LEGISLATIVE OVERVIEW & SUMMARY

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

FAIR ACT

BACKGROUND

The biopharma industry is routinely opting to launch clinical trials outside of the United States[1] to avoid what can be a lengthy review and approval process at the U.S. Food and Drug Administration (FDA). The result is a growing imbalance in the number of clinical trials between the U.S. and the rest of the world. Already, China is dramatically ramping up the number of registered clinical trials[2] and has stated its intention to dominate the race for global biopharmaceutical innovation.[3] Simultaneously, Chinese companies are leveraging publicly available patent and press release data from U.S. biopharma companies to create copycat or fast-follow drugs.[4] As a result, China is poised to leapfrog the U.S. in medical innovation. There have been several historical examples of U.S. drug approvals lagging trusted nations and regulatory authorities,[5] resulting in delays in patient access to innovative medicines, including life-threatening diseases with inadequate therapeutic options.

THE CHALLENGE

When clinical trials move abroad, it means U.S. patients lose out on the opportunity to participate in cutting-edge biomedical research and the potential health benefits it can bring. It also sets the stage for delays in access to innovative medicines as U.S. approvals could occur long after approvals in other nations. Furthermore, we are seeing clinical research jobs move abroad, eroding the U.S.'s historic leadership in biomedical innovation.

THE SOLUTION – THE FAIR ACT

The FAIR Act would require the FDA to conduct an accelerated review within 30 days of any products or clinical trials (for drugs or biologics) for life-threatening diseases that are approved by trusted regulatory authorities but not yet approved in the U.S. The Act contains the following key provisions.

1. Eligibility Requirements:

Authorized for marketing or study by the following regulatory authorities:

- European Medicines Agency (EMA)
- Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom
- Health Products and Food Branch (HPFB), Canada

1. https://endpts.com/us-drugmakers-seek-clinical-trials-abroad-as-confidence-in-fda-wavers/
2. https://www.fiercebiotech.com/biotech/chinas-share-trials-jumps-along-enrollment-times-iqvia-report
3. https://carnegieendowment.org/research/2025/01/biopharmaceuticals-rising-chinas-strategic-pivot-to-southeast-asia-amid-great-power-tech-competition?lang=en&center=china
4. https://www.statnews.com/2025/05/06/how-to-stop-the-shift-of-drug-discovery-from-the-u-s-to-china/
5. https://www.gene.com/media/press-releases/14893/2021-01-20/fda-grants-priority-review-to-genentechs

Additional eligibility requirements:

- Have no prior safety or efficacy-related withdrawals or bans
- Intended to treat a life-threatening disease

2. Establishes Reciprocal Approval Mechanism for Clinical Trials (IND) and Marketed Products (NDA or BLA):

Clinical trials allowed to proceed by a trusted regulatory authority, but not yet allowed in the U.S., will be allowed to proceed in the U.S. if requested by the sponsor. The FDA may request modifications to the trial protocol within a 30-day review period.

Medical products (drug or biologic) approved by a trusted regulatory authority, but not yet approved in the U.S., are eligible for an accelerated 30-day review at the FDA. The review shall be triggered by a manufacturer request. During the 30-day review period, the FDA and sponsor shall finalize product labeling.

3. FDA Oversight and Safeguards:

The FDA may deny reciprocal trial allowance or marketing approval if it determines the product is unsafe or ineffective. Denials and justifications (while respecting proprietary and confidential information) must be reported monthly to Congress and relevant committees (House Energy & Commerce; House Ways & Means; Senate Finance; Senate Health, Education, Labor & Pensions). The FDA may require post-market studies or Risk Evaluation and Mitigation Strategies (REMS).

4. Regulatory Parity:

Once approved via this pathway, the product is treated the same as if it were approved through traditional U.S. processes.

5. User Fees and Raising Awareness:

Sponsors must pay the same fees as traditional applicants. The FDA must launch an outreach campaign to inform eligible sponsors about the new approval pathway.

6. Agency Guidance:

Within 180 days of the FAIR Act becoming law, the FDA shall release guidance to industry.

CONCLUSIONS

The FAIR Act directly confronts threats to U.S. leadership in biomedical innovation and delayed patient access to critical new therapies. By creating an accelerated 30-day review for products and clinical trials already approved by trusted international regulators, the FAIR Act aims to bring cutting-edge research and innovative medicines to American patients faster, while simultaneously bolstering the U.S. biopharmaceutical sector and retaining clinical research jobs.

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FAIR ACT

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