DRUG DISCOVERY & DEVELOPMENT: MANUFACTURING AND COMMERCIALIZATION

On average, out of **10,000 COMPOUNDS** tested, **250** will move to pre-clinical stage; **5** of these compounds will move to clinical trials, and ultimately **1** will receive FDA approval. The full research, development and approval process can take **12-15 YEARS** or longer.

Developing a new prescription medicine that gains marketing approval is estimated to cost drugmakers **$2.6 BILLION** according to a recent study by Tufts Center for the Study of Drug Development.

Manufacturing

Pharmaceutical companies strive to make their products as safe and effective as possible so they can provide the most benefit to people who need them. The FDA regulates all pharmaceuticals and biologics by enforcing **Current Good Manufacturing Practices (CGMPs)**.

The FDA reviews the manufacturer's compliance of **CGMPs** and inspects the facility during the drug approval process. Working with pharmaceutical companies, the FDA ensures the systems in place are safely manufacturing the treatment.

Commercialization: The 5Ps

Product
Ensuring quality control and effective supply chain

Physician
Disease awareness, patient identification, educating prescribing information from start of treatment and maintenance

Patient
Remain patient centric by listening to the patient voice and journey from symptoms to diagnosis through treatment

Pharmacy
Ensuring effective supply chain through pharmacies and specialty pharmacies

Payor
Work with insurance companies on pricing to help all patients access the medications

The Patient's Voice

Patients can impact the process by:

- Providing input in drug trial design
- Enrolling in clinical trials
- Sharing disease state feedback and identifying unmet educational needs
- Contributing to standard of care development
- Participating in advisory boards and patient registries
- Joining Patient Advocacy Groups

Connect with resources to help guide you through this journey

1-833-PTC-HOPE (1-833-782-4673), or in Spanish 1-833-PTC-VIDA (1-833-782-8432)

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