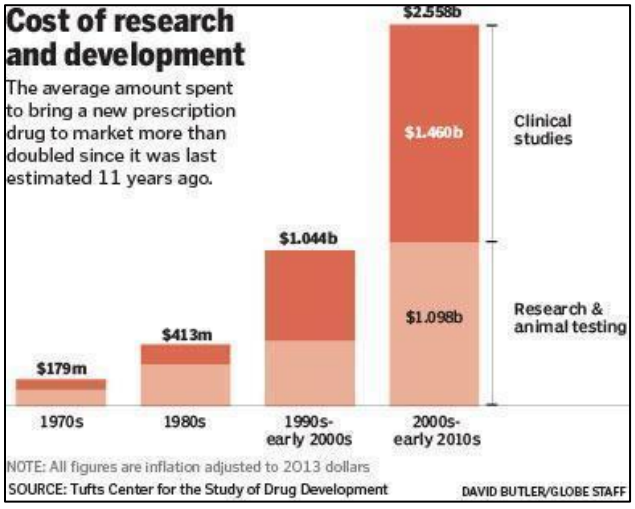
Pharmacy Industry Revenue Streams

During the next few weeks, we will review ways in which revenue streams are generated in the pharmacy industry, more specifically focusing on drug manufacturers, drug wholesalers, pharmacies, pharmacy benefits managers (PBMs), and plan sponsors. To get a holistic view of this topic we must first start with the basics. Pricing and revenue streams in the pharmacy industry are primarily based on the negotiated price of the drugs themselves. With that in mind, we need to establish the difference between brand and generic drugs and the process of how each separate drug enters the market. It is important to understand this difference because as we will later see, PBMs negotiate the prices for these two categories separately. We will also discuss why brand name drugs tend to be more expensive than generic drugs. For this article, we will primarily be focusing on brand drugs, also referred to as single source drugs.

For any drug, vaccine, or medical device to be marketable in the US, it must first be approved by the **Food and Drug Administration (FDA)**[1]. During the coronavirus pandemic we often see on the news how drug companies are beginning to produce vaccines, but then the news anchor announces that the vaccine may not be available until 2021. Why is this? To simply put it, it takes a lot of time and money for a product to get FDA approved. This may seem unfair to the public, but the reasoning behind it is to ultimately ensure that the product works as intended and is safe for human administration.

To be FDA approved there are several steps the manufacturer needs to go through. On average it takes about 10 years and over $2.6 billion dollars for any drug to become FDA approved[3]. Not only does the drug manufacturer have to invest capital into drug research and development, they must also pay for applications submitted to the FDA. The fees are often several thousands of dollars and are based on how many drugs the drug maker already has on the market. Not only is the overall process very costly to the manufacturer, but they also risk not receiving FDA approval. If the drug is not approved it cannot be marketed, and therefore no return on investment can be made.



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Once a drug maker has created a molecule, they must first obtain a patent for that molecule[1]. The US Patent and Trademark office will grant the drug maker a patent that is on average valid for 20 years. After the drug maker has obtained a patent, they will begin preclinical trials. In preclinical trials they will test the drug in animals and other lab studies to make sure it is safe and does not cause harm.

After the drug is determined to be safe, they must then submit an **Investigational New Drug Application (INDA)** to be able to begin human clinical trials. The INDA will establish the chemical structure of the drug and how the researching company intends to conduct clinical trials. Clinical trials have three phases and each phase serves a different purpose. The data collected in these trials eventually goes into a **New Drug Application (NDA)**. A report published by the Biotechnology Innovation Organization stated that just 9.6% of drugs that enter clinical trials ultimately get approved.

Phase 1 Clinical Trials

- Aim to establish human safety and dosing
- Typically feature a small group of 20-100 healthy volunteers or people who have the disease the drug is designed to treat
- About 70% of drugs move on from this stage to the next

Phase 2 Clinical Trials

- Aim to establish efficacy (if the drug works) and side effects
- Several hundreds of people with the disease participate
- Only 33% of drugs move on to the next phase

Phase 3 Clinical Trials

- Aim to establish efficacy and continue monitoring adverse events
- There are typically 300-3,000 volunteers in this phase
- After completing phase 3 trials, only 25-30% of drugs go on to get approved and marketed.

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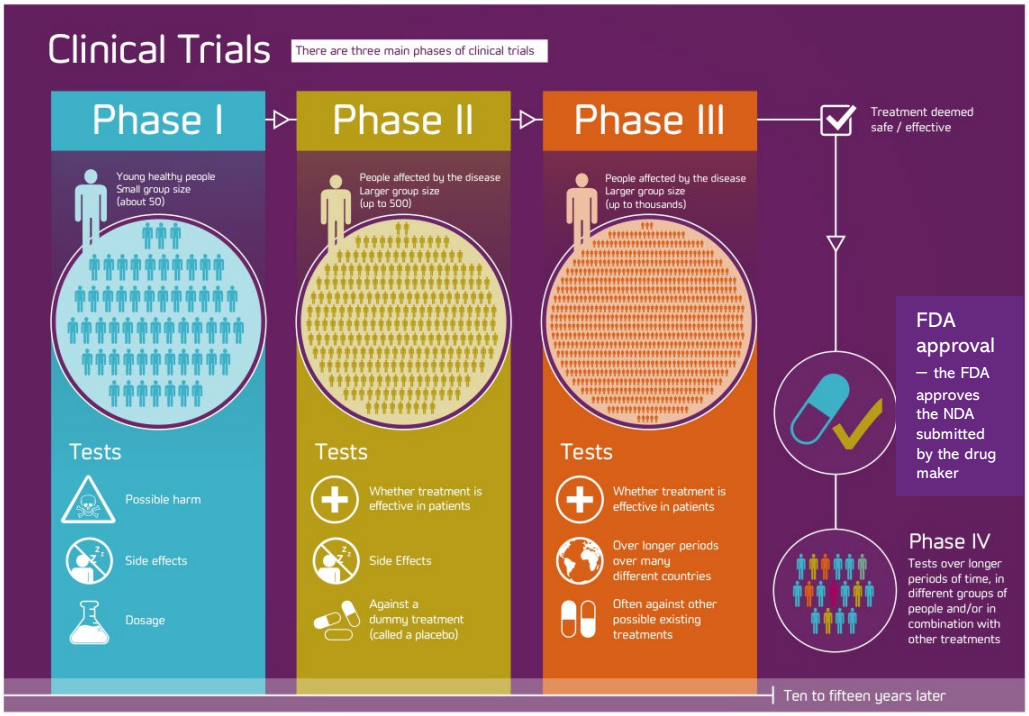

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FDA Approval

- The NDA is what the FDA reviews when approving new drugs to go on the market
- Once the drug is ready to be marketed, it usually enters the market as a brand name drug.

Phase 4 Clinical Trials (sometimes referred to as post-marketing studies)

- The purpose of these trials is to continue gathering safety and side effect data on the drug
- This is because a larger amount of people will be taking the drug so side effects that were not seen previously seen in a controlled environment will appear in the general population.
- Therefore, we sometimes see drugs being pulled off the market after several years.
    - The popular drug Vioxx (rofecoxib) was approved in 1999 to treat arthritis. Post-marketing observation found that Vioxx increased the risk of having a heart attack, so it was withdrawn from the market in 2004[2].

The FDA will also grant the creator a period of exclusivity in which only they can produce that drug[1]. In most cases the exclusivity period is 5 years from the date that drug was FDA approved. The period of exclusivity is granted to allow the manufacturer to market the drug even if their patent has expired (remember, patents are only good for about 20 years). The purpose of the exclusivity period is to allow the drug maker a period of time to make a return on their investment. Since this exclusivity period is relatively short compared to the time and amount of money spent on research and development, this causes the drug price to be high.

So, when we hear about how expensive brand name drugs are, consider the billions of dollars that were invested to produce the drug and the others that never made it to market. Manufacturers have several ways that they can extend their period of exclusivity such as conducting pediatric trials and finding new indications for the drug. Once this period of exclusivity is over, generic versions of the drug have the opportunity to enter the market.

To summarize, brand name drugs must first be FDA approved before they can be marketed. This approval process involves billions of dollars in investment and several years of research and development. The reason why brand name drugs carry a high price tag is due to the need for a return on investment in a short period of time. Next week we will explore the generic drug process, learn why they tend to be much less expensive, and compare the two.

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Resources

[1] FDA Drug Approval Process. (n.d.). Retrieved from https://www.drugs.com/fda-approval-process.html

[2] Finkel, R. (2012, October 13). 8 FDA Approved Drugs That Were Pulled from The Market. Retrieved from http://www.drugsdb.com/blog/fda-approved-drugs-pulled-from-market.html

[3] Seiffert, D. (2016, May 25). Report suggests drug-approval rate now just 1-in-10 . Retrieved from https://www.bizjournals.com/boston/blog/bioflash/2016/05/report-suggests-drug-approval-rate-now-just-1-in.html

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