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ONE HUNDRED NINETEENTH CONGRESS

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July 13, 2026

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee Majority Staff
Re: Subcommittee on Health Hearing on July 15, 2026

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, July 15, 2026, at 10:15 a.m. (ET) in 2123 Rayburn House Office Building. The hearing is entitled "Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development."

II. WITNESSES

- **Cynthia Verst, PharmD, MS,** President, Design and Delivery Innovation, R&D Solutions, IQVIA
- **Susan C. Winckler, RPh, Esq.,** CEO, Reagan-Udall Foundation for the FDA
- **Aaron J. Kowalski, PhD,** CEO, Breakthrough T1D
- **Thomas Hwang, MD,** Assistant Professor of Medicine, Brigham and Women's Hospital and Harvard Medical School
- **Thomas K. Bollyky, JD,** Bloomberg Chair in Global Health, Senior Fellow for International Economics, Law, and Development; and Director of the Global Health Program, Council on Foreign Relations

III. BACKGROUND

In the United States, the Food and Drug Administration (FDA) is responsible for the approval and regulation of drugs in the U.S. market, which includes regulatory processes broken into the premarket approval or preapproval review and the post-market or post-approval regulatory procedures.[1] Figure 1 below depicts the drug development process.

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[1] Agata Dabrowska et al., CONG. RSCH. SERV. (CRS), R41983, How FDA Approves Drugs and Regulates Their Safety and Effectiveness (2018), https://www.congress.gov/crs_external_products/R/PDF/R41983/R41983.14.pdf.

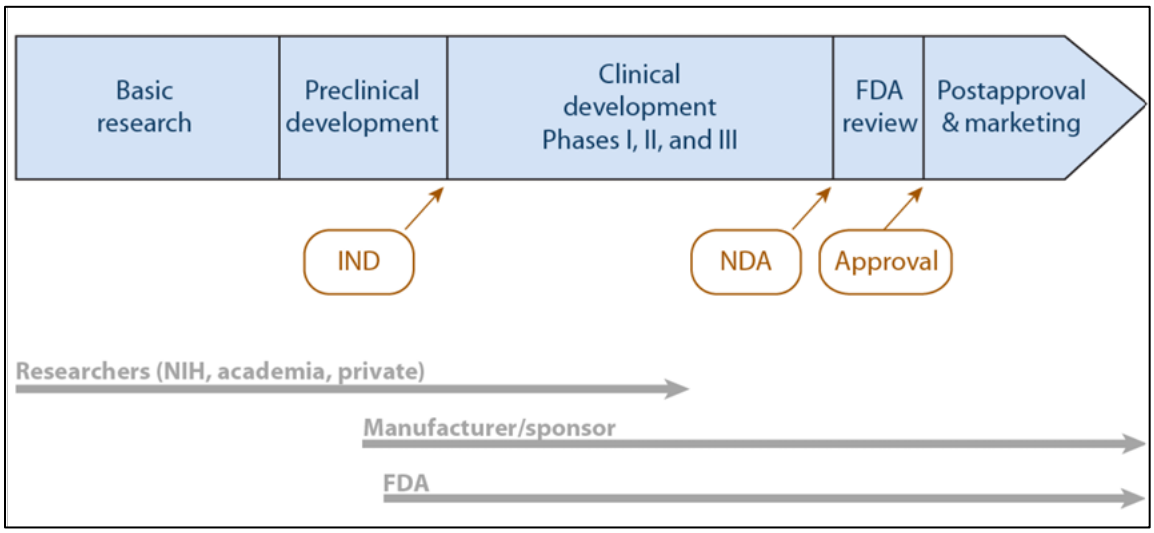

Figure 1. Overview of the Drug Development Process.[2]

There have been increasing concerns surrounding U.S. global competitiveness within early-stage drug development. Although the United States remains the global leader in biomedical innovation, inefficiencies in the preclinical and early clinical trial ecosystem have contributed to a growing shift of preclinical, Phase 1, and Phase 2 clinical research to foreign countries, particularly China, Australia, and certain European countries.[3]

Compounding these domestic challenges, other countries have implemented policies that reduce the time and cost required to initiate early-stage clinical trials. China, for example, has rapidly expanded its biopharmaceutical innovation sector and is projected to account for roughly 35 percent of U.S. FDA approvals by 2040.[4] Likewise, Australia has experienced substantial growth in early-stage clinical research, with Phase I trials increasing from nine percent of all active trials in 2006 to 40 percent in 2020, representing roughly 18,000 active trials during that period.[5]

Both countries have adopted regulatory and operational approaches that accelerate early clinical development. Australia utilizes a Clinical Trial Notification (CTN) pathway that delegates scientific and ethical review to accredited Human Research Ethics Committees, allowing sponsors to initiate studies more quickly through a streamlined notification process. China has shortened discovery-to-investigational new drug (IND) timelines through reforms including an implied IND approval process, expanded regulatory capacity, a large contract research organization (CRO) ecosystem, and greater use of investigator-initiated trials.[6] China also conducted more than 7,100 registered clinical trials in 2024 compared to roughly 6,000 in

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[2] *Id*. at 4.
[3] Reagan-Udall Foundation for the FDA, *Enhancing Early-Stage Drug Development in the United States* at 6, https://www.reaganudall.org/sites/default/files/2026-06/Enhancing%20Early-Stage%20Drug%20Development%20in%20the%20US_1.pdf (last accessed Jul. 8, 2026).
[4] National Security Commission on Emerging Biotechnology, *The Future of U.S.-China Biotechnology Competition* at 4 (Dec. 2025), https://www.biotech.senate.gov/wp-content/uploads/2025/12/NSCEB-Future-of-U.S.-China-Biotech-Competition-Dec-2025.pdf.
[5] Reagan-Udall Foundation for the FDA, *supra* note 3 at 7.
[6] *Id*. The number of reviewers within China's drug and biologics regulator entity increased from 200 in 2017 to 1,300 in 2024.

the United States, while offering lower-cost and faster Phase 1 trial execution.[7] However, some observers have noted that differences in clinical trial oversight, data integrity standards, and patient safety and research ethics requirements may also contribute to China's accelerated timelines and lower costs.

Against this backdrop, on June 22, 2026, the U.S. Department of Health and Human Services (HHS) announced *Operation TrialBlazer*, a department-wide initiative to reinvigorate domestic clinical research and accelerate the development of lifesaving treatments.[8] Under this initiative, HHS aims to modernize regulatory requirements and processes, improve transparency for regulated entities, and promote more efficient clinical research practices to strengthen domestic early-stage clinical research.[9] Alongside these efforts, industry stakeholders have highlighted the need for modernized IND requirements and processes to accelerate the initiation of Phase 1 clinical trials domestically. They have advocated for risk-proportionate IND submission requirements, rolling IND submissions, and use of a Phase 1 Clinical Trial CTN pathway.[10]

This memorandum provides an overview of the U.S. drug discovery and development process and examines opportunities to drive efficiencies across the early-stage research and development continuum.

A. Discovery and Development

During the early stages of the drug development process, researchers assess compounds as potential candidates for the development phase as a medical treatment.[11] Once a promising candidate is identified, researchers gather information about its absorption, distribution, metabolism, and excretion; potential benefits and mechanism of action; optimal dosage; and route of administration.[12]

B. Preclinical Research

Before a drug is tested in humans, researchers conduct preclinical studies to evaluate whether the product has the potential to cause serious harm. These studies assess the drug's toxicity, or potential to cause serious harm, either using a study that is *in vitro*, in which tests are conducted on blood or tissue outside of the body, or *in vivo*, in which tests are conducted within

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[7] National Security Commission on Emerging Biotechnology, *supra* note 5 at 8.
[8] Press Release, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), *HHS Launches Unprecedented Department-Wide Effort to Restore American Leadership in Clinical Trials* (Jun. 22, 2026), https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative html; HHS, Operation TrialBlazer, *HHS Roadmap to Maintaining U.S. Leadership in Early Clinical Research and Development* (Jun. 2026), https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf.
[9] HHS, Operation TrialBlazer, *HHS Roadmap to Maintaining U.S. Leadership in Early Clinical Research and Development* at 2 (Jun. 2026), https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf.
[10] HHS, *supra* note 9; see also, Reagan-Udall Foundation for the FDA, *supra* note 3.
[11] U.S. FOOD AND DRUG ADMINISTRATION (FDA), The Drug Development Process, *Step 1: Discovery and Development* (Jan. 2018), https://www fda.gov/patients/drug-development-process/step-1-discovery-and-development.
[12] *Id*.

the body.[13] Following testing, researchers assess whether or not the drug should be tested in humans within a clinical trial.[14]

C. IND Submission and First-in-Human Studies

Once sufficient preclinical evidence has been generated, a sponsor that intends to begin a clinical trial generally submits an investigational new drug (IND) application. Under 21 C.F.R. § 312.23, an IND includes, among other things, an investigational plan, investigator information, study protocols, manufacturing information, and animal pharmacology and toxicology data. The sponsor must also commit that an IRB complying with FDA requirements will be responsible for the initial and ongoing review of each proposed study. A sponsor may proceed with clinical investigation 30 days after submitting an IND, unless FDA places a clinical hold or otherwise authorizes the investigation sooner.[15] In the U.S., it takes approximately 145 days to begin a clinical trial given the multi-site IRB processes after the 30-day IND review.[16] Alternatively, in Australia, lower-risk clinical trials typically begin between 6-12 weeks after the notification, and in China, it takes roughly 30 working days for IND review.[17]

D. Early Clinical Research

Clinical research begins once the IND is in effect and required human-subject protections are in place.[18] FDA describes Phase 1 studies as generally small, early trials focused on safety and dosage, often involving 20 to 100 participants, and Phase 2 studies as studies in up to several hundred patients that are intended to assess efficacy signals and side effects and to refine subsequent study design.[19] Studies follow a protocol developed by the investigator or manufacturer and are informed by eligibility criteria, duration, dosing, control groups, and how the data will be collected and analyzed.[20]

E. FDA Review and Approval

When sufficient clinical data has been generated, the sponsor can file a New Drug Application (NDA) with FDA to market the drug. An NDA contains reports of all preclinical and clinical studies conducted to assess the drug's safety and effectiveness, proposed labeling and directions for use, manufacturing information, and documentation of compliance with IRB requirements.[21] An NDA contains all reports on all studies, preclinical and clinical data conducted to assess safety and effectiveness, proposed labeling and directions for use, as well as

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[13] FDA, The Drug Development Process, *Step 2: Preclinical Research* (Jan. 2018), https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research.
[14] *Id*.
[15] FDA, The Drug Development Process, *Step 3: Clinical Research* (Jan. 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research.
[16] Thomas J. Bollyky et al., *The Pharma Choke Point: How to Reduce U.S. Dependence on Chinese Pharmaceutical and Biotechnology Supply Chains*, COUNCIL ON FOREIGN RELATIONS (CFR) at 55 (Jun. 2026), https://assets.cfr.org/images/BOLLYKYpharmaJul6/BOLLYKYpharmaJul6.pdf.
[17] *Id*.
[18] FDA, *supra* note 16.
[19] *Id*.
[20] *Id*.
[21] FDA, The Drug Development Process, *Step 4: FDA Drug Review* (Jan. 2018), https://www fda.gov/patients/drug-development-process/step-4-fda-drug-review.

information relating to IRB compliance. After FDA determines that the application is sufficiently complete to review, an FDA review team generally has six months for priority review applications and ten months for standard review applications to evaluate the drug's safety, effectiveness, labeling, and manufacturing quality.[22] FDA may approve the application, request additional information, or issue a Complete Response Letter (CRL) identifying deficiencies that must be addressed before the application can be approved.

F. Post-Market Drug Safety Monitoring

FDA oversight of a drug continues after approval through post-market safety monitoring. As drugs are used more widely, FDA reviews reports of adverse events, conducts active safety surveillance, inspects manufacturing facilities for continued compliance with current good manufacturing practices (cGMPs), and oversees prescription drug advertising and promotional labeling to ensure they are accurate and not misleading. When new safety information emerges, FDA may require labeling changes, additional post-market studies, or other regulatory actions to help ensure a drug's benefits continue to outweigh its risks.[23]

V. KEY QUESTIONS

1. How can Congress and FDA modernize regulatory requirements for early-stage clinical development while continuing to uphold FDA's gold standard for safety and effectiveness?
2. What opportunities exist to improve the efficiency of the U.S. clinical research enterprise through innovative trial designs, digital health technologies, and greater use of high-quality clinical data?
3. How can greater transparency and coordination across clinical protocols reduce delays in trial activation, improve patient enrollment, and accelerate the development of new therapies?
4. What are the consequences for patients, public health, and national biosecurity if the U.S. loses its global leadership in clinical research, biopharmaceutical innovation, and domestic manufacturing capacity?

VI. STAFF CONTACTS

If you have questions regarding this hearing, please contact Claire Richey of the Majority Committee staff at (202) 225-3641.

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[22] *Id*.

[23] FDA, The Drug Development Process, *Step 5: FDA Post-Market Drug Safety Monitoring* (Jan. 2018), https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring.