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PODCAST: Health Care Sector Innovation and Insight

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The biopharma industry has the potential to save lives with dramatic breakthroughs in new therapeutic drugs. In our latest <u>"Talking Markets" podcast</u>, our Head of Equities Stephen Dover speaks with analysts Steven Kornfeld and Krzysztof Musialik about health care innovations, particularly in the area of biopharma. They point out that in some cases, emerging markets are actually leading the way.

After the podcast, for an even deeper dive, check out our recent <u>Franklin Templeton Thinks: Equity Markets</u> quarterly issue, which explores how biotechnology is entering the most transformative phase our health care analysts have seen in 25 years.

A transcript of the podcast follows.

Host/Richard Banks: Hello and welcome to Talking Markets: exclusive and unique insights from Franklin Templeton. I'm your host, Richard Banks.

Ahead on this episode, we go deep into the health care sector, focusing on biopharma and learning about global investment opportunities during this transformative time.

Franklin Templeton analysts Steve Kornfeld and Krzysztof Musialik join Stephen Dover, Head of Equities at Franklin Templeton, for this conversation. Stephen, take it away.

Stephen Dover: Steven, when you talk about biopharma, what does that mean?

Steven Kornfeld: Biopharma is the innovation industry that develops therapeutic drugs. It could be big molecules known as biologics or small pills, chemical entities. And it is the companies that we all know who develop and innovate the cures and the disease modifications that propel a modern society.

Stephen Dover: So Krzysztof, when people think about real innovation in the health care industry, perhaps the first thought—at least for those of us in the developing world—isn't an emerging market, but there is a lot of innovation [there]. Can you give us a broad idea of what's happening in emerging markets in the biopharma area?

Krzysztof Musialik: Yes, in emerging markets, there are a few countries which are really developing and putting lots of effort into innovation in the pharma [pharmaceutical] space. The examples would be India, China, [South] Korea and Taiwan. So, let's maybe talk about India.

India started conquering the US market 15 years ago, producing and supplying the US market with generics. But now, this route is over because prices dropped and this market is not attractive anymore. So Indian companies are trying to be more innovative.

Stephen Dover: Well, we see that in so many places, emerging markets were a place with lower-cost labor, lower-cost production, and they've really moved up the value chain and are actually adding innovation in a way that certainly wasn't anticipated 15 or 20 years ago. I'm wondering Steven, can you just tell me sort of the difference between biologic drugs and biosimilar drugs and maybe generics? What those three things mean?

Steven Kornfeld: Sure. Biologics refer to big molecules, proteins of a certain size. For the most part, they require an injection or infusion to get into the blood system. So frequently, or for the most part, they're proteins. Biosimilars are a replica, but not an exact copy of a biologic. So, they are a "generic" version of a biologic. But it's because it's a natural, human-derived antibody, you cannot necessarily say it's exactly the same. Basically, the authorities have said—the FDA [Food and Drug Administration] and the European authorities, the Japanese authorities have said—if you can show the same profile in terms of drug dispersion, in terms of uptake, you can prove through some testing that is a biosimilar. It, more or less, has the same properties.

So, the simplest way to think about it is biosimilars are generics for complex, large medicines, mainly proteins that we consume mainly by injection, either through an infusion or just an injection. So for example, insulins that we now have biosimilars for insulins, right? We take those via injection. Some of the autoimmune drugs now we have biosimilars for.

Stephen Dover: When these companies are trying to be innovative, there's a great risk. They don't know the outcome of their research. They have to put a lot of money into the research and then there's a revenue cycle. Maybe Steve, you could talk a little bit about what is happening with the revenue cycles for these companies.

Steven Kornfeld: Right. The revenue cycle can be 20 years. Usually, it will emulate the patent life, which in the US will be 20 years, but it'll take six to 10 years to develop a therapeutic molecule to get to market and generate revenues. So for the first six to 10 years, it's all costs, investments in R&D [research and development] and development costs and trials. And then, a company will get the drug approved in the United States by the FDA and then they'll launch it. And over time, the quality of the drug or the differentiation will sort of resonate with physicians and patients. The drug will grow—sometimes dramatically—if it's actually changing how the drug can sort of change people's health outcomes. But at a certain point in time, those revenues will come to either a major decline or a slow decline, depending on the complexity of the drug.

And so for the most part, by year, let's say, eight or 10 or 12, the drug will either decrease dramatically or it will be slower if it's a biologic and it'll take a longer time for a competitor to adopt and convince the community—whether it's the health care providers or consumers—that this is a safe replica to take.

Adoption of biosimilars is different in the United States than Europe because the way drugs are dispersed and the government involvement. So a lot of times when a drug loses a patent, a biologic loses a patent in Europe, very quickly the incumbent brand company will lose, you know, 80%, 85% of their revenue. In the US we haven't really had that yet, biosimilar industries [are] lagging by about five or six years.

Stephen Dover: Krzysztof, we're talking about the revenue cycles and is that different within the emerging markets, particularly around generics?

Krzysztof Musialik: I think to start, we have to say that prices of drugs, whether they are originals or generics, they are lower in emerging markets. So, this patent cliff will not be as severe as it is in the United States.

Stephen Dover: A lot of innovation needs to happen for this biopharma industry to work. Steve, in your opinion, how important are our scientific innovation hubs or certain places? And how is that dominated by one hub or another place, either within the United States or Europe or around the world?

Steven Kornfeld: That's a great question. The hubs are essential. You have ecosystems, especially in the US between academic medical centers, and companies where there is a free flow of information and there is a partnership where companies are relying on some of the academic thought leaders to do a lot of the discovery research and even lead some of the trials. So, putting hubs in key spots in Boston, San Francisco, San Diego, New York, [and] New Jersey is crucial for the success of the biopharma industry.

Stephen Dover: And how about collaboration across companies and across countries? Is there a lot of that?

Steven Kornfeld: I think collaboration happens when there is a need, or when another company can provide a need that the one company can't do themselves. So, I think, ideally companies will want to do everything themselves. But the reality is whether it's scientific capability, financial capability or a commercial expertise, a lot of times companies will partner with either equals or even the small companies will find the big companies. Because of the cost of drug development and the cost of the challenge to launch drugs, collaboration is becoming adopted, it seems like a lot more seamlessly.

Stephen Dover: One of the things that seems to be the case about this industry, is that it's based a lot on probability or finding the needle in the haystack. And so, I'm just wondering how data-driven and new analytics, how has that changed the industry?

Steven Kornfeld: I think your point about probabilities and finding the needle in the haystack is true. And I think historically it was very true and the idea was let's have as many shots on goal cause we know we're going to have some kind of success rate and the more shots we have, the better we're going to have output. I think now, as we move to a world where we could identify molecules, we could run testing through a lot more molecules at one time and we can use data analytics to see what kind of real-world outcomes we're getting. It's a much more targeted approach and more efficient. We haven't seen the efficiency yet in terms of cost, but we have the seen efficiency in terms of time. It feels like drugs are moving from discovery to market much faster.

Stephen Dover: So that timeline is going to help the profitability of the companies to some degree.

Steven Kornfeld: Yes, right, that'll help two ways. Well, the first way is that the less cost to develop the drug and secondly, you'll have more years to generate revenue before you lose your patent expiration.

Stephen Dover: I think Krzysztof, perhaps some of the listeners in the United States would be surprised how innovative both India and China are in the biopharma industry. Can you talk a little bit about both India and China, and the differences between them and how you see them developing?

Krzysztof Musialik: Okay, so I'll start from China. In the past, Western companies made money in China by selling simple chemical drugs which went off patents in the West. But those big pharma companies were able still to sell those drugs in China at attractive prices. But this has changed because the Chinese regulator pushed local producers towards higher quality. And now, the Chinese patients and Chinese hospitals, they buy more of those locally produced generics. So that's number one.

And in the innovation space at the same time, that money that is saved on this generic side, it's invested more into innovation. Basically, there is more money for innovative drugs in China. And this attracts Western companies because even though the prices are not as attractive as in the United States, the volumes are enormous because you have a population which is 1.4 billion people. And at the same time, the Chinese government made pharma one of the key areas of the strategy "Made in China 2025." And even now, there are plenty of pharma companies, both listed and unlisted, who are developing innovative therapies.

Stephen Dover: How is India involved in this industry?

Krzysztof Musialik: So India is trying to find [a] new area of growth after generics. So they are pushing towards so-called complex generics. And complex generics is a group of chemical compounds, chemical drugs, which are difficult to manufacture because as a principle, chemical drugs are very easy to replicate, to copy. But some of them, five, 10, 15% of them would be very hard to manufacture, and Indian players are focusing on them.

Stephen Dover: So what strikes me is that many of today's drug treatments almost sound like science fiction. When you look at something like having your own immune cells reprogrammed to fight leukemia. And so, it's incredible and it's exciting. And yet, so many of the biopharma CEOs seem to be under tremendous pressure to speed up these innovations because their biggest blockbuster drugs have lost some of their patent protection. How do they push faster scientific innovation, Steven?

Steven Kornfeld: Well, I think companies now realize they can't do it all themselves. So we're seeing the idea of reaching out to partnerships, whether it's other commercial organizations, academic centers or smaller companies who are providing new ideas. And so, I would say many of the large biopharma companies have become very aggressive on business development. Whether it's partnering, acquiring or taking options in smaller companies who may only have one or two therapeutic candidates, but those two can be huge opportunities in the longer term.

Stephen Dover: So what do you see as sort of the pros and cons of the biosphere mergers?

Steven Kornfeld: Well, you know, positively you're diversifying your science expertise and your knowledge base and, hopefully, diversifying your pipeline. There's always a risk that, you know, the due diligence that you do as an outsider isn't as robust as what the insider knows and maybe you're not always acquiring what you think you're acquiring. And then, at the end of the day, even if it works, you're still sharing the economics with the innovator. It's sort of a risk/reward thing and you're trying to diversify, but with diversification, you're probably giving up some of the upside.

Stephen Dover: So Steve, biosimilar uptake in the US seems quite low relative to Europe, whereas generic drugs—many of them made in India—are quite prevalent in the US. How do you see that changing and how did generics take such a hold in the US, but less so with biosimilars?

Steven Kornfeld: If you go back to 1982 when the laws were passed to encourage generic adoption, we did not have the generic penetration for several years. So it took time and I think the FDA and other policy leaders recognize that there is a process and a time period where the ecosystem has to get comfortable with biosimilars, just like they did with generics 30 years ago, 35 years ago. So, I think there is a concern that no one wants to rush it and make mistakes. So, they're a little slower to adopt the approvals from the FDA. And then, there's a commercial part of it which takes time for all the various parties who are involved in the US commercial payment system to sort of have economic incentives that are aligned to encourage biosimilar consumption and that will take a few more years.

Stephen Dover: One key takeaway I get from our discussion is that you really have to look at all the different countries, not only the innovation of the companies in the countries, but also how the countries are going to adopt particular drugs. Right? Europe's not very similar to the US and of course, emerging markets, especially China and India with their huge populations are quite different.

Steven Kornfeld: So I think it's important that we identify the idea that the United States is a unique payment system. We're really the only developed country where it's a for-profit system and the government is not involved in paying for health care. And because of that, there are many facets that change incentive structures for physicians, consumers, intermediaries. And so, there are different outcomes in the short term on how drugs are adopted and how drugs are used and which ones are chosen. Over time, the best therapeutic option will win, but there is a cost benefit. And I think in the United States there's more flexibility for innovation because there are individual and commercial payers. But over time the world will gravitate towards the best therapeutic option that is based on the value to the patient and to the ecosystem.

Stephen Dover: Here in the US, of course, there's a lot of political noise about how the system might change and how we might end up in a more government-controlled pharmaceutical industry. As an analyst, how do you think about that? How do you analyze companies and take that into account, uh, when you're valuing a company?

Steven Kornfeld: One of those questions that we wrestle with all the time, is this existential discussion that used to just come up every four years or so, but now it comes up a lot more frequently. There are realities that we pay attention to, that the US spends probably twice as much on health care than the rest of the developed world, but our outcomes are not necessarily better. We are excellent in terms of most complicated diseases and innovation, but some of the basic care concepts, we're no better than our European or Japanese or South Korean counterparts. So, you know, it's a reality that we have to think about it. We also have to follow public opinion and policymakers and try to understand how things change. The current economy is relatively robust now, so there is a wherewithal to pay, but it's something we monitor.

Stephen Dover: So I think one of the questions is, you've got these giant biopharma companies and can they still innovate in the way the smaller biotech companies can? And where do you see value, generally in the bigger companies or the smaller companies?

Steven Kornfeld: You know, there's no real black-and-white answer. It's much more fluid. What's interesting is the recent level of innovation in oncology. After a really good run, in terms of the biotech companies providing a lot of the innovation, I would say the last five or six years, some of the oncology treatments have really come from the big pharma companies. So, it kind of ebbs and flows. Whether there is a capability at a big company that the small companies don't have in terms of running trials or having connections with more academic centers. Sometimes it's just therapeutic categories that are just focused on a certain niche or a certain approach that makes sense to what they're good at.

So for example, the new immunotherapy drugs for cancer, while a lot of these came out of companies that were very good at making drugs for infections, other immunology issues, whether it was an autoimmune diseases or inflammation or bacterial infections. You know, a company like Merck, which is dealing with viruses and just has a history of dealing with vaccines. They've become a leader in immune oncology, which is really the forefront of cancer treatment today. So, it kind of ebbs and flows and it's really hard to make black and white conclusions. It flows kind of with time and therapeutic changes.

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