# Market Analysis of Development of New Antibiotics

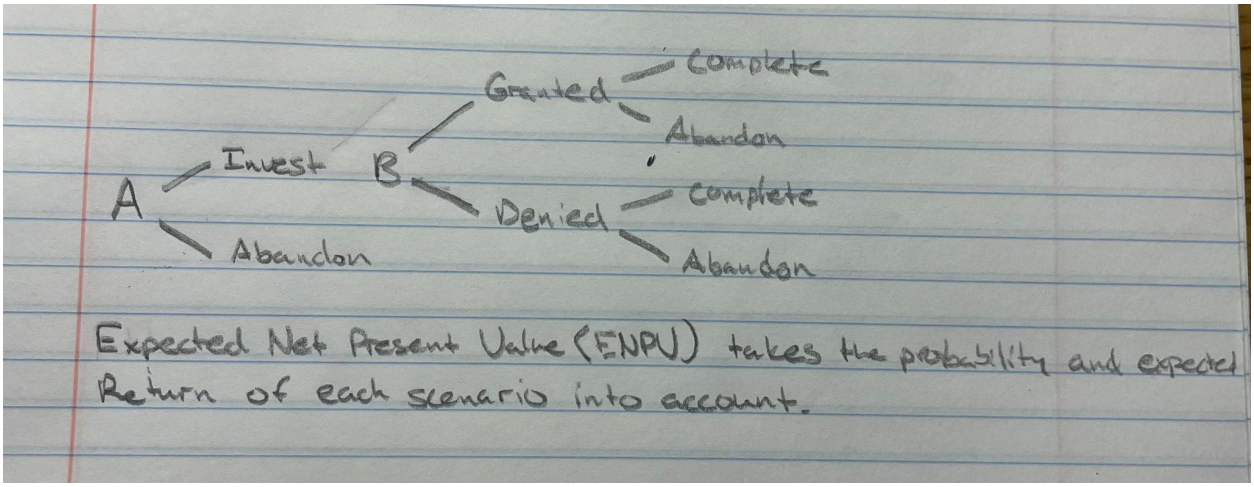
In the struggle against a constantly evolving enemy, scientists are fighting to keep up. The process of developing new antibiotics is crucial to help dampen the impact that antibiotic resistance has on our health. However, the process of developing antibiotics becomes very complicated when taking into account the political and economic barriers to this development.

The political process of developing antibiotics includes an excess of red tape and regulations that aim to confirm the safety of newly generated drugs but often overcomplicate the process of bringing the drug to market. This, in turn, can disincentivize the pharmaceutical industry as they may not wish to engage in the long and drawn-out process of being granted approval on a new antibiotic by the FDA(Food and Drug Administration) or an international equivalent. Additionally, those that profit from pharmaceutical innovations (the corporate shareholders, CEOs, etc.) finds that the development of other new drugs, such as cholesterol medication, is a safer and more profitable business venture. As a result, the capitalist economy that drives corporate motives, coupled with the political regulations surrounding the pharmaceutical industry, yield few incentives to encourage the development of antibiotics. However, the unprofitability of developing new antibiotics can be challenged by alternative financing options that distribute the risk and political actions that give priority to antibiotic development over other drugs. These actions can make antibiotics a less risky and more viable investment for pharmaceutical companies and should break the deadlock and allow new antibiotics to reach the market.

**What causes reservations amongst pharmaceutical companies to invest in antibiotic development? What makes antibiotics not profitable to pharmaceutical companies as opposed to other drugs?**

The global market for antibiotics grew by 5% per year, which is low compared to an increase of >16% for vaccines and antiviral drugs. Antibiotic development is not prioritized because of low anticipated returns in investment. Long development times and low probability of success means that rational investors must expect sales well beyond R&D (Research and Development) costs, which in the case of antibiotics is not realistic. Also, many antibiotics are prescribed for a relatively short course, anywhere from 3 days to 2 weeks, as compared to a course of years or decades for anti-hypertensive or cholesterol medications. This makes antibiotic development less profitable for the corporate sector.

The graph below perfectly illustrates the importance of corporate investment over the entire course of development. Everything depends on incoming cash flow. Anytime the cash flow stops, the project is put on a hold and reversed back to the fundraising stage.




Pharmaceutical companies need to make monetary decisions to start, continue, and complete development projects at specific thresholds and they make these decisions based on criteria such as available funds or the likelihood of FDA approval. They use the probability that they will be granted the necessary criteria to develop the drug to determine whether or not it is a worthwhile business venture. As a result, sometimes pharmaceutical companies start the development of antibiotics, but after a certain phase abandons these projects to cut their losses.

**How does the government support or hinder antibiotic development?**

As antibiotic resistance has peaked over the last decade, the United States government has taken measures to incentivize the research and development of antibiotics. Given that antibiotic development has at times not been profitable for pharmaceutical companies, the United States government has launched programs to financially support research and development and has also installed mechanisms to promote such things. One of the most important mechanisms that the US government uses to promote R&D is the "push" and "pull" mechanisms (sometimes referred to as "push" and "pull" interventions). To accelerate research on antibiotics, the US government uses the "push" mechanism to provide funds to pharmaceutical companies upfront as an incentive, as well as uses the "pull" mechanism to provide funding after the research has been completed. The US government has also installed numerous programs to support antibiotic research funding such as the National Action Plan for Combating Antibiotic-Resistant Bacteria, or the Biomedical Advanced Research and Development Authority (BARDA). BARDA for instance has provided 1.2 billion

dollars in research funding and development. The majority of US government antibiotic regulation comes from the Centers for Disease Control and Prevention (CDC) and the FDA.

**Who are currently the big players in the pharmaceutical industry? What kind of influence do these companies have in antimicrobial resistance?**

The pharmaceutical industry in the United States is currently being dominated by companies such as Johnson and Johnson, Pfizer, Roche, Eli Lilly, and Novartis. These companies are worth upwards of a billion dollars on the stock market. The pharmaceutical industry, otherwise known as Big Pharma, has a great influence on the ongoing trend of antibiotic resistance. Consumers of antibiotics are at times considered victims of mass-market manipulation, played out by Big Pharma. Big Pharma uses tactics such as abuse of the patent system and increasing drug prices. What many consumers don't realize is that this kind of unfair practice and manipulation is majorly enriching manufacturers and further contributing to the antibiotic resistance crisis.

**Should the United States be learning from other pharmaceutical funding models?**

The question of: Should the United States learn from other pharmaceutical funding models is a bit more complicated than just yes or no. There are many factors to consider with funding models and not every funding model is going to work for every country the same way. What we have to look at is what aspects of our current funding models work and what don't and what we can take from other funding models. There are two good examples of funding models utilized by different countries. The first is the US's program known as BARDA or Biomedical Advanced Research and Development Authority. The second is known as IMI or Innovative Medicines Initiative which was implemented by the EU. Both initiatives vary greatly when it comes to who can be funded by them. IMI for example only provides funding to companies in the EU(European Union) whereas BARDA provides funds regardless of location. BARDA only funds projects that are "dual-use" which means they are used both for biodefense and also for commercial use. For IMI, biodefense isn't necessary and in addition, it focuses more on the developmental path of the antibiotic. Both models have their pros and cons but to truly improve our current system, the US should be looking at alternative models either to switch to those models or to take parts of them to improve our current model.

**What are some models that have yet to be implemented by the US government that may help?**

**Call Options for Vaccines (COV) Model:**

The COV model proposes an incentive mechanism combining both push and pull methods, based loosely on the principles of call options in equity markets.
Instead of buying the right to purchase a stock at a future date, the purchaser buys the option to purchase a set number of pharmaceuticals at a date in the future if the drug comes to the market. The purchaser has to pay a small buy-in at the time of buying the option. This buy-in facilitates the R&D costs of antibiotic development.
The purchaser is not exposed to the risks and potential costs of any further development, and companies are potentially given money at crucial, earlier stages in the development process.

**Public-Private Partnerships(PPP):**
When the drugs for diseases such as Malaria, Tuberculosis, and Filariasis were deemed to be low in return, they, like antibiotics, were not developed, but public-private partnerships or PPPs utilized multiple parties to bear the R&D costs to help distribute them. These PPPs took funding from charities, pharmaceutical companies, and biotech firms to fund the development of the drugs. However, with all parties working together, the drugs were produced in a not-for-profit format. As such, the pharmaceutical companies only participated to a certain degree. With the development of antibiotics, the PPPs can be more productive if they create monetary benefits for all contributing parties. For example, a PPP might rely on a pharmaceutical company, the government, and academia for funding and after the development and sale of the antibiotics, each party would share in the revenue. Additionally, if the government is involved, the process will lack much of the government-imposed red tape that would be made subject to the pharmaceutical companies that run programs unaffiliated with the PPP.

**Regulations:**
In Europe, the Innovative Medicine Initiative (IMI) attempts to decrease regulations and the costs associated with them by providing the pharmaceutical companies with the trials necessary to receive approval on a certain drug rather than make them pay for and conduct the trials themselves. If implemented by the U.S. pharmaceutical companies would have the extra initiative to develop antibiotics as the U.S. recently added five years of exclusivity to newly developed drugs that fight "pathogens with 'potential to pose a serious threat to public health.' " (Schäberle and Hack) This allows the pharmaceutical companies that produce drugs that fit the criteria a patent or exclusive right to produce and sell those drugs for an additional five years. This makes them quite profitable because the pharmaceutical companies stand to gain an additional five years of revenue on a drug for which they set the price and have no competition. This gives a specific boost to antibiotics over various other drugs as the pathogens it fights do pose a serious threat to public health.

**Conclusion:**

Many different factors come into play when trying to push new antibiotics to market. Unfortunately, antibiotics are inherently unprofitable which means that most companies aren't willing to produce them. This lack of incentive means that governments or private investors must create artificial incentives if they want antibiotics to be reliably produced. Governments often use different funding models to create this incentive but they don't always work as well as expected meaning it may be good to look at other models for inspiration. A variety of other factors come into play too when the antibiotics hit the market such as the regulations placed on them. The market for antibiotics is a complex but critical part of fighting against the invisible threat that is bacteria.

**Citations:**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