Drug Approval

From Development to Your Medicine Cabinet

Discovery and Application

1 Drug Development

- Researchers choose what disease to focus on and what drug compounds will best fight the illness.
- Research assesses how the drug is absorbed, metabolized, and should be administered.
- Testing on different animal species helps researchers better understand the drug compounds.

2 Investigational New Drug (IND) Process

- IND Application is submitted to the FDA, proving that the drug is ready to test on humans.
- The IND includes results of animal testing, drug composition, and a plan for human trials.

3 Clinical Trials

Full approval process can take up to a decade to assess safety and efficacy.

PHASE 1: Safety

- This phase usually consists of 20–80 participants.
- Healthy participants are used to ensure drug is safe to use and to understand it's effects on the body.

PHASE 2: Effectiveness

- This phase usually consists of hundreds of participants.
- Patients are compared with those receiving a placebo or another drug used to treat the same illness.

PHASE 3: Expanded Safety and Efficacy

- This phase usually consists of thousands of participants.
- Additional factors are tested, such as dosages, combinations with other drugs, and a diverse patient population.

THE LOOPHOLE

Accelerated approvals can cut corners on safety and efficacy, resulting in drugs hitting the market within less than half the time—sometimes less than two years.

PHASE 4: Post Market Analysis

- Phase 4 trials are optional and the FDA does not request that all companies perform phase 4 trials.
- Phase 4 trials are **typically** conducted after a drug is approved by the FDA and made available to the public.
- Approximately 25–30% of drugs that started in Phase 1 make it to Phase 4.

Drug Review

4 Submission and Review of New Drug Application (NDA)

- NDA is formally submitted to FDA, including all animal and human data.
- Between 60 days and 10 months, FDA determines if the application will move forward for evaluation.
- FDA Review Team evaluates research on drug safety and effectiveness.
- FDA then reviews the drug's labeling and communication to health care providers and patients.
- FDA will also inspect the facility where the drug will be manufactured.

Approval

At this point, the drug can be advertised, manufactured and prescribed. Advertisements for prescription drugs are not approved by FDA prior to launch. Prescription drug advertisements are not approved prior to airing to the public, which means according to the FDA, "*…the public may see ads that violate the law before we can stop the ad from appearing or seek corrections to the ad.*"