

What's Next for Health Care Investors?

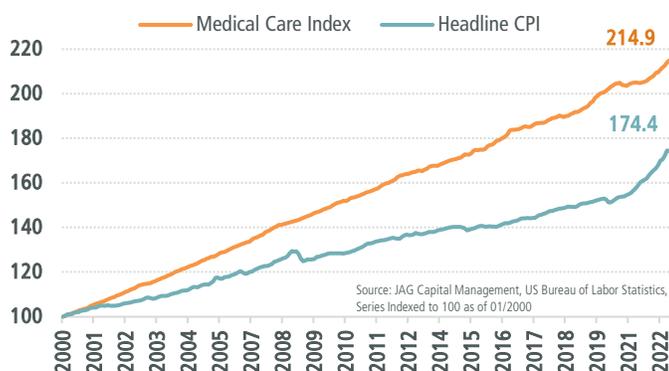
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Summary

The Inflation Reduction Act has major implications for many investment sectors, including Health Care. This Insight focuses on the powers granted by the Act to Medicare to negotiate drug prices over a multi-year path. The effects will not be felt evenly across the industry. Drug companies with the forethought to have built robust pipelines of next generation assets remain positioned to continue to grow through the eventual pricing pressures, while drug companies reliant on one or two blockbuster drugs stand to suffer.

Despite the well documented problems that have long plagued the US health care system, policy makers have historically struggled to pass major reforms. This has contributed to decades of higher rates of inflation in US health care costs compared to the broader Consumer Price Index (CPI).

**Headline CPI vs Medical Care Index Growth
Jan 2000 - July 2022**



The recent passage of the Inflation Reduction Act establishes a framework policymakers hope will start to address the high costs of health care for Americans. Several of the more notable provisions include:

- Grants Medicare the authority to negotiate prices on certain drugs
- Establishes a cap on price increases for Medicare covered drugs
- Redesigns key components of the Medicare Part D framework
- Officially repeals the Trump Administration's drug rebate rule

Implementation Timeline/Eligible Drugs

For the small percentage of drugs that survive the regulatory hurdles between discovery and commercial approval, the average time on market prior to generic entry is 14 years. This "exclusivity period" exists due to patent protection for the intellectual property of drug developers. After patent expiry, generic/biosimilar alternatives are introduced, resulting in lower prices for both the brand name and duplicate drugs. Pfizer's mega blockbuster drug Lipitor, which helps reduce high cholesterol in patients, provides a good case study to understand a drug's natural lifecycle. Following its launch in 1997, Lipitor's worldwide sales grew from \$865M in year one to a peak of \$12.9B in 2006, making it one of the best-selling drugs of all time. In late 2011 Lipitor's patents expired, allowing numerous generic alternatives to enter the market. In the first year following generic entry, Lipitor's average out of pocket costs in the US declined by >50% and by 2015 the drug was priced at an 80% discount to levels prior to when the drug lacked generic alternatives.

Although many proponents of drug pricing reforms overlook this point, the profits generated during a drug's exclusivity period may serve a broader purpose beyond just the drug in question. Drug manufacturer economics hinge on a company's commercial portfolio to cover overhead costs, make up for the many other drugs that have failed at one stage or another, support future R&D efforts, and reward shareholders who play a small but critical part in enabling the underlying innovation process. However, there have been bad actors in the past who have utilized loopholes in the system to charge exorbitantly high prices for drugs. Martin Shkreli, the former pharma CEO who acquired the rights of antiparasitic drug Daraprim and subsequently increased pricing by more than 5,000%, is the most notorious example of abuse of power. But while some drug pricing can be flawed and flagrant, high prices can be nuanced and not all are necessarily outside the realm of reason.

The Inflation Reduction Act sets up a multi-year path to overhaul the legacy drug pricing model. Beginning in 2026, the top 10 Medicare Part D (outpatient) drugs based on total spend will be subject to a negotiation process involving the drug's manufacturer and the Department of Health and Human Services. In the years following, the number of eligible drugs will gradually expand from 10 in 2026 to 20+ by 2029. Further, drugs covered under Medicare Part B plans (physician administered drugs) will become eligible for inclusion beginning in 2028. The structure of the negotiation

process itself has been criticized by major drug makers, who call the policy price setting. This criticism stems from the pre-defined discounts relative to a drug's "fair price" which begin at 25% in the first year a drug becomes eligible, with further increases thereafter.

Winners/Losers

While the new pricing framework outlined under the Inflation Reduction Act certainly presents risks for the industry, companies who have built their cultures around innovation have an opportunity to capitalize on disruptions that the new rules impose to further strengthen their competitive position.

JAG's research team believes there are opportunities to identify forward thinking management teams that are cultivating broad pipelines of new drugs and have a demonstrated track record of successfully converting candidates into commercial products. Two examples include Eli Lilly and Vertex Pharmaceuticals. Lilly is on the leading edge of scientific research — remarkable for a company approaching its 150th year. It is a leader in the industry in the number of clinical trials evaluating novel scientific approaches, in contrast to companies largely focused on studying "me too" drug modalities. Vertex meanwhile is well known for the game-changing impact it has had on thousands of people living with Cystic Fibrosis (CF). Since taking the reins at Vertex in 2017, CEO Reshma Kewalramani has made it a top priority to diversify the company's reputation beyond CF. In just the past several months these efforts have produced impressive data from clinical studies across numerous different targets including a common form of kidney disease, two different blood diseases, and even a potentially curative treatment for Type 1 diabetes.

Not all companies have a culture of innovation, and companies that lean solely on one or two blockbuster drugs to carry the day will be affected by the lower Medicare pricing imposed ahead of drugs losing their exclusivity status. Investors are wise to carefully examine healthcare companies individually and the impacts the Inflation Reduction Act could have given each company's unique characteristics.

JAG's research team strives to differentiate companies through fundamental research within the context of the changing macro-environment to curate portfolios for long-term growth for our valued clients.

JAG's investment approach helps us identify great companies that can capitalize on durable sector and industry-specific trends and opportunities. We welcome your comments and questions any time!

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Ownership: Fifty-one percent ownership by a Veteran or Veterans. The applicant must share in all risk and profits commensurate with their ownership interest.

Control and Management: Proof of active management of the business. Veteran must possess the power to direct or cause to direct the management and policies of the business.

Contribution of Expertise and Capital: Contribution of capital and/or expertise by Veteran owner(s) to acquire their ownership interest shall be real and substantial and be in proportion of the interest acquired.

Independence: The Veteran owner(s) shall have the ability to perform in their area of specialty/expertise without substantial reliance on non-Veteran-owned businesses.

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