Why Are U.S.A Drugs So Expensive?

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The United States has long been a country with increasingly expensive drug pricing. A hypothesis that presents a reason for this is the fees and regulations the FDA puts on the market. When truly diving into the interworking of the FDAs regulations on drugs most are impractical. Looking at the outcome data on these proves that. Especially with the required testing procedures, user fees, and improper regulations. Overall all these issues are creating an continuing influx in drug pricing. This paper aims to dive into these intertwined problems to show how they contribute to the expense of healthcare.

To begin with, the FDA requires an intense testing process that can cost upwards of a billion dollars. There are three phases for this testing process: animal qualification, biomedical qualification, and clinical outcome assessments. (“Drug Development Tools”) Of course this has not always been required as safety measures add on with the intent of improving our health. However as more regulations affect the market, approval pricing rapidly rises. In 2010 a study by Steven Paul exploring the rapid decrease in R&D concluded that drug approval from hit identification to approval cost $1.8 billion (Paul). Then another study just by Tufts University found that just three years later it cost around $2.8 billion.(DiMasi) These increases in drug approval pricing had huge hits on R&D, which is an evaluation on how much new revenue is associated with dollars invested into these drugs. Pharma companies hit an all time low as even when making drugs with minimal improvements it still cost them around $6 billion per drug, in 2020 to 2024. So to combat this the market sees an evident steady increase in pricing.

It is not just extensive safety procedures that keep these prices rising, but also the annual fees of the FDA. The FDA racks in around $2.7 billion annually in users fees making up 45% of their overall budget. User fees were originally initiated in the early 1990s only starting with the Prescription Drug User Fee Act.

TOTAL USER FEES COLLECTED DURING EACH PERIOD ($ in millions)

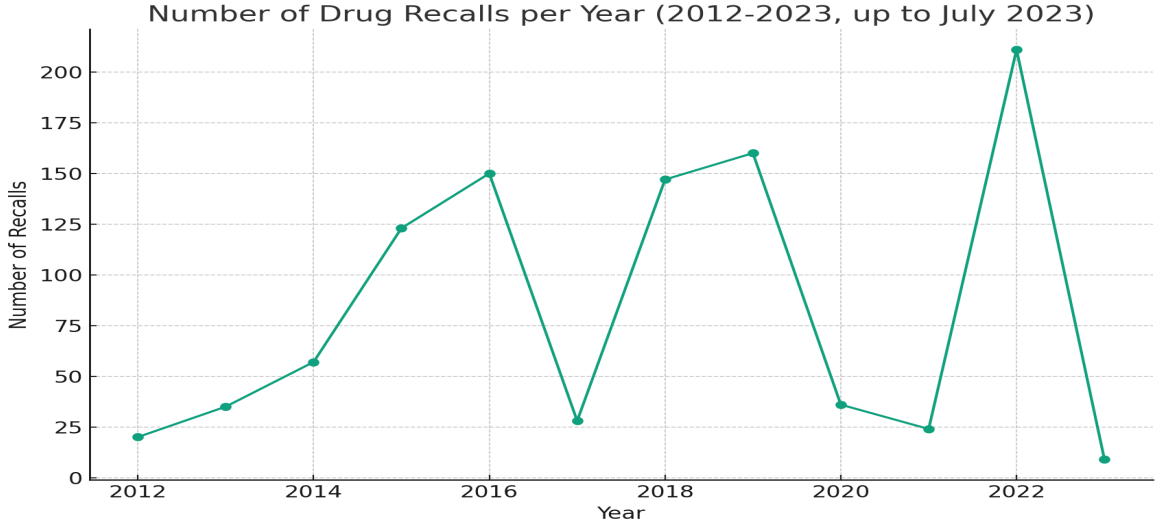
	1993-97	1998-2002	2003-07	2008-12	2013-17
PDUFA	$328.8	$680.2	$1,435.9	$2,848.5	$4,009.8
MDUFA			$143.3	$315.4	$631.1
GDUFA					$1,555.2
BsUFA					$92.6

(Hayes)

This chart shows how much they have collected from these fees in previous years, always being in the millions even the first year. The reason why this is shocking is that most members of the FDA at the time were against user fees. They feared that it would stifle innovation, and it has. With the user fees drastically increasing, smaller drug companies fall off and new companies can not afford to appear. In the years of 2013-2017 they collected a total of $4 billion while only 5 years later in 2022 each user fee was increased to $1.15 billion (Barnhorst). That means they are now taking around ¼ ,of what they totaled in four years, from each individual company. All this leads to this expensive upheaval in drug prices as companies try to keep afloat.

Despite all the regulations the FDA does have it does not put a regulation on price as many other countries do. It is one of the key reasons why our prices are so expensive compared to others. The country truly saw this when Florida was given the greenlight to import drugs straight to consumers from Canada. Canada and many other countries have crucial systems in places to keep drug prices from getting out of hand. There are boards that evaluate the effectiveness of a drug and the maximum amount the drug should be worth. (Houston Healthcare). Unfortunately importing drugs is not a permanent solution as Canada can not afford to supply the entire USA and there are risks involved. One thing Canada does that is also highly resourceful is they evaluate what the drug is meant to accomplish and if there is something already similar on the market they do not move forward with the drug. This system promotes improvements keeping companies and the government from wasting their time as the U.S. is.

Some might debate that all these requirements for drugs are an assurance to keep citizens safe. However there is proof that the FDA does not need to go to such extensive matters. For example, emergency use can be granted to drugs even when they don't go through the entire testing process. One instance is with the Pfizer-BioNTech vaccine which gained emergency use approval on December 11, 2020. People were alarmed by this, so the Acting FDA Commissioner Janet Woodcock put out a statement announcing, “this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires…”. This proved correct when after more testing it became fully approved May 10, 2020 (“FDA Approves First COVID-19 Vaccine”). Therefore, even the FDA was confident that it already met the required standards without needing to spend the extra money on the full process most do. That is just one example though, surely the added testing and requirements has displayed safer drug outcomes. Except it hasn't, showing instead an increase in drug recalls.



(Bruntz)

These drug recalls did not occur because they violated new regulations, or more testing proved them harmful. Instead these drugs were mainly recalled because of in field incidents that negatively affected consumers. Clearly with more expensive precautions it's not helping to increase safety. What it is helping to do is drive up cost.

In conclusion, the hypothesis that the FDAs fees and regulations on drugs are causing the extreme expensiveness, has effectively been proven by this paper. The intensive testing requirements are making creating a profit near impossible unless companies increase their pricing. Then on top of that annual fees continue to pile up stifling new companies ability to contribute and furthering pricing increases. The regulations they are adding are not the ones that need to be prioritized, which is proved by the success of other countries and data. It is apparent that this is something to take note of.

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