EQUITY

The Politics of Health Care

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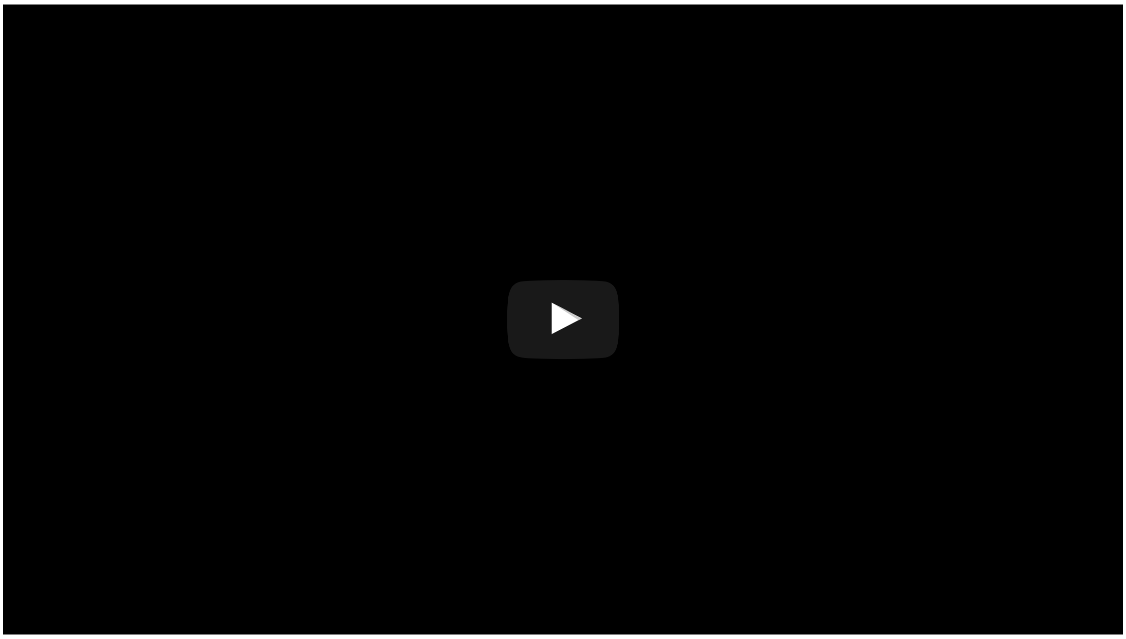
Evan McCulloch
Senior Vice President, Director of Research
Franklin Equity Group®
Portfolio Manager, Franklin Biotechnology Discovery Fund

Changing political policies and priorities can impact certain market sectors—for better or worse. Health care costs and prescription drug pricing were hot-button issues in the United States during the 2016 presidential election, and the Trump administration has been pushing forward its own health care agenda. So far this year, the health care and biotechnology (biotech) sectors have shaken off uncertainty, but are investors too optimistic? Evan McCulloch, portfolio manager, Franklin Biotechnology Discovery Fund, says drugs actually behave more predictably than politicians—but he sees reasons to affirm the market's positive outlook.



I'm a pharmaceutical drug analyst, but every few years I'm forced to be a political analyst as well, which can be challenging. In most cases, drugs are more predictable than politicians!

To recap what's been going on in the United States this year, in March, the US House of Representatives (House) bill to replace the Affordable Care Act (also called Obamacare) essentially stalled. There were not enough votes to pass the bill, and President Trump gave the House an ultimatum: Either get it done, or he would move on to other priorities. While they didn't get the bill passed then, they didn't move on either.

During the Easter recess, negotiations continued between the various conservative factions in the House, and eventually there was a compromise deal which succeeded in getting enough votes to move the bill to the Senate. Crafting a bill that can pass the Senate, however, will be more difficult and could meet significant delays, in our opinion. The Senate is currently more moderate than the House and will likely pass its own version of the bill. If that happens, the two versions will need to be reconciled before going back to both chambers for a final vote. In addition, the current plan is to have the bill deal solely with budgetary matters so it can pass the Senate with a simple majority and avoid a filibuster, which limits the scope of what it can address.

We’re long-term investors, and it’s hard for us to envision a repeal or replacement of Obamacare in place by year end. The Republicans have been attacking Obamacare for seven years now. On the campaign trail they promised to repeal it, and now some commentators believe President Trump is eying the notional savings from a repealed or replaced health care bill to fund tax reform, which is arguably a more popular agenda. Thus the delay in passing health care reform is impacting other legislative priorities as well.

Despite this uncertainty, the health care and biotech sectors have appreciated since the US presidential election in November. Hillary Clinton, the Democratic candidate, had made the high cost of many prescription drugs a major issue of her campaign. There were fears that if she were elected president, she would propose legislation that would cap prices and negatively impact the pharmaceutical sector.

The Republicans had been opposed to changes in pricing of pharmaceuticals, so when Trump won (and more importantly when Republicans maintained control of both the House and the Senate), the likelihood of onerous drug-pricing legislation significantly dropped.

Attempts to repeal and replace Obamacare could still impact companies in this space if Medicaid expansion is scaled back and people lose insurance coverage, but the current Republican plan doesn’t call for changes in drug pricing. The absence of any significant legislation since the election has in part been driving the positive returns in the sector.

As a result, the industry has refocused its research-and-development efforts on finding drugs that deliver significant clinical benefits, in terms of new treatments or meaningfully better treatments, and the long-term winners are the patients.

Looking Forward: Taxes and Regulation

We believe the possibility of tax reform will likely be the next big legislative issue to impact the biotech sector, but perhaps not in the way many people think. Most profitable biotechnology companies already have corporate tax rates in the 20%-25% range, so the currently proposed corporate tax rate reduction plan doesn’t represent a huge change.

However, with the current tax structure and companies’ use of offshore subsidiaries, cash often times get trapped overseas. Trump has proposed a tax break to incentivize US companies to repatriate this cash—that is, bring it back home—and use it to invest in their businesses. Many US companies able to repatriate that cash could use it to deliver value to shareholders, potentially through share repurchases or dividends, or what we hope to see, more mergers and acquisitions (M&A). M&A can unlock value in several ways. It allows larger companies to bolster their pipeline with new products, and gives smaller companies access to expertise and personnel of more well established companies to increase their distribution efforts.

On the regulatory front, we don’t anticipate major changes coming from the new US administration in this area. We believe new Food and Drug Administration (FDA) Commissioner Scott Gottlieb will be good not only for the FDA, but also for the pharmaceutical and biotech sectors. The FDA continues to work closely with the industry and seems more committed than ever in getting important new drugs to patients quickly.

Outside of tax and regulatory considerations, there are several other big-picture trends we continue to think support health care and biotech. One relates to demographics. The world’s populations are aging (particularly in developed markets) and the elderly consume significantly more health care products and services than the younger generations.

New Advancements and Breakthroughs

At an individual company level, we continue to see significant research advancements. There have been huge breakthroughs in gene therapy as well as in the area of cancer treatment. Major waves of innovation are a reflection of the exponential leaps in basic research and our understanding of human biology, which are now bearing fruit.

We also see potential opportunities in companies that have recently launched drugs. Investors remain skeptical of new drug launches in general, but we see a number of drugs (particularly in oncology) where we believe the revenue estimates are too low, leading to attractive valuations. Further, companies with FDA-approved, de-risked products represent an M&A sweet spot for the sector, and we expect more consolidation among these types of companies later in the year.

Large-cap biotechnology stocks have generally been performing well, with recent earnings reports in line with estimates. We continue to think the overall backdrop is very good for the biotech sector, and large-cap companies are potentially undervalued. While reflecting the maturation of their businesses, we think valuations right now generally underestimate the possibility of a reacceleration in growth.

From a therapeutic-area standpoint, we retain a favorable outlook for companies involved in oncology, neurology and rare (orphan) diseases. All of these areas have a significant unmet medical need, have seen major innovations and have a protected reimbursement environment. These are treatments for either severely debilitating or fatal conditions where it is very difficult to deny someone treatment. These types of treatments are very resistant to pricing pressures, regardless of the political environment.

Personalized or precision medicine is another area we are quite excited about. It involves tailoring a drug to a patient based on a genetic marker or other clinical information that can determine an individual's response to a treatment. While it used to cost millions to sequence an individual genome, the cost now has come down to the thousands, which is in line with other diagnostic tests. We are already seeing application of this, such as with the drug Herceptin.[1] Herceptin is a breast cancer treatment targeted specifically for HER2 positive tumors; a laboratory test can determine if a patient's cancer is HER+, in which case he or she is a candidate for Herceptin as part of their therapy. In an HER- patient, the drug has no effect.

Companies are increasingly looking for targeted patient subsets for which a particular drug may be more effective and are tailoring their clinical trials to take advantage of that. This is positive for drug development, as drugs are more likely to generate positive trial data with more narrowly focused patient populations. It also benefits future patients who will get the most efficacious treatments based on their specific genetics or variations of a disease. Companies can charge more for tailored drugs given their effectiveness, so this encourages new drug development. We've seen data for several diseases where we think functional cures are possible. We think we are at the tip of an iceberg in this area.

Although these cutting-edge developments are exciting, we remain disciplined in our investment approach. We typically avoid earlier-stage companies that lack clinical proof of concept or are targeting diseases where the biology is poorly understood. We are also finding fewer opportunities in therapeutic areas like cardiovascular disease and infectious disease as those areas are fairly well treated right now.

As part of our investment process, we consider many factors within a wide range of companies. We constantly balance the potential opportunity we see with valuation and risk.

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What Are the Risks?

Franklin Biotechnology Discovery Fund

All investments involve risks, including possible loss of principal. The fund is a non-diversified fund that concentrates in a single sector, which involves risks such as patent considerations, product liability, government regulatory requirements, and regulatory approval for new drugs and medical products. Biotechnology companies often are small and/or relatively new. Smaller companies can be particularly sensitive to changes in economic conditions and have less certain growth prospects than larger, more established companies and can be volatile, especially over the short term. The fund may also invest in foreign companies, which involve special risks, including currency fluctuations and political uncertainty. These and other risks are described more fully in the fund's prospectus.

Investors should carefully consider a fund's investment goals, risks, sales charges and expenses before investing. Download a prospectus, which contains this and other information. Please carefully read a prospectus before you invest or send money.

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1. Genentech, a member of the Roche Group, is the manufacturer of Herceptin. As of 4/30/2017, Franklin Biotechnology Discovery Fund did not hold any Genentech or Roche common stock. Holdings are subject to change.