Neal Kaufman and Josh Riegelhaupt: Investing in growth and innovation in the Health Care sector

This is an edited transcript of an April 27, 2023, update with Baron Health Care Fund Portfolio Manager Neal Kaufman and Assistant Portfolio Manager Josh Riegelhaupt. To access the full video, please visit our website.

Executive Summary

- Health Care underperformed the broader market in the quarter due to a rotation out of last year's outperformers coupled with several sub-industry-specific headwinds.
- COVID-related headwinds are fading, device companies and hospitals are seeing medical procedure volumes recover, and valuations are compelling in the managed care space.
- In a major development, Medicare reimbursement will now be subject to drug price negotiating or price setting. While this new policy will ultimately change the way Medicare reimbursement is handled, much remains to be clarified.
- Our long-term outlook for the Health Care sector remains bullish.

Introduction

Neal Kaufman joined Baron in 2005 as a research analyst specializing in health care and has managed Baron Health Care Fund since its 2018 launch. He has 22 years of research experience. Josh Riegelhaupt joined Baron in 2014 as a research analyst and was named assistant portfolio manager of Baron Health Care Fund in 2018 and portfolio manager of our small-cap biotechnology portfolio in 2021. He has 13 years of research experience and a Ph.D. in genetics & molecular biology from Rockefeller University.

Q&A with Neal Kaufman and Josh Riegelhaupt

Please provide an update on the Health Care sector in the first quarter of 2023.

Neal Kaufman: Health Care underperformed the market for a variety of reasons. There was a rotation out of last year's outperformers. There were also some sub-industry-specific headwinds, mainly in managed care, large-cap pharmaceuticals, and small- and mid-cap biotechnology.

Several issues weighed on managed care stocks during the quarter.

- First, Medicare finalized the Medicare Advantage audit rules, which will facilitate its collection of overpayments to these plans. This was an investor concern early in the quarter, but we believe it will ultimately have a small and manageable impact.

- Second, 2024 Medicare Advantage rates came in below market expectations. Investors reacted negatively to the initial rates published in early February; the final rates that came out early in April were slightly better but still lower than in recent years.
- Third, the pharmacy benefit manager (PBM) industry is once again the subject of political attention. While many managed care companies have internal PBM segments, we think they will successfully manage their PBM businesses through the various proposals targeting the industry. It's also possible the proposed legislation won't pass. Nevertheless, we reduced our stake in **The Cigna Group**, which makes a meaningful percentage of its earnings from its PBM business.
- Lastly, investors in managed care stocks reacted negatively to earnings reports because it appeared companies were hitting their numbers by dipping into reserves. We think investors in managed care stocks overreacted to the downside, and valuations are compelling.

Pharmaceutical stocks also underperformed in Q1. These were strong stocks last year, and the market rotated out of last year's winners. In addition, investors started to factor in the impact of the drug pricing provisions of the Inflation Reduction Act.

Finally, small- and mid-cap biotech stocks underperformed due to concerns about funding and access to capital in the wake of the collapse of Silicon Valley Bank.

Can you share an overview on what's happening with Medicare and drug pricing?

Josh Riegelhaupt: For the first time in the history of Medicare, drugs will be subject to price negotiating or price setting, as part of the Inflation Reduction Act. Starting in 2026, annual pricing for the highest-spend drugs will be up for negotiation. The negotiation will start with 10 drugs in the part D segment of Medicare, which are pharmacy-dispensed medications. In 2027, another 15 drugs will be negotiated. In 2028, another 15 drugs will be negotiated, but part B (infused drugs) will be included with part D. Ultimately, billions of dollars will be subject to negotiation.

How will this work?

Josh Riegelhaupt: A list of the first 10 drugs to be negotiated, along with guidelines, will be published on September 1, 2023. Each subsequent year, a new list will be released on February 1 for drugs to be negotiated two years later. At the risk of oversimplifying, prices for small molecule drugs (pills) will remain at market rate for about nine years and biologics about 13 years. After that, Medicare can negotiate to determine the drug’s pricing.

There are a lot of exemptions. Many orphan drugs for rare diseases will be protected, and low-spend drugs have certain exemptions. Immunoglobulin infusions are exempt. Cell therapy drugs, gene therapy, and gene editing will probably be exempt. Some small biotechs are exempt. The Congressional Budget Office estimates about $286 billion in Medicare savings. We'll see if that proves to be true.

What happens if a company does not agree to the negotiated price?

Josh Riegelhaupt: The government would impose an excise tax. That tax will probably be more than the revenue the company would have generated, even before the Medicare negotiation, so it would be a real burden. Some observers have questioned the legality of this provision. It will be interesting to what ultimately happens, but it is clear the way Medicare works is going to change.

Currently, Medicare has about 66 million enrollees, with 46% of those (about 30 million) in Medicare Advantage, the part of Medicare administered by commercial insurance companies like **UnitedHealth Group Incorporated, Humana Inc.,** and Cigna**.** Drugs in those plans are already negotiated, so it's unclear what more would be negotiated.

Overall, how much will actually be negotiated? We think of global drug consumption as half U.S. and half the rest of the world. For the U.S. portion, roughly half is commercial and half is Medicare, which we believe is likely to grow to 60% or 70% by the end of the decade. We think the implications of this new policy probably sound scarier than how they will ultimately play out.

What do you see as the bright spots within the Health Care sector?

Neal Kaufman: Over the past couple of years, labor shortages have cut into hospital procedure volumes, but we're starting to see that lift. Medical device companies are reporting strong results. For example, **Intuitive Surgical, Inc.**, which makes the da Vinci robotic surgical system, reported 26% year-over-year procedure growth in the most recent quarter. Hospital companies like **HCA Healthcare, Inc.** are also reporting strong results. Merger and acquisition activity has picked up as well. **Prometheus Biosciences, Inc.** recently announced its acquisition by **Merck & Co., Inc.** at a premium to its current stock price.

Josh Riegelhaupt: Prometheus has a drug for ulcerative colitis and Crohn's disease. It has best-in-class efficacy and is the first drug for this type of disorder with a genetic biomarker, which means that patients identified with this biomarker could potentially have better response rates.

Neal Kaufman: Merck is acquiring Prometheus at $200/share. The stock was trading around $114/share prior to the announcement. Two other names we own have also become subject to takeover speculation: **Dechra Pharmaceuticals PLC,** which is in the animal health space; and **ShockWave Medical**, **Inc.,** a medical device company.

What stocks are you particularly excited about?

Neal Kaufman: **DexCom, Inc.** is a stock we have held for many years. It is a medical device company that sells continuous glucose monitoring (CGM) devices for diabetes patients. The company is in the early stages of launching its seventh-generation device, called the G7. The G7 is 60% smaller than the sixth generation; has a disposable transmitter, a huge improvement over its predecessor, which required wearing the transmitter for several months at a time; and an industry-leading 30-minute sensor warmup. We believe the G7 will accelerate revenue growth. DexCom also has an opportunity to penetrate the global insulin-intensive diabetes population.

In addition, Medicare is now covering CGM for people with Type-2 diabetes, who use insulin daily but not necessarily at a meal or multiple times. This decision expands DexCom's market opportunity by a few million patients. Long term, we think DexCom will have the chance to expand into the even larger category of non-insulin users with Type-2 diabetes, as CGM has proven benefits for all diabetic patients.

Josh Riegelhaupt: **Rocket Pharmaceuticals, Inc.** is a gene therapy developer for non-oncology purposes such as cardiology and hemotology, in contrast to early gene therapies predominantly focused on the oncologic space. The company expects commercial launches for three products between 2024 and 2026. We estimate these products will generate billions of dollars in revenue by the end of the decade for a company currently valued at about $1.5 billion.

Genetic medicine, particularly gene therapy companies, have been notable underperformers over the past one to two years. Shares were down 60% to 70% on average. Given this broad underperformance, we thought to investigate potentially investible ideas with relatively lower biologic risk. In general, gene therapy is not biologically risky. The much bigger risk is commercial, as gene therapy is relatively new and is a somewhat alarming proposition for many patients. Imagine how you would feel about the risk/reward of a one-time infusion that would result in a drug in your system for quite a long time. It's not like a pill that leaves your system when you stop taking it. If you were dying, you would likely agree to try it, but otherwise, you may very well hesitate.

There's also the question of how insurance companies or payers will handle reimbursement. Do you pay all at one time? If you infuse a 15-year-old with a gene therapy, will it work for 65 years? How much is that worth? One country may set the cost at $50,000 a year, while another may set the cost at $200,000 a year. The good news is that Peter Marks, probably the most important person in the FDA for these issues, has publicly pushed to prove the efficacy of gene therapies. As a result, following a trough over the past two or three years, movement in this field is picking up.

Currently, Rocket is focused on treatment for Danon disease, a rare genetic disorder that causes the heart to grow from two to five times the normal size. It affects boys starting at 10 to 20 years old and girls at 30 to 40. Besides the obvious quality of life issues, these patients are in constant risk of sudden death. There are between 20,000 and 40,000 patients in the U.S. alone. In a world where prenatal genetic testing continues to rise, we will likely be catching many more of these cases.

What are the key messages you have for investors?

Neal Kaufman: Health Care offers the opportunity to invest in innovation and growth while offering defensive characteristics and stability in the event of an economic slowdown. We feel good about how the Fund is positioned. COVID-related headwinds are fading, device companies and hospitals are seeing medical procedure volumes recover, and valuations are compelling in the managed care space.

Josh Riegelhaupt: Aging demographics are going to continue. Plenty of people are going to need health care. Biotech is part of the technology space, and technology is continuing to improve. As computing power improves, so does this space. In some ways, the human body is the most sophisticated computer. We continue to make advances in navigating the human body, treating and preventing disease, and helping people live healthier and longer.

____

Investors should consider the investment objectives, risks, and charges and expenses of the investment carefully before investing. The prospectus and summary prospectuses contain this and other information about the Funds.You may obtain them from the Funds' distributor, Baron Capital, Inc., by calling 1-800-99BARON or visiting www.BaronFunds.com. Please read them carefully before investing.

The performance data quoted represents past performance. Past performance is no guarantee of future results. The investment return and principal value of an investment will fluctuate; an investor's shares, when redeemed, may be worth more or less than their original cost. The Adviser reimburses certain Baron Fund expenses pursuant to a contract expiring on August 29, 2033, unless renewed for another 11-year term and the Fund's transfer agency expenses may be reduced by expense offsets from an unaffiliated transfer agent, without which performance would have been lower. Current performance may be lower or higher than the performance data quoted. For performance information current to the most recent month end, visit www.BaronFunds.com or call 1-800-99BARON.

Baron Health Care Fund's annualized returns for the Institutional Shares as of March 31, 2023: 1-year, (11.13)%; 3-year, 14.72%; Since Inception (4/30/2018), 12.29%. Annual expense ratio for the Institutional Shares as of March 31, 2022, was 0.90%, but the net annual expense ratio was 0.85% (net of the Adviser's fee waivers). The **Russell 3000 Health Care Index**'s annualized returns as of March 31, 2023: 1-year, (4.84)%; 3-year, 13.85%; Since Fund Inception (4/30/2018), 10.67%.

Risks: In addition to general market conditions, the value of the Fund will be affected by investments in health care companies which are subject to a number of risks, including the adverse impact of legislative actions and government regulations. The Fund is non-diversified, which means it may have a greater percentage of its assets in a single issuer than a diversified fund. The Fund invests in small and medium sized companies whose securities may be thinly traded and more difficult to sell during market downturns.

The discussion of market trends is not intended as advice to any person regarding the advisability of investing inany particular security. The views expressed in this document reflect those of the respective writer. Some of ourcomments are based on management expectations and are considered "forward-looking statements." Actual future results, however, may prove to be different from our expectations. Our views are a reflection of our best judgment at the time and are subject to change at any time based on market and other conditions and Baron has no obligation to update them.

Portfolio holdings as a percentage of net assets as of March 31, 2023, for securities mentioned are as follows: The Cigna Group – 0.8%; **HCA Healthcare, Inc.** – 2.4%; **Prometheus Bioscience, Inc.** – 2.3%; **Dechra Pharmaceuticals PLC** – 0.7%; **ShockWave Medical, Inc.** – 0.3%; **Rocket Pharmaceuticals, Inc.** – 1.9%

Top 10 holdings as of March 31, 2023

Holding	% Assets
UnitedHealth Group Incorporated	8.9
Eli Lilly and Company	6.0
Thermo Fisher Scientific Inc.	5.1
Merck & Co., Inc.	4.0
Intuitive Surgical, Inc.	3.9
Vertex Pharmaceuticals Incorporated	3.6
DexCom, Inc.	2.9
Elevance Health, Inc.	2.9
Mettler-Toledo International, Inc.	2.8
Humana Inc.	2.7
Total	42.7

Portfolio holdings are subject to change. Current and future portfolio holdings are subject to risk.

The **Russell 3000® Health Care Index** is an unmanaged index representative of companies involved in medical services or health care in the Russell 3000 Index, which is comprised of the 3,000 largest U.S. companies as determined by total market capitalization. Russell Investment Group is the source and owner of the trademarks,service marks and copyrights related to the Russell Indexes. Russell is a trademark of Russell Investment Group.

BAMCO, Inc. is an investment adviser registered with the U.S. Securities and Exchange Commission (SEC). BaronCapital, Inc. is a broker-dealer registered with the SEC and member of the Financial Industry Regulatory Authority, Inc. (FINRA).