Support the Fast-tracking Approval for Innovative Rare Disease Therapies (FAIR) Act

FAIR ACT

For many Americans living with rare and life-threatening diseases, time is a terminal luxury. The FAIR Act is a bipartisan effort to modernize how the U.S. Food and Drug Administration (FDA) evaluates therapies for rare and life-threatening diseases. By establishing a structured, harmonized framework with trusted international regulatory authorities, the FAIR Act would accelerate patient access to lifesaving treatments and clinical trials.

The FAIR Act responds to the growing threats to U.S. biomedical innovation and leadership, as well as the delays in patient access to critical, new therapies by:

Creating a 30-day FDA pathway for reviewing and approving clinical trial requests and marketing authorizations for certain lifesaving drug and biological products already approved by trusted international regulators

Strengthening the long-term competitiveness of America's biopharmaceutical sector while helping to keep clinical research jobs in the U.S.

FAIR Act **Facts**

SAFETY STANDARDS

FACT 1

The FAIR Act **preserves FDA's authority over safety, labeling, and post-market oversight**. It does not grant automatic approvals and the agency has full discretion to accept, condition, or reject applications. The pathway is strictly limited to a subset of trusted international regulators with rigorous safety and evidence standards.

SCOPE OF THE LEGISLATION

FACT 2

The FAIR Act features a highly targeted, narrow disease scope. Harmonized marketing approvals and clinical trial allowances are strictly restricted to drugs and biologics intended for the diagnosis, treatment, or mitigation of immediately life-threatening diseases or conditions. It intentionally prioritizes rare diseases where the unmet patient need is greatest and options are limited.

SCOPE OF THE LEGISLATION

FACT 3

The U.S. is actively losing ground to international competitors like China, Australia and others, which have made drug innovation a national priority. China now advances innovative assets from lab to first-in-human trials 50-70% faster than the rest of the world.[1] In 2024, China registered roughly 7,100 clinical trials compared to just 6,000 in the U.S.[2] Unnecessary regulatory duplication and uncertainty are pushing clinical trials overseas and disproportionately burdening small and emerging U.S. biotechs, which have historically been the vital testing grounds for the next generation of cures.

PATIENT ACCESS TO INNOVATION

FACT 4

While various policies and incentives throughout the years established the U.S. as a preferred first market for clinical trials and approvals, this reality has been changing. There is a significant increase in licensing Phase 1/2 assets from China, effectively outsourcing early innovation. When clinical trials shift abroad, U.S. patients battling rare and life-threatening conditions lose the vital benefit of access to trials that offer hope and cutting-edge research. If the EU and U.S. harmonized their drug approvals, 72 additional rare disease therapeutic indications would become available to U.S. patients.[3]

FDA PRIORITIES

FACT 5

The FAIR Act directly complements the FDA's ongoing IND modernization efforts and its focus on expediting drug development. The bill supports the agency's stated core mission to accelerate approvals of safe and effective drugs by making the review process more consistent, predictable, and transparent. It maintains rigorous, science-based evaluations while eliminating redundancies, allowing the FDA to focus its career staff and valuable resources where they matter most.

USER FEES

FACT 6

The FAIR Act does not reduce user fees for manufacturers who request expedited review under its framework. Sponsors leveraging the FAIR Act pathway continue to pay applicable user fees, preserving the FDA's funding base and its capacity to conduct rigorous, timely reviews.

FDA AUTHORITY AND INDEPENDENCE

FACT 7

The FDA remains fully in charge of scientific review and decision-making. The FAIR Act simply increases the agency's accountability to report and justify its decisions under the framework, prioritizing science and objectivity and reducing concerns about unpredictability.

1. https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future#/
2. https://itif.org/publications/2025/06/09/china-surpassed-us-number-drug-clinical-trials-1-100-more/
3. https://pubmed.ncbi.nlm.nih.gov/28372595/

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