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New Drug Development Process

At one time or another everyone has relied on prescription drugs to help treat or cure a symptom or illness. In fact, approximately 2 billion prescriptions are filled each year in the United States, but few know of the complicated and lengthy process involved in creating and providing a new medication to the public – humans and animals.

Who is involved in developing new drugs?

Many various scientists and researchers are involved in the development of a new drug. For many years, traditional organic chemists, scientists, physiologists, and statisticians have been involved in the research process. In more recent years, they have been joined by new kinds of specialists. For example, biochemists study the chemistry of life processes. Molecular biologists study the molecules that make up living matter. Toxicologists investigate chemicals' potential for harm. Pharmacologists look at how drugs work, and computer scientists apply the power of their sophisticated machines to analyze and assess new chemicals. Each of these individuals plays a critical and necessary role in new drug development.

How long does the new drug development process take and how many trial drugs work in the end?

It takes an average of 12 years for a drug to travel from the research lab to the patient. Of all the tens of thousands of new drug compounds that begin the research process on the laboratory benchtop, only about five in 5,000 of the drugs that begin preclinical testing (animal trials) ever make it to human testing. Only *one* of these *five* is ever approved for human usage.

How much money is spent on the development of one new drug?

On average, it will cost a company more than a billion dollars to develop a new drug from the research lab to the patient bedside.

Who regulates the new drug development process?

The new drug development and approval process may be one of the most difficult processes in the world. The Food and Drug Administration (FDA) monitors and regulates the new drug development process. The FDA's role in the preclinical research stage is minimal. However, once a company finds sufficient evidence that a drug is successful in animals, human trials will begin. The FDA plays a much more crucial role

during the various clinical trial phases. If the drug shows successful effects in humans and the FDA approves it to be prescribed by physicians to humans, the FDA will determine what information should be placed on the label including, directions for use, potential side effects, and other necessary warnings.

What are the various types of drugs currently being developed and tested?
At any one time, thousands of new drugs are being researched and developed to treat and cure the diseases the effect both humans and animals. New drugs for diseases such as AIDS, Cancer, Diabetes, Arthritis, Asthma, Parkinson's Disease, Feline Leukemia, and other chronic diseases are continuously being researched and developed. Health crisis throughout the world require new research and development of vaccines or drugs to treat emerging health issues – Ebola and Zika are just two examples. That is why it is critical to support biomedical research. Continuous and on-going research is important also to the discovery of new treatments and unexpected benefits. For example, the popular hair growth treatment Rogain begun its existence in a research lab as a potential heart medication.

What steps are involved in developing a new drug?
There are many steps researchers take when developing a new drug, steps that can be divided into seven different phases.

Preclinical Research
The first place researchers start is in the lab. Preclinical research is the process where scientists and researchers determine what germs, viruses, or bacteria cause a specific disease. Once this is accomplished, researchers and scientists will work to break down the different components that make up a disease to find out what abnormal events or processes are taking place in the body. Scientists then work to develop a drug that will treat these abnormalities by conducting experiments in test tubes where they will add various compounds to enzymes, cell cultures, or cellular substances. The goal is to determine which compound additions result in some sort of chemical effect on the disease. Whenever possible, scientists will use computer models to test different compounds, however, computers don't provide any final answers. These compounds still have to be placed into a living biological system to see if they work. Therefore, after successes in the "Benchtop" process (test tubes and cell cultures), scientists then test these compounds that have shown some desired effects in living animals. The entire process of preclinical research can take up to three and a half years. Once the process is complete, a pharmaceutical company will then file an Investigational New Drug Application (IND) with the FDA.

Investigational New Drug (IND) Application
The IND becomes effective if the FDA approves it within thirty days. At this time a pharmaceutical company can begin to test the potential new drug in humans. This process includes three phases of *clinical* trials.

Phase 1 Trials
A new drug is administered to approximately 20 to 80 healthy volunteers, to study the activity and monitor potential toxicity in people. This process takes about one year and if successful, will lead to phase II clinical trials.

Phase II Trials

During the phase II trials, the drug is given to 100 to 300 volunteers with the disease being studied to determine the drugs effectiveness. Proper dosages are established during this time. This process can take about two years to complete before moving to phase III clinical trials.

Phase III Trials

This phase involves anywhere from 1,000 to 3,000 volunteers with the specific disease that are in clinics or hospitals. Physicians will monitor these patients closely to determine the effects of the drugs and determine if any side effects are involved. This phase confirms if the drug is effective and safe and can take about three years.

New Drug Application (NDA)

After all three phases of clinical trials have been completed successfully a pharmaceutical company must file a New Drug Application (NDA) with the FDA. The pharmaceutical company must be able to clearly demonstrate the effectiveness and safety of the drug and must provide all of the scientific information the pharmaceutical company has collected on the specific drug. The FDA can take up to six months to review the application. Often times, this process takes longer than six months.

Approval

If the FDA approves the drug, it is then made available for physicians to prescribe to patients. The pharmaceutical company is still responsible for submitting periodic reports to the FDA regarding any unknown side effects that may occur after approval. For some medications, the FDA requires additional studies after approval. These are known as Phase IV Clinical Trials and serve to determine if there are any long-term side effects.

**SOURCES: FDA Special Consumer Report: The Beginnings: Laboratory and Animal Studies; FDA Drug Discovery, https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405382.htm; PhRMA,* The Biopharmaceutical Pipeline, http://www.phrma.org/report/the-biopharmaceutical-pipeline; *Congressional Office of Technology Assessment; The Drug Development Process from the NIH, an infographic, www.faseb.org/portals/2/PDFs/opa/Natural%20products%20FDA%20infographic.pdf.*