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FridayFocus

BaylorScott&White HEALTH

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FDA Approval of Drugs - what does it mean?

When health care personnel refer to drugs, we often think of the prescription, generic, and over-the-counter medications used to treat or diagnose a disease. However, the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research considers drugs to be more than just medications. "For example, fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens are all considered "drugs"" (FDA, 2015, para2). Thus, they require FDA approval to be sold in the U.S.

In 1938, the Food and Drug Act was amended to include that new drugs be approved for safety, but it was not until 1962 that Congress passed an amendment requiring that all new drugs must also be tested for effectiveness.

Unfortunately, according to the FDA, "many healthcare providers are unaware of the unapproved status of drugs and have continued to unknowingly prescribe them because the drug's labels do not disclose that they lack FDA approval" (FDA, 2016, para 2). Even generic drugs must be FDA approved and proven to meet the same quality, strength, purity, stability, safety, and effectiveness as the original medication.

On average it takes more than 12 years of research and more than $2.5 billion to move a drug from concept through testing and onto the pharmacy shelf (Mullin, 2014).

- **Step 1 — discovery and development of new drugs:** This step requires substantial trial and error. Often, new drugs are found to potentially benefit something other than what was originally intended.
- **Step 2 — preclinical (animal or laboratory) testing:** During this step, researchers refine the prototype and assess the product's potential and risks for use in people. Once ready, the drug company asks the FDA for approval as an investigational new drug (IND). Less than 1:1,000 drugs make it past Step 2.
- **Step 3 — clinical (human) trials:** Trials are done to see if the drug is safe and effective at diagnosing and/or treating a specific disease or condition. This step is broken down into four phases:
  - Phase 1 is the smallest scale, lasts for a couple months, and focuses on safety and dosage. Only 70% of new drugs pass this phase.
  - Phase 2 is slightly larger, can last for up to two years, and focuses on the efficacy and side effects. Only 33% of new drugs pass this phase.
  - Phase 3 is significantly larger, can last for one to four years, and is typically where the FDA is consulted and their design is implemented. Only 25% to 30% of all new drugs pass this phase.
  - Phase 4 is the large scale testing and it marks the time in which the pharmaceutical company asks the FDA for a new drug application (NDA).

A new drug is FDA approved only after it undergoes this entire process and being found to meet at least the minimum standards for safety and effectiveness.

As always, we appreciate your ideas and feedback. Thank you for the quality work you do. All editions of the Friday Focus are available on the SWHP website: https://swhp.org/en-us/prov/news/providers-friday-focus.

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