



# Has Big Pharma Become an Unhealthy Place to Invest?

Connor Cloetingh, Senior Lead Research Analyst

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For the first time, the US government (via Medicare) is now directly setting prices for 10 US-manufactured drugs, potentially giving rise to other drugs being subjected to similar treatment and possibly marking a sea change for the pharmaceutical industry. Will this new era make big pharma un-investible? How should investors position their portfolios to capitalize on innovations occurring elsewhere in the healthcare ecosystem?

With the passage of the Inflation Reduction Act, the Center for Medicare and Medicaid Services (CMS) was granted expanded powers to negotiate lower drug prices for Medicare recipients in the hopes of reducing government expenditures and costs for consumers. Recently, a list of 10 popular drugs was published by CMS that will be first up for negotiation in 2024, with these negotiated prices going into effect in 2026. Following these first 10 drugs, CMS plans to negotiate an additional 15-20 drugs per year.

The manufacturers of these drugs have been pushing back against this legislation, claiming it is unconstitutional. Lawsuits by a number of drug makers claim that their First, Fifth, and Eight Amendment rights have been violated. The basis of these claims centers on the drug makers' belief that what is taking place is not a negotiation, citing large financial penalties or risk of Medicare not covering the drug at all if the prices offered by CMS are not implemented.

With courtroom battles likely to span several years, trying to predict the outcome of the various lawsuits is counterproductive, in our view. However, as investors we need to understand the financial risks and opportunities that may exist as a result of the most significant healthcare legislation since the Affordable Care Act. To do so, we need to understand explicit financial impacts the pharmaceutical companies may face and the implicit long-term impacts to the pharmaceutical industry's business model as a whole.

A 2021 report by the Congressional Budget Office compared Medicare drug pricing to the prices paid by other federal agencies. Its analysis showed that historically, the Department of Veterans Affairs (VA) paid approximately 50% of what Medicare paid. It would be reasonable to assume that this kind of discount would be what CMS would be targeting for the Medicare program.

Armed with this assumption, the potential earnings impact facing pharmaceutical companies ranges from a relatively negligible 1% decline to a more modest 12% decline in 2026. The latter (2026) is far enough out in the future to afford investors with time to recalibrate their expectations, but not knowing what's next could limit the outperformance of some companies' stock prices.

Longer-term, as drug makers seek to adapt to the changes imposed by the Inflation Reduction Act, a shift in big pharma's business model could materialize. This could result in a decline in research and development spending on new drugs, particularly for patients 65 and older (the primary Medicare cohort).

Additionally, given that pharma companies could expect a lower return on investment for drugs that fall (or may fall) under the Inflation Reduction Act, they may be more likely to invest in areas with higher return potential. Higher

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returns could come from partnering with or acquiring biotech companies that focus on rare diseases or genetic disorders. While these patient populations are smaller, there are usually limited options for these patients, meaning that prices can be higher and are less likely to be negotiated by CMS.

Another implication could be reduced competition from generics. This may seem counterintuitive, but the logic is that if an on-patent drug's price is already low, there is less room for a generic drug to come in and take market share once a drug's patent expires.

Pharmaceutical companies are often portrayed as trying to maximize profits at the expense of consumers. The reality is they have a limited window of time when they can earn a return on investment. If the potential for returns is reduced, investments may be reduced, and patients could suffer.

While we are in the early stages of understanding the true impacts of the Inflation Reduction Act, other innovative areas of healthcare less exposed to government intervention, such as medical devices or biotechnology, may be a better place to look for higher returns in the future.

Medical device companies face similar levels of regulatory scrutiny as pharmaceuticals in getting products approved. Years of research and development and clinical trials are needed before a product can be offered to the market. Where things differ from pharma is the way in which the products are sold. Some devices are considered capital equipment, which are purchased by a

hospital for the benefit of thousands of patients over a multiyear period. Other products used during a surgery are just one component of an overall procedure. This distinction makes it much more challenging for CMS to negotiate a singular price like it can with oral medications, given the larger variety of factors at play.

Biotechnology may also benefit from Inflation Reduction Act legislation. Biologics will have 13 years from approval until they are eligible for Medicare negotiation, compared with 9 years for traditional small molecule pharmaceuticals. This means that large pharma will likely be acquirers of biotechnology companies, in the hopes assembling a product portfolio more protected from government intervention. Equity prices could therefore outperform, reflecting the potential for higher interest from strategic buyers.

In summary, large pharmaceutical companies will likely need to make a shift in strategy to focus on areas less impacted by the Inflation Reduction Act. Some companies may make a successful pivot, while others may not. The winners and losers will be sorted out over the next several years, and in the meantime other areas within the healthcare sector may be a better place to invest.

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