



**Question:**

*What does it take to get a medication to the American public?*

**Answer:**

The purpose of this question is to piggyback onto the previously answered question of “Why do psychiatric medications cost so much?”

To begin with, as stated previously, a “Brand” drug is a product with a patent that allows a manufacturer to sell it exclusively for a certain period of time before other manufacturers can produce the same drug and create competition. Why is this allowed? The complex process of getting that medication onto the market explains this. The main focus of this process is to ensure the safety and efficacy of medications before they are used by the public.

In the US, the Federal and Drug Administration (FDA) is responsible for reviewing compounds (drugs) prior to them being taken by the general public. On average, a drug manufacturer will screen 10,000 compounds only to test 10 of these compounds as possible medications. Of these 10 tested compounds, only 2 will make to the public market as a medication.

**Drug Discovery:**

To begin with, it takes on average 2-5 years to develop a compound. All this time is necessary to find a single molecule that may be used as a medication.

**Drug Development:**

This is another 5-9 years to determine what the drug does and if it is safe for human usage. The drug manufacturer starts this process by determining how much drug is too large of a dose, so no one will be harmed in the upcoming trials. Afterwards, the compound is put through Phase I tests. This is when the compound is tested in 20-100 healthy humans to establish tolerability and basic safety profiles. The company is looking for how the drug moves in, around and out of the body (absorption, distribution, metabolism and elimination).

From here, the drug moves to Phase II studies which is when the drug is used on several hundred patients who are sick with the disease that the compound is intended to treat. This phase helps to establish what kind of dose should be given to patients, if the drug works and gives short-term safety information.

If the compound is a success, it will go to Phase III trials. For this phase, hundreds to thousands of sick patients are tested. This establishes longer-term safety information, while still looking at dosage and efficacy information.

At this point, the compound’s information will be submitted to the FDA. After (if) the FDA approves the compound, it will be produced and introduced to the public for use.

This entire process costs the drug company \$800 million to \$1.7 billion dollars (1) which is why they are allowed to hold a patent-to recoup the money they just spent.

(1)Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy. Second Edition. Golan DE et al (eds), Lippincott Williams & Wilkins, 2008

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