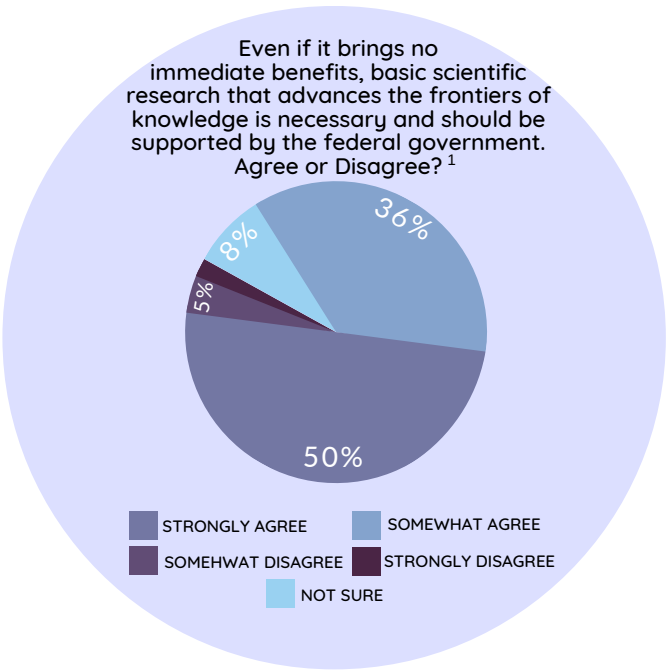
THE BIOMEDICAL RESEARCH AND DEVELOPMENT PIPELINE

WHAT ARE THE BASIC PHASES OF THE RESEARCH AND DEVELOPMENT (R&D) PIPELINE?

There are five main phases in research and development (R&D): basic research, applied research, clinical trials, regulatory review, and production & distribution. Academic and independent research institutions, private companies, and the federal government play unique and complementary roles in the R&D ecosystem.

Basic Research | **Applied Research** | **Clinical Trials** | **Regulatory Review** | **Production & Distribution**

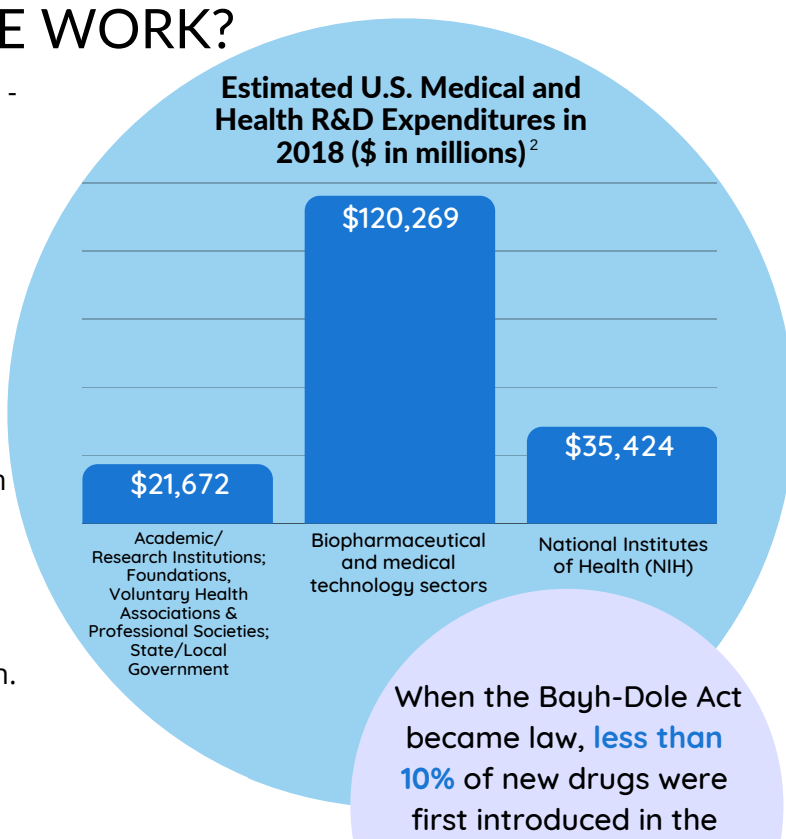


- **Basic Research** explores living systems, seeking to understand how they are structured and work, the function or functions they carry out, and other defining information about these systems. Key findings are referred to as targets, because targeting and researching these findings further may yield critical medical advances.
- **Applied Research** investigates the targets basic research reveals, conducting further studies and developing promising medical advances into interventions that are screened for potential can be tested for safety and effectiveness.
- **Clinical Trials** test the safety and effectiveness of potential medical interventions identified via applied research in broader, more diverse samples of the population.
- **Regulatory Review and Scale-Up** If regulatory review determines that an intervention is safe and effective, manufacturing and distribution is initiated at scale.

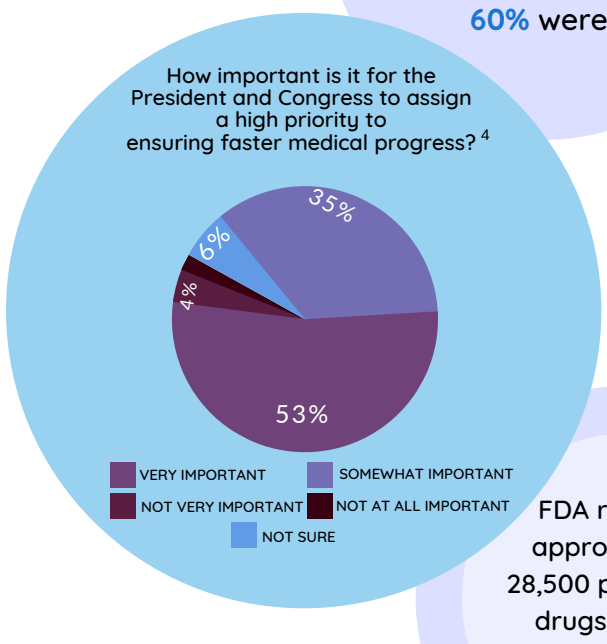
HOW DOES THE R&D PIPELINE WORK?

Health-focused R&D is not the responsibility of one sector - it is more like a relay race that plays to strengths of the public sector, academic and independent research institutions, and the pharmaceutical and medical technology industries.

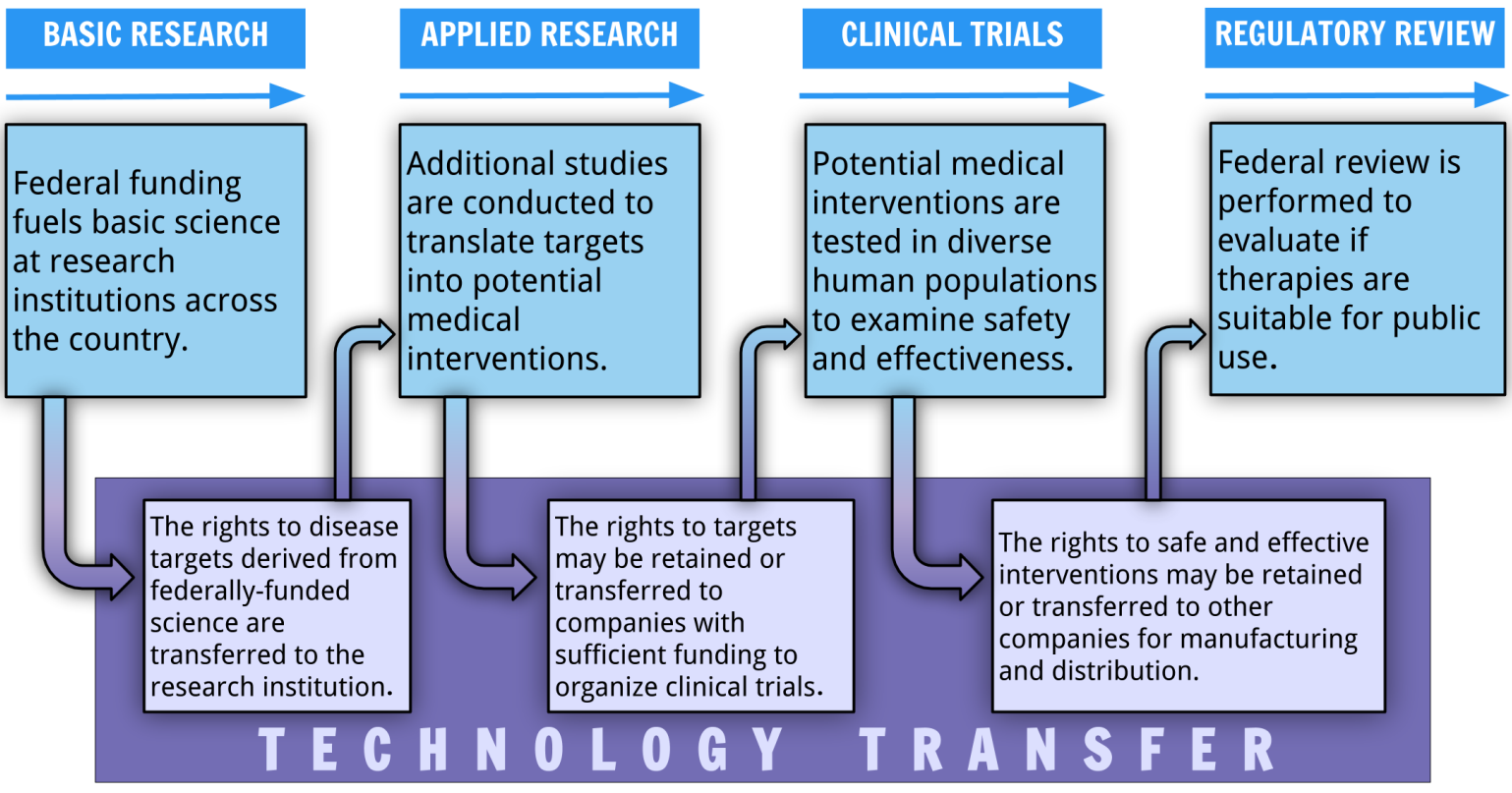
- **Grant Funding** The federal government is the largest U.S. funder of basic research. Intramural research conducted at federal agencies like the National Institutes of Health and at federal laboratories across the country contributes significantly to medical and scientific progress, but most federally-funded research is not conducted "in-house." Instead, federal agencies make use of a competitive "peer review" process to provide grant funding to universities, independent research institutes, academic health centers and small businesses across the country to conduct this research.
- **Bayh-Dole Pathway** Similarly, while federally-funded basic research is the "first leg" of the relay race, the federal government does not conduct or finance the bulk of R&D that leads to new medical advances. In fact, the private sector finances nearly 70% of U.S. biomedical R&D. Originally, the lack of a mechanism for incentivizing the entire discovery, development, delivery pipeline created a serious bottle neck, but the landmark 1980 Bayh-Dole Act addressed this chokepoint by ensuring that intellectual property rights can be transferred from the federal government to the institutions and businesses executing each phase of the R&D pipeline.
- **Patient Contribution** Patients and non-patient clinical trial volunteers play a critical and growing role in the research pipeline. Not only do they enable clinical research, but they inform every step of the research process to ensure progress reflects true patient need.
- **Regulatory Review** The federal Food and Drug Administration assesses clinical trial results and other evidence to verify product safety and effectiveness before large-scale manufacturing and distribution occurs.



When the Bayh-Dole Act became law, **less than 10%** of new drugs were first introduced in the U.S. By the 2010s, **over 60%** were.[3]



FDA regulates approximately 28,500 prescription drugs, medical devices and biologics. [5]



*U.S. spending includes both public and private sector spending .
Source information is available here.