THE PHARMACEUTICAL DRUG DEVELOPMENT PROCESS

The pharmaceutical drug development process includes three stages: research and development (R&D), approval, and postmarketing. On average, drugs take 10-15 years from discovery to approval. Before a drug can be marketed in the United States, it must be approved by the Food and Drug Administration (FDA). To obtain approval, the manufacturer submits to FDA a new drug application (NDA) or a biologics license application (BLA) containing safety and effectiveness data generated in preclinical and human clinical trials. FDA also has a number of programs to expedite development and review of drugs that address unmet medical need. Costs facing drug manufacturers include the cost of R&D, application fees, post-market studies, and advertising. There are widely ranging estimates for clinical trial costs, depending on the therapeutic area and study's assumptions. This infographic uses clinical trial cost estimates from a 2014 study conducted under contract to the Department of Health and Human Services.* To help offset these costs and incentivize drug development, the federal government offers pharmaceutical manufacturers orphan drug and R&D tax credits, as well as research deductions. While comprehensive data on use of these credits and deductions by the industry are not available, CRS analysis shows that the R&D tax credit can be a significant tax subsidy, resulting in negative tax rates in some cases. In addition, there is a federal tax deduction available for business advertising expenses.

1 RESEARCH & DEVELOPMENT

Basic Research
The study of the fundamental mechanisms of biology and behavior. Leads to knowledge of disease/condition that aids in drug development.

Iterative Process

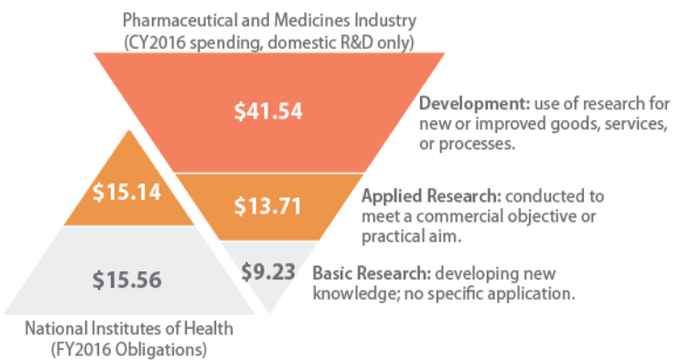
Discovery
Identification of chemical or living compounds capable of managing or curing a disease.

Preclinical Research
Research on potential drug candidates, usually using lab animals, cell cultures, samples of human/animal tissue, and/or computer models.

Investigational new drug application (IND) is submitted to FDA

RESEARCH AND DEVELOPMENT BY SECTOR

Billions of dollars



Source: CRS analysis of National Science Foundation (NSF) Business, Research, Development and Innovation Survey data and Federal Funds for Research and Development Survey data
Note: This figure is for illustrative purposes only and is not a comprehensive accounting of all R&D by federal agencies or industry related to pharmaceutical drug development.

CLINICAL RESEARCH

Phase I Clinical Trials
Participants: 20-100
Purpose: safety and dosage
Length of study: several months
Average cost: $4 million ($1.4-$6.6 million)

MOVE ONTO NEXT PHASE

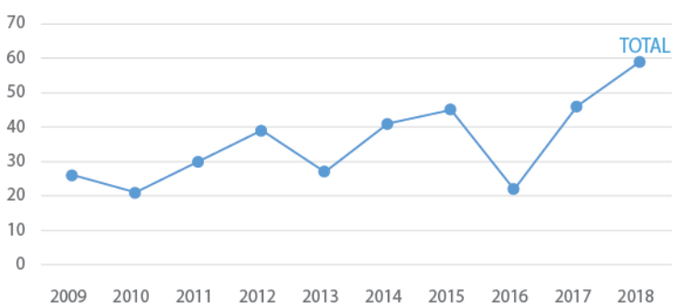
Phase 2 Clinical Trials
Participants: 100s
Purpose: effectiveness and side effects
Length of study: 2 years
Average cost: $13 million ($7-$19.6 million)

Phase 3 Clinical Trials
Participants: 1,000s
Purpose: effectiveness and monitoring adverse events
Length of study: 1-4 years
Average cost: $20 million ($11.5-$52.9 million)

2 APPROVAL

In 2018, of the 59 novel drug approvals, 43 (73%) were designated in at least one expedited program.

FDA'S CENTER FOR DRUG EVALUATION AND RESEARCH NOVEL DRUG APPROVALS (NDAs AND BLAs)



Note: Novel drugs include new molecular entities approved under NDAs and new therapeutic biologics approved under BLAs. The active ingredient(s) in a novel drug has never been approved in the U.S.

Application Submission
NDA or BLA is submitted to FDA. For FY19:
Application fee = $2.6 million/application
Annual program fee = $309,915/approved drug

FDA files (or refuses to file) NDA/BLA within 60 days

Application Review Goals
Standard review= 10 months
Priority review= 6 months

Application Approved

Application is not Approved

3 POSTMARKETING

TOP 5 DRUGS BY REVENUE IN 2017

Source: IQVIA Institute, "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022"

Billions of dollars

In **2016**, pharmaceutical companies spent **$20.3 BILLION** on marketing to health care professionals and **$6 BILLION** on direct-to-consumer advertising

Source: L.M Schwartz and S. Woloshin, "Medical Marketing in the United States, 1997-2016," JAMA, 2019, 321(1), p. 80-96.

Drug is marketed and sold by company

Note: New drugs are often shielded from competition for a number of years due to patents and regulatory exclusivities.

Phase 4 Clinical Trials or Studies
Participants: 1,000s
Purpose: effectiveness and monitoring long-term effects
Average cost: $20 million ($6.8-$72.9 million)

Prepared by Agata Dabrowska (Analyst in Health Policy), Kavya Sekar (Analyst in Health Policy), and Jamie Hutchinson (Visual Information Specialist).
For more information, see CRS Reports R41983, R44832, R44620, IF11083, and *Eastern Research Group, Examination of Clinical Trial Costs and Barriers for Drug Development, (July 2014).

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