example stays covered.[28]

Licensors that hold a minority stake. In our practice, and in the deals described in section 2, we see U.S. companies formed around a medicine licensed from a Chinese developer, which usually takes a minority stake. Treasury should confirm that a company incorporated and headquartered in the United States in which a covered foreign person holds less than 50 percent of the equity, no more than one board seat and customary minority protections is not "subject to the direction or control" of that person. Stakes that fall outside that test, such as the expected 30-40 percent with two board designees described in section 2, should be judged on their facts, with non-binding feedback available. Such investment runs into the United States and may already fall within the jurisdiction of the Committee on Foreign Investment in the United States. For the same reason, the consent and approval rights customary in license and collaboration agreements, such as a joint steering committee's vote on a development budget, should not make a party "subject to the direction or control" of its counterparty.

Principal place of business. Section 851.224(b) treats as a principal place of business "the location where an entity conducts its main business activities". Some biotechnology companies managed from the United States are incorporated abroad and run trials or contract manufacturing in China. The final rule should say that contracting with research, clinical or manufacturing service providers in a country of concern, or running trials there, does not by itself make that country the place of an entity's main business activities where its headquarters, management and most of its employees are in the United States. Treasury should also confirm that, under § 851.214(a)(2), an entity organized under U.S. law cannot be a covered foreign person under § 851.208(a)(2) whatever its principal place of business; an example in the preamble suggests otherwise.[29]

5. Operations of U.S. companies in countries of concern

Because greenfield investment is covered (§ 851.209(a)(5)), a U.S. company's own subsidiary in China that develops or produces a biologic would be limited by the intracompany exception to maintaining operations begun before the effective date (§ 851.216(b)). Of the three readings of "maintain" that Treasury offers,[30] we support at least the second, which allows existing operations to be upgraded or improved without expanding production. We also ask Treasury to confirm that a subsidiary that only sponsors or manages clinical trials, and does not produce the compound, does not engage in § 851.226(r)(4).

[28] 91 FR 67399.

[29] 91 FR 67403.

[30] 91 FR 67410.

6. Knowledge, the public database and non-binding feedback

Treasury information. The preamble describes the new factor in § 851.104(c)(8) as information that Treasury "has provided to such U.S. person", but the rule text speaks of information "made available".[31] The text should match the preamble, and should count only information delivered in writing to the U.S. person or published in the public database.

The public database. Treasury is considering a public database,[32] while its fact sheet says it "does not intend to establish such a database at this time".[33] It should establish one, for both prohibited and notifiable technology, with a published evidentiary standard, dated entries and a petition process for removal. Checking the database, obtaining written representations from the target and documenting the inquiry should weigh in favor of a finding of reasonable and diligent inquiry under § 851.104(c).

Non-binding feedback. Section 851.901(c) does not require an executed contract, but it requires the material terms to be identified in "a binding written agreement or other binding document". In our experience, cross-border biotechnology transactions are negotiated on non-binding term sheets. Treasury should accept a non-binding term sheet accompanied by a signed exclusivity or confidentiality agreement that identifies the parties and the asset, extend feedback to whether a transaction is notifiable and whether an agreement is a joint venture, and aim to respond within 30 days.

7. A streamlined exemption for public health

Treasury is considering a streamlined national interest process for one or more sectors, and asked about criteria and timelines.[34] Section 851.502(b) already lists "U.S. public health needs" as a consideration. If Treasury keeps any part of § 851.226(r)(4) prohibited, it should offer a streamlined track for transactions in which (i) the target is not a listed entity and engages in no activity under paragraphs (r)(1), (r)(2) or (t); (ii) the U.S. person acquires no board seat or governance rights beyond standard minority shareholder protections; and (iii) the transaction secures U.S. development and commercialization rights to a specified medicine. Decisions should come within 45 days of a complete request, with anonymized grants published.

8. Costs and small entities

Treasury estimates that about 150 investors make about 200 potentially covered transactions a year, at a direct cost of $2,772,000 to $5,860,000 a year.[35] In 2024 Treasury tripled its PitchBook annual average in the final rule, after commenters said doubling undercounted; the Proposed Rule returns to doubling

[31] 91 FR 67398 (preamble); 91 FR 67420 (rule text).

[32] 91 FR 67412.

[33] Treasury, *Public Fact Sheet & FAQs: COINS Act NPRM*, p. 10.

[34] 91 FR 67410.

[35] 91 FR 67413 (investors and transactions), 67415 (costs).

without explaining why.[36] We also ask Treasury to say how many of the roughly 100 transactions a year in its data are in biotechnology, and how it defined the sector, since § 851.226(r)(4) follows a method of production. Diligence costs fall on every transaction a U.S. person must screen, including the license and collaboration agreements described in section 2, which investment databases do not record as investments. Treasury acknowledges indirect costs but does not quantify them, and offers no breakeven analysis.[37] It should estimate them for biotechnology, including transactions that U.S. companies lose to companies outside the United States.

The Regulatory Flexibility Act certification rests on Treasury's experience with "transactions currently subject to the existing OISP",[38] which never covered biotechnology. In this sector small U.S. companies are regulated directly, as collaboration partners and licensees that take equity in their licensors. Treasury should prepare an initial regulatory flexibility analysis for biotechnology.

9. Timing and allies

Title VIII directs Treasury to encourage allies to develop similar mechanisms, and § 851.501(k) allows exceptions for transactions with persons of countries the Secretary designates.[39] We are not aware of any other G7 government that restricts outbound investment in biotechnology. The European Union's January 2025 recommendation asks member states only to review outbound investment in semiconductors, artificial intelligence and quantum technologies.[40] We recommend that the biotechnology provisions take effect 180 days after the final rule is published; that § 851.501(d) apply to binding commitments entered into before publication, including milestone and tranched equity commitments; and that Treasury use § 851.501(k) to reward allies that adopt comparable measures.

10. How we would like to support the Treasury

We would be glad to help Treasury test the proposed provisions against the evidence in section 2. While the docket is open, we will file updated versions of the deal dataset on it. Any definition that Treasury publishes or other commenters propose, of a joint venture, of direction or control or of a notifiable tier for pharmaceutical compounds, can be run against the attached deals, and we would file the results on the docket. We would also be glad to answer staff questions on how cross-border licensing and NewCo transactions are negotiated, from a non-binding term sheet through signing to milestone payments, which bears on when notification and non-binding feedback are most useful. A summary of any meeting could be placed in the docket. If pharmaceutical compounds become notifiable, we can help define what a notice of an equity investment or joint venture in this sector should contain, such as the asset, its stage of

[36] 2024 final rule, 89 FR 90455-90456; 91 FR 67413.

[37] 91 FR 67415-67416.

[38] 91 FR 67417.

[39] 91 FR 67408.

[40] European Commission, press release IP/25/261, January 15, 2025, on Recommendation (EU) 2025/63.

development, any equity and the terms of any accompanying license, so that it gives Treasury the evidence it lacks at modest cost to filers. And because the dataset also covers deals signed by drugmakers in Europe and Japan, we can help Treasury compare how companies there structure these transactions as it pursues the coordination described in section 9.

Parting statement

Congress stated its sense that Treasury should adopt "the least burdensome alternative that achieves regulatory objectives".[41] For biotechnology, that alternative is a narrow prohibition with notification for the development of medicines.

Respectfully submitted,

Julien Willard, MD MPH
Managing Member
Arcstone

Biographical note. Julien Willard, Arcstone's managing member, trained in medicine and health economics. At Oxfam GB, where he became head of health economics, he was Oxfam's liaison to the United Nations General Assembly for its pharmaceutical program. As a senior health economist at the World Bank he managed a $130 million HIV vaccine development program, overseeing coordination among the governments of the United States, the United Kingdom and Japan, donors and research institutions. He went on to lead corporate strategy for North American biotechnology at Accenture and, as a partner, life sciences strategy at IBM Consulting, advising drug companies on acquisitions, separations and restructurings.

[41] 91 FR 67397.