CAPITOL STREET

June 22, 2026

FDA Pilot Positive for Biopharma & Novel Developers

RFI + Pilot Tilts Ecosystem In Favor of US (to Compete with China)

Relevant Companies: BIOPHARMA

Our Take & Next Up

We are optimistic on the new FDA RFI for an expedited IND pilot, and additional initiatives across HHS announced today. The FDA's new Expedited Investigational New Drug (IND) pilot program (RFI here) and other announced HHS initiatives (NIH, ARPAH, ONC, OIG) are a part of the administration's focus on improving domestic competitiveness over China. This is a positive for biotech and innovators that may lack internal resources to identify potential deficiencies in their pre-IND plans.

Additionally, we expect a new FDA Commissioner nominee to be named within the next 1-2 weeks, while confirmation likely takes longer. Any new FDA commissioner is likely to be supportive of the clinical trials reforms proposed. Possible candidates include: Richard Pazdur, M.D. (former OCE director), though we envision him as more of a Supercenter leader versus Commissioner, if he does indeed come back to FDA, Richard Pops (CEO of Alkermes), Heidi Overton, M.D., Ph.D. (Deputy Director in the White House Domestic Policy Council), and Stephen Ferrara, M.D., FSIR, FACR (Former Principal Deputy Assistant Secretary of War for Health Affairs). We note that while the nominee may be publicly announced, confirmation will take several more months (if the confirmation is politically possible).

Key Points

The IND pilot would create rolling review for INDs and a network of stakeholders that can advise on an IND to reduce review time (with the FDA still having the final regulatory authority).The White House continues to leverage RFIs as any new regulation involves rescinding 10 so this is the easier route to propose and move forward with new policies. As with any pilot it will take time to (a) get results and (b) refine the pilot so that the agency may (c) roll out more extensively beyond a demonstration.

The pilot is a response to increased biopharma utilization of Investigator Initiated Trials (IIT) in China, a faster pathway for human trials (and clinical validation). ITTs are researcher-led, early phase trials that are less regulated than traditional IND pathways.

The administration continues to focus on China with FDA leadership collecting feedback from industry and investors (8VC). *Biocentury* notes FDA senior officials' public calendars include meetings with Joe Lonsdale, founder and managing partner of 8VC, who is vocal on the need for FDA reform ("make the FDA great again") and proposes regulatory initiatives aimed at accelerating review speed to keep ahead of competition from China. He frames China as an unfair, predatory competitor and argues the next commissioner must be a "fighter" willing to confront and, at times, overrule the agency's own bureaucracy.

The goal of the IND pilot is to reduce the time to first in human trials, which we have said is likely in 2026. We previewed a pre-IND initiative earlier this year. The expedited IND pilot would:

- establish a network of qualified research institutions (QRIs) who would partner with sponsors to develop and review protocols for first-in-human clinical trials intended for an IND submission to FDA.
- reduce FDA review time through a rolling submission process.
- test whether clinical trial initiation activities, such as Institutional Review Board (IRB) review and site contracting, can be conducted in parallel with IND development and review.

The FDA defines "QRIs" using a broad range of stakeholders: academic medical centers (AMCs), contract research organizations (CROs), regulatory advisors, and/or other research or third-party review organizations. We note that the most likely candidates will be those that already have strong relationships to drug developers: CROs, regulatory advisors, health networks with current clinical trials, and less patient organizations. FDA is also collecting feedback to create a potential process for establishing a QRI certification.

The expedited IND pilot program will allow QRIs to make recommendations for the pharmacology and toxicology, clinical, and chemistry, manufacturing and controls (CMC) components of the Phase 1 IND submission. The pilot allows this network of QRIs to participate in developing and reviewing protocols for first in human clinical trials in the U.S. The role of third parties is restricted to providing advice and preliminary review, not engaging in regulatory decision-making as the FDA will maintain full regulatory oversight.

FDA is also exploring the use of a rolling submission for INDs in the pilot. This would allow the FDA to review recommendations regarding completed components of the IND submission on a rolling basis. Completed individual IND components could be reviewed prior to formal IND submission. Since all the IND submission components would have been reviewed by FDA on a rolling basis, the drug developer may receive a safe-to-proceed notification faster, potentially before the 30-day IND review period ends.

The announcement comes as the White House is preparing a FDA commissioner nominee (within the next 2 weeks). As a reminder, HHS is looking for an individual who can rebuild trust with agency staff, while continuing to drive the admin's innovation and approval reforms. Potential candidates include:

- **Richard Pazdur, M.D.,** is an oncologist and former director of Oncology Center of Excellence (OCE). He briefly served as CDER director in Nov-Dec 2025, before retiring from the FDA due to friction with the administration. We view Pazdur as a more of a Super Center leader (CBER, CDER, etc.) versus Commissioner.
- **Richard Pops** is the current CEO of Alkermes who is set to retire at the end of July. He is one of biotech's longest-serving CEO with 33 years at Alkermes and a notable figure in the biopharma industry, serving as Chair of the Board of Directors of the Midsized Biotech Alliance of America (the MBAA) and on the Boards of BIO and the PhRMA.

- **Heidi Overton, M.D., Ph.D.** is the current Deputy Director in the White House Domestic Policy Council. She closely aligns with the administration as she previously worked as the Chief Policy Officer & Director at Center for a Healthy America at America First Policy Institute (AFPI), a conservative think tank.
- **Stephen Ferrara, M.D.,** FSIR, FACR, is a dual board-certified physician in both diagnostic and vascular and interventional radiology. He previously served as the Principal Deputy Assistant Secretary of War for Health Affairs from January to May 2026 and is a former military medical professional.

BACKGROUND

Biopharma companies have been and are expected to continue conducting early trials in China due to the availability of the Investigator Initiated Trials (IIT) pathway. China's Investigator-Initiated Trial (IIT) is a clinical study initiated and sponsored by a qualified Chinese investigator and medical institution. As a result, the regulatory requirements are more lax than a China IND which requires formal submission and approval by the Center for Drug Evaluation (CDE), along with full compliance with IND dossier and regulatory review requirements. Australia's regulatory system also prioritizes speed to FIH trials as clinical trials do not require direct review by the Therapeutic Goods Administration (TGA) after an institutional review board approval.

Other anti-China reforms are also in the mix: COINS, clinical trial restrictions, domestic supply chain policies. We continue to monitor additional anti-China efforts both from the White House and Congress.

- **The Treasury Department is considering whether to include biotech in its upcoming COINS (Comprehensive Outbound Investment National Security Act) draft rule.** Treasury must issue final implementing regulations by March 13, 2027. If biotech is included, both equity investments and specific intellectual property licensing arrangements (that are new) would be monitored or banned. The Treasury dept. has some flexibility to include new industries and other deal types into its purview when they enable the military, intelligence, surveillance, or cyber capabilities of a country of concern (Section 809 of COINS).
- **The Senate Appropriations committee will consider FY 2027 FDA funding on June 25 (possibly without the anti-China House report on banning CTs from China, N Korea, Iran and Russia).** The House Appropriations Committee passed draft report language for the FY2027 FDA funding bill that directs the FDA to restrict clinical trial data from China, Russia, Iran, or North Korea in support of Investigational New Drug (IND) applications. This is a non-binding committee report rather than the formal bill text which is unlikely to be included in the Senate version. See our analysis here.
- **The White House announced an invitation-only roundtable on policy solutions for ensuring a domestic pharma supply chain, on July 1**. The administration is meeting with stakeholders to discuss how to improve the domestic pharma supply chain and potentially obtain additional industry commitments with policy recommendations. Conversations are likely to include recommendations how to reduce reliance on Chinese API and generic sources.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET