Examination of the Steps of Medicine Drug in FDA Approval Process

Pharmaceutical companies go through a seven-step process just in order to get the FDA to approve a drug for the general population. Although that may seem like an over-exaggeration of the importance of the FDA, each individual step has its own purpose. By the time it's said and done, the entire process takes about twelve to thirteen years to be complete. The FDA forces pharmaceutical companies to thoroughly test potential drugs to ensure that the benefits outweigh the risks. In doing so, they protect consumers from being taken advantage of.

Pre-clinical testing is the first stage of testing the drug. In this process, lab(in vitro) and animal testing is done in order to prove the safety of the drug. The pharmaceutical company will also be made aware if the drug properly targets the disease it's after. On average, it should take about three and a half years to complete pre-clinical testing.

At this point, the pharmaceutical company files an Investigational New Drug Application, or an IND, with the FDA. If the application is not turned down within thirty days, the IND becomes effective and the next step can begin. However, only about five in five thousand drugs are approved to pass this stage. After the IND becomes effective, the company is still responsible for its maintenance. This means any new protocols, changes and safety reports must be turned in.

After the IND's approval, the next step is Phase 1 clinical trials. This is the first part of in vivo testing. In vivo testing is a very controversial matter due to ethical issues and some people believing that humans should not be treated as test subjects. Twenty to eighty healthy volunteers will help to determine a decent dosage range by showing how well they handle the drug. This takes about a year.

Phase 2 clinical trials takes the next step by using one hundred to three hundred volunteers with the targeted disease. The minimum and maximum dosage is now checked. With the volunteers having the disease itself, the effectiveness of the drug can be closely monitored as well. It takes an average of two years for phase 2.

One thousand to three thousand patients that are already in clinics or hospitals, are used for phase 3 clinical trials. The hospital setting allows for more testing of effectiveness and watching for adverse effects. Finding a solution for the adverse effects is done quickly and easily as long as it's spotted early. This step should take another three years.

At this point, the drug manufacturer analyzes all of the data about the drug and clinical trials. If everything looks good, the pharmaceutical company will now file a New Drug Application with the FDA. With all of the data gathered on the drug to date, the application contains about one hundred thousand pages. Two and a half years may pass before the application is accepted.

Phase 4 studies is considered post-marketing studies. The drug has already been approved but the patients still report side effects. As of 2014, the cost of manufacturing a new drug exceeded $2.6 billion. Another $312 million is spent on post approval development.