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> By valuing these medicines as a cornerstone of healthcare affordability and accessibility, we can ensure the long-term sustainability of the entire system.

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Christine Baeder, President of USA and LATAM at Apotex, discusses the companyâ??s evolution following private equity investment, its Generics Plus strategy, and the critical role of the US market. She highlights supply chain resilience, the challenges facing biosimilar adoption, and the need for structural policy reforms to sustain affordability, innovation funding, and long-term healthcare system stability.

Having joined Apotex during its transition from a familyâ??owned Canadian firm to a private equityâ??backed organisation, how has the companyâ??s strategic DNA transformed over the past two years?

What originally attracted me to Apotex was the compelling vision and the journey the company was undertaking. Having spent most of my career at a competitor, I was consistently impressed by Apotexâ??s ability to punch above their weight. Their track record in firstâ??toâ??file launches, successes within the Hatchâ??Waxman regulatory framework, and strategic settlements was formidable. Apotex has mastered what I consider to be the triangle of success for any generic organisation: the seamless integration of highly creative R&D, a strategic regulatory team, and a robust legal component.

This specific DNA was instilled by the founder, whose passion for science and patent law allowed him to weave those elements together to create immense business opportunities. That culture remains evident today and is the primary reason the company continues to outperform its size. When the management transitioned following the private equity acquisition, we were careful to preserve that core brilliance. We intentionally retained the Global Head of Regulatory and the Global Head of R&D to ensure our scientific and regulatory foundation remained undisturbed.

We supplemented that legacy expertise with a new management team designed to support the rest of the business, which has allowed us to take that original DNA and amplify it. This shift has introduced a far more disciplined and strategic focus to our operations. It has been a highly appealing journey; we have experienced several exceptional years of performance as we continue our trajectory toward becoming a truly global healthcare company.

How central is the US market to the broader Apotex organisation, both as a commercial driver and as an operational hub?

As a Canadian company, we take immense pride in our heritage, yet the US remains a prominent and highly strategic piece of our business. In many ways, our North American roots provide us with a distinct advantage over our peer set, particularly those located further offshore. This proximity allows for a more integrated and resilient approach to the market.

Operationally, the US is home to critical infrastructure that supports our global ambitions. While our global headquarters remains in Canada, our US headquarters is based in the Fort Lauderdale area, and we maintain a significant presence in Indianapolis, which serves as the site for our primary distribution centre. Furthermore, we leverage partnership deals with US manufacturers to strengthen our regional capabilities. The US market is a foundational pillar for both our current operations and our future commercial growth.

Apotex maintains a significant US portfolio of 130 products across 12 therapeutic areas. Within this broad breadth, what are your primary technological focuses and the future drivers for the organisation?

In the generic sector, our strategic focus is defined less by specific therapeutic categories and more by the underlying technology required for production and the complexities of the patent and Hatchâ??Waxman landscapes. We have achieved substantial success and established a high concentration in nasal sprays, as well as oral solid doses of all types â?? ranging from simple formulations to complex extendedâ??release products.

As Apotex continues its Journey of Health strategy, we are differentiating our offerings. This involves a transition into more sterile manufacturing, biosimilars, and the 505(b)(2) regulatory pathway, which allows for the improvement of existing drugs. While we may eventually incorporate more branded products, generics remain our foundation. We take immense pride in the patient impact and access we provide as a generic company. We have no intention of turning away from our core. Instead, we are pursuing a Generics Plus strategy â?? identifying what we can execute in addition to our current strengths to better serve patients.

Our recent acquisition of the US rights to Provigil and Nuvigil â?? specialty medications used to treat excessive sleepiness â?? is a supplement to this model rather than a replacement. I am currently developing a 10-year strategic plan which reinforces that generics are our core DNA and our

foundational block. We will continue to allocate resources to excel in that space while simultaneously expanding into complex specialty items, biosimilars, and the 505(b)(2) pathway. This is not an eitherâ??or scenario. It is a â??thisâ??plusâ??thatâ?• approach, building upon our foundational strengths to create a more diverse and robust specialty portfolio.

Apotex has documented approximately 18 billion USD in savings for the Canadian healthcare system over the past five years. How does this significant impact translate to your operations and the value you provide within the US?

While our regional data is not always broken out in the same manner as the Association for Accessible Medicines (AAM) reports, I can state with confidence that our impact in the US is equally significant. Apotex remains a cornerstone of the healthcare system here, consistently delivering substantial value through our generic and biosimilar offerings.

Our performance in the market serves as a primary indicator of this impact. Last year, our position in the IQVIA rankings fluctuated between fifth and eighth in terms of dollar value. This standing is highly representative of the scale at which we operate and the immense cost savings we generate for American patients and the broader healthcare infrastructure.

In a landscape marked by PBM challenges and rebate barriers, how do you perceive the current level of systemic gratitude for the generic and biosimilar industries, and what are the risks if this value is not sustained?

The narrative for generics and biosimilars is still being written, and I am concerned that the biosimilar trajectory may mirror the challenges faced by the generic industry. Generics represent perhaps the pre-eminent success story of government and industry partnership. I cannot think of any other intentional piece of legislation in the US that has provided a comparable return for the American public as Hatch Waxman. As highlighted by the AAM, the billions saved annually have made generics a cornerstone of a healthcare system that the nation implicitly relies upon.

However, there is a delicate balance that must be maintained. The promise of the system is that savings from generics and biosimilars provide the headspace to fund the next wave of innovation on the branded side. It is a continuum where savings on one side of the balloon create the necessary room for growth on the other. If we do not establish a sustainable framework to ensure the success of biosimilars, we risk depleting the capital required to fund future medical breakthroughs. My fear is that without this systemic support, the financial resources necessary for innovation will simply cease to exist within the system.

While the FDA continues to issue significant new guidance, how do you evaluate the current state of the US biosimilar sector compared to Europe and Canada, and is regulatory action alone enough to bridge the gap?

The recent FDA guidance is certainly more than just a preliminary effort and represents a significant, positive step forward. The FDA remains deeply committed to lowering entry barriers, streamlining market access, and reducing the costs associated with bringing competitive products to market. These efforts are commendable and essential. However, regulatory streamlining alone does not solve the systemic issues embedded in the US biosimilar market model.

What distinguishes the European and Canadian markets are the structural incentives for biosimilars, particularly from a reimbursement perspective. These structural drivers do not yet exist in the US. While our regulators are performing exceptionally well within their purview â?? evidenced by the March 2026 Revision 4 draft guidance which further cuts PK study requirements â?? there is a systemic disconnect involving reimbursement frameworks, incentives, and dispensing protocols.

To truly incentivize biosimilars, we must look beyond the FDA. Significant progress likely requires coordination with the Centers for Medicare & Medicaid Services (CMS) or perhaps even direct congressional action. We need a more comprehensive effort directed at the market system itself to create an environment where patients are educated, comfortable with biosimilars, and, most importantly, able to realize a tangible financial advantage from choosing them.

Given that the US biosimilar landscape is more complex than Canadaâ??s, what is your current strategy for the US, and how do you view the return on investment in light of current market dynamics?

Currently, Apotex does not have a biosimilar portfolio represented in the US market, but we do have biosimilar products in our pipeline for US. We do have biosimilars in Canada, where the market model is more predictable and structured differently. In the US, our plans are focused on specific molecules, but these are targeted for the 2030 horizon. Our hope is that by then, the structural noise that currently makes the US biosimilar market unpredictable and uncertain for investment will have cleared.

The core issue is the ability to build a sustainable business case based on return on investment. According to reports from the AAM and IQVIA, many biosimilars are simply not being developed because the ROI is not attainable. While we see a heavy concentration of effort around blockbuster molecules, many other drugs that serve vital patient populations are being overlooked. Although the FDAâ??s recent moves will help soften the financial burden of bringing these products to market, they do not address the fundamental market dynamics.

Sarah Yim, Director of the CBER Office of Therapeutic Biologics and Biosimilars at the FDA, recently noted that biosimilars are at a point of inflection â?? citing a significant increase of 18 approvals last year. Do you share this optimism?

I agree that we are at an important inflection point, and the FDAâ??s handling of these approvals is certainly improving. However, approvals are only one part of the equation. What is more critical is that we have biosimilars available for all biologics as they reach patent expiry, and we are nowhere near that goal.

The primary barrier remains the business case. Even with regulatory support, a company needs certainty that it can actually sell its molecule. Right now, the market is lumpy with some players are succeeding while others are not. This is often dictated by the order of market entry and the concentration of buyers. These are market dynamics that fall outside the purview of the FDA, but they must be examined if we are to see the biosimilar market reach its full potential.

Beyond structural and financial hurdles, how significant is the education gap for patients and providers, and what lessons can be applied from the early days of the generic industry?

There are significant parallels between the current state of biosimilars and the early trajectory of the generic industry. If you look back at the history of generics, many brand companies initially established their own generic divisions â?? a pattern we are seeing repeat itself today within the biosimilar space. In those early days, there was a profound need for both healthcare and patient education. People naturally had questions. Is it safe to switch? How do we know it is as effective as the brand? These are valid concerns that required a concerted effort to address.

While we do not yet have a one size fits all solution for biosimilar education, the industry has learned a great deal from building the generics market. We can repeat those successful strategies to increase comfort levels among providers and patients alike. However, education is only one part of the equation. To truly open the market to its full potential, we must address the education gap in tandem with the structural barriers regarding reimbursement and market share concentration.

It is important to clarify that while Apotex does not currently have biosimilars on the US market, we possess a robust pipeline of assets. It is the market environment that dictates the timing of their introduction.

As you develop the 10-year strategic plan for Apotex in the US, what are the primary objectives or topâ??tier goals you have identified for the coming years?

The generic and biosimilar industries are fundamentally built on operational excellence. Success requires consistent, disciplined execution. You must be rigorous regarding revenue allocation and pipeline selection, specifically identifying where you have a competitive advantage that others lack.

We take a longâ??term view. These are not shortâ??term assets. Interestingly, the timeline for brands, biosimilars, or 505(b)(2) products can often be shorter â?? perhaps three to four years â?? compared to the 15-year horizon sometimes required for a generic. This is not due to the complexity of the science, but rather the intricacies of the patent landscapes involved. My focus is on the precise allocation of resources to balance our commitment to generics with our expansion into these more complex areas.

Would you say that this focus on operational excellence is the key differentiator that separates Apotex from offshore competitors?

One of the attributes of Apotex that I found truly remarkable upon joining is our exceptionally high service level. While I had heard these reports from customers throughout my career, I initially suspected they might be exaggerated. However, the reality is that our service levels are worldâ??class, and our backorder rates are among the lowest in the industry. This commitment to our patients and customers is foundational to our identity.

Our manufacturing footprint in Canada provides a significant strategic advantage in this regard. In the event of logistical disruptions or geopolitical volatility, we are not reliant on air or sea freight. We simply require a truck to cross a bridge into the US. This proximity creates a safe space that is far less susceptible to disruption. I believe that utilizing a supply chain footprint that encompasses both North and South America is a fundamentally superior design for pharmaceutical security.

There are currently between 300 and 350 ongoing drug shortages in the US. How does the Apotex footprint across Canada, Mexico, and the US mitigate these supply chain risks, and what is your perspective on the broader on-shoring debate?

I am a strong advocate for maintaining a diverse network of global partners. The true advantage for any pharmaceutical entity lies in a redundant supply chain that spans multiple regions. This prevents us from having all of our eggs in one basket and ensures that a single geopolitical shock or regional disruption does not collapse the entire system.

I have long maintained that domestic manufacturing is not the sole solution to drug shortages. This perspective was underscored when a tornado struck a major manufacturing facility in North Carolina, resulting in a massive national shortage of sterile water. Simply being located in the US is not a guarantee against shortages. While on-shoring is a useful tool that may be underutilised in our current global footprint, it is redundancy, not location alone, that protects the American patient.

Apotex is focused on the right strategies for our supply chain within the US. There is an undeniable national security element to that which makes strategic sense. However, a US-only strategy is not a complete solution. It is the global supply chain, with its inherent redundancies, that provides the most robust protection for the healthcare system. Canadian based supply chain provides a North American option with a long history of cooperations.

As a final message on behalf of Apotex and the broader generic and biosimilar industry, what should the healthcare community and policymakers understand about the value you provide?

The generic and biosimilar industries are unique and should be treated as such. Too often, we are governed by policies that were originally written for innovative pharma, the defense industry, or the technology sector. This industry is a specific, essential engine that affects the quality of life of every American at some stage in their life.

It is imperative that policymakers approach our sector with the same level of strategic intentionality that they apply to other critical industries, such as agricultural policy or the semiconductor and chip sectors. We need thoughtful, specific policies designed to protect the generic and biosimilar industry and ensure it can continue to deliver the results that the nation relies upon. By valuing these medicines as a cornerstone of healthcare affordability and accessibility, we can ensure the long-term sustainability of the entire system.

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