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Citron Research Explains Why AbbVie is on its way to $60.

The changes to drug pricing are in the early innings and AbbVie just got up to bat.

Last week Citron tweeted about AbbVie being the **"next great drug short"** based on recent comments made by FDA Chief Scott Gottlieb about biosimilars and the removal of the safe harbor act. Citron contends that if the government is going to act accordingly and stand by their words than AbbVie stock will trade at $60.

What makes AbbVie a short is not the fact that they are one of the worst abusers of the system for years, as Citron will explain in further stories, including pay for delay and double-digit price increases. This is well known and has been.

AbbVie's egregious pricing practices are well documented. Blue Cross Blue Shield ranks ABBV #1 in its list of the "10 worst drug price offenders".

Everybody knows that AbbVie (ABBV) is a story of Humira. It's a story of the world's highest selling drug that has been on market for 20 years now without competition and unfettered pricing power. It's a story of $18 Billion in estimated sales for 2018, pay for delay cases that extend the patent exclusivity to 2023 (in the US), and a slow ramp of biosimilar due to interchangeability issues and the "rebate trap".

What makes AbbVie a short is that there finally seems to be changes coming to the system in two words, Biosimilars and Rebates.

Gottlieb on Biosimilars

Last week in a speech to the Brookings Institute FDA Chairman Scott Gottlieb all but called out AbbVie in his strong remarks regarding the tactics of pharmaceutical companies in blocking biosimilars from the marketplace.

> *"We're not going to play regulatory whack-a-mole with companies trying to unfairly delay or derail the entry of biosimilar competitors. We're not going to wait a decade or more for robust biosimilar competition to emerge."*
>
> - Speech to the Brookings Institute **FDA Chairman Scott Gottlieb**

These are not the words, of Citron, this is the head of the FDA.

https://www.brookings.edu/events/u-s-market-for-biosimilars-fda-scott-gottlieb/

This is the video of Gottlieb's speech (good stuff starts at 42:00).

In his speech we learn that:

- Biologics represent 70% of pharmaceutical spending growth
- The current payment system isn't taking advantage of potential savings
- The fact is that the biosimilar market isn't as robust as people hoped
- "Competition is anemic"
- "It's anemic because litigation has delayed market access that are, or shortly will be, available outside the US"
- "Consolidation across the supply chain has made it more attractive for manufacturers and pharmacy benefit managers and distributors to split monopoly profits through lucrative volume based rebates on biologics"
- 35%/43% lower prices for biosimilars

This speech was also discussed in the following article from Bloomberg.

"Drugmakers Game the Patent System and Reap Billions, FDA Says"
By Anna Edney | July 18, 2018, 10:38 AM PDT | Bloomberg Business
https://www.bloomberg.com/news/articles/2018-07-18/fda-blasts-drugmakers-thwarting-competition-on-costly-biologics

In a double whammy to AbbVie, last week also came a proposed change in government policy to get rid of the safe harbor provision and eliminate the rebates that have allowed AbbVie to maintain dominance.

Rebates

Last week the Office of Management and Budget posted a new proposed rule for review that would remove the safe harbors that PBM's use to negotiate rebates and not be subject to the Anti-Kickback Statue. Without these safe harbors it could be considered a bribe to offer a discount to a PBM in exchange for an advantageous formulary spot – WHICH IS EXACTLY WHAT IT IS.

https://reginfo.gov/public/jsp/EO/eoDashboard.jsp

How Does the Rebate Trap Work?

An article in the Journal of the American Medicine Association describes in a more complex way the rebate system that plagues the pharmaceutical industry. (https://jamanetwork.com/journals/jama/article-abstract/2625049?resultClick=1).

Its complicated but it works like this:

- Let's assume you're an insurance carrier with a sufficient number of rheumatoid arthritis and psoriasis patients to generate $1 Billion in Humira claims per year
- ABBV offers you a 50% discount (rebate) through your pharmacy benefits manager (PBM) who is operating under the safe harbor that has been granted to them (legal kickbacks)

The Net of your rebate is a capital outlay of $500m/year to ABBV

****The rules around biosimilars are different than the average generic drug, importantly biosimilars may not be approved as "A/B rated" or "Interchangeable" – which is a fancy way of saying that the pharmacist won't be able to tell existing patients that a new, less expensive, biosimilar has been approved and they should switch to it… because there is no switching if you don't have an "A/B rating"… only NEW patients are eligible for the less expensive alternative.*

Now lets jump back into roll play

- You're an insurance company that – net of a 50% rebate – spends $500 Million on Humira per year
- A new biosimilar is approved but it is NOT interchangeable so only new patients are eligible for the drug, your existing population will be on the branded drug for 10+ years to come (this drug treats chronic but not deadly diseases so the patients stay on for a long time)
- The biosimilar is going to be priced at a 50% discount to your current net price, which will be great because all the new patients will get the less expensive alternative right?

Wrong

- As soon as the biosimilar is approved you get notification from ABBV that should you choose to add the generic version of Humira to your own formulary they will immediately pull their rebate from you
- Now you can't switch your current patients to the generic Humira – because of the tricky "interchangeability" stuff so you are looking down the barrel of a now $1 Billion expenditure due to the loss of the rebates. AND THERE IS NOTHING YOU CAN DO ABOUT IT
- So you never put the biosimilar on formulary because the upfront hit to profit is simply too high, the public never gets to use the biosimilar generic, and there is no cost savings realized for the system

AND ALL OF THIS IS POWERED BY THE PBM'S ABILITY TO BUILD LARGE REBATES INTO THE SYSTEM UNDER THE SAFE HARBOR PROVISION THAT IS BEING TORN UP BY THE TRUMP ADMINISTRATION.

All of the information that we will backfill into the story in future reports will show the problems to the system created by AbbVie. Citron will detail the years of litigation, egregious prices increases, and pay for delay in their attempt to achieve exclusivity and hinder interchangeability. Citron will also show the money paid to consultants and politicians to keep the stranglehold on the system.

If any talking head on television or analyst defends AbbVie in this matter, they are simply showing they have no faith in government to right a wrong. No one will ever doubt that AbbVie has "gamed" the system the only thing that was in doubt is do we have a system that can be fixed.

Citron hopes yes.

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