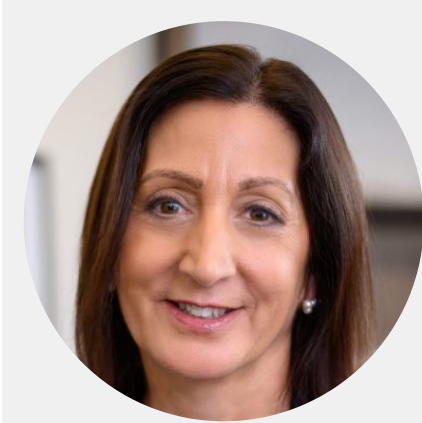


Tanya Carro - EVP US Entities, Duchesnay Pharmaceutical Group



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Tanya Carro details Duchesnay Pharmaceutical Group's organic expansion from its women's health core into rare diseases and generics. Operating across three geographic pillars, the privately held firm leverages Canadian pricing discipline and US entrepreneurial agility. Carro emphasizes navigating complex reimbursement landscapes through holistic patient support and securing global supply chains to ensure equitable access to innovation.

To begin, could you introduce Duchesnay Pharmaceutical Group and explain how your values-driven approach shapes the company's identity and global strategy?

Duchesnay Pharmaceutical Group (DGP) is based in Quebec. Although we maintain operations in both the US and Canada, we operate through three distinct companies within each of those markets. Through our network of partners, our products are commercialized in over 50 global territories across Europe, North America, South America, and Asia.

When viewed as a whole, our group structure is defined by three specialised pillars: our women's health business, Duchesnay and Duchesnay USA; our rare disease divisions, Medunik and Medunik USA; and our generic operations, Analog and Analog Canada.

DGP's central business originated with women's health, and it remains the core of our identity. Our expansion into rare disease and generics was a natural, organic evolution based on opportunities we saw within our own business. While developing the first treatments for nausea and vomiting in pregnancy, we

explored the potential for treating hyperemesis gravidarum as a rare disease. This led the company to spend significant time with the rare disease community to understand that specific clinical pathway. The connections made during that period eventually facilitated our entry into the rare disease market with other products.

The progression into generics was equally natural, prompted by the loss of exclusivity on our proprietary products. We began by launching authorized generics of our own assets and have since expanded that portfolio to include third-party products. While we now operate across diverse segments, these businesses remain fundamentally interrelated.

How significant is the United States to Duchesnay's growth ambitions and your approach to global impact?

When we evaluate our business, we view it through three geographic pillars: the US, Canada, and the rest of the world. Our objective is total diversification as development focus is never restricted to a single pillar. However, the strategic emphasis within each varies. For instance, our export markets focus on out-licensing and R&D, whereas in the US and Canada, we prioritize in-licensing and R&D to expand our portfolio.

While all three pillars are equally vital, we recognise that the US is a cornerstone of the pharmaceutical industry despite the unique set of challenges that differentiates it from Canada. While these differences can create obstacles, they also provide opportunities to approach problems through a different lens and bring those learnings to other markets.

A prime example is reimbursement. While Canada's reimbursement scheme is less complex, securing coverage can still be difficult. In the US, we are very accustomed to multifaceted payer dynamics and the complexities of securing access. Because our Canadian team can draw on our US experiences, they are better equipped for negotiations within their own market. Ultimately, our teams learn from one another, which strengthens our global position.

Could you provide more context regarding the specific strategies Duchesnay is focusing on to navigate the complexities of US reimbursement through Medicaid expansion?

The reimbursement landscape in the US resembles a patchwork quilt. It is composed of many distinct pieces, including commercial access, Medicaid, and Medicare, alongside the critical question of how to support patients who are uninsured or underinsured. Consequently, it is essential to have a holistic access strategy. It is impossible to focus on just one area as many patient populations exist across all these areas.

While we work diligently to secure Medicaid access, the realities of this differ across the country. You may encounter a situation where one state designates your drug as preferred and accepts a supplemental rebate

offer, while another state rejects the exact same cost–benefit proposition. This inconsistency persists across the commercial and Medicare sectors as well. We strive to present a fair offering that maximizes coverage, but since it is rare to succeed across the board, we must constantly manage the gaps in that patchwork quilt.

To fill these gaps, we implement essential backstops. For commercial patients facing high out–of–pocket costs due to non–preferred status, we offer co–pay assistance. For those who are uninsured or lack coverage, we provide cash–pay options through specialty pharmacies and vendors like GoodRx, which offer discounts at the point of sale. Finally, if a patient meets specific eligibility criteria and all other avenues are exhausted, we provide the medication at no cost through our patient assistance program. These various mechanisms are vital. Without a diverse set of options, many patients would simply be left without access to necessary treatment.

How do you find synergies within your market access strategy across the three pillars of women’s health, rare disease, and generics, and how much variation exists between them?

From a synergy perspective, we are able to utilize the same vendors for co–pay assistance, patient support, and cash–pay options across our rare disease and women’s health businesses. We even extend these programs to our generic products, which is not standard industry practice but is critically important in the rare disease space.

Typically, when a rare disease drug faces generic competition, the branded manufacturer terminates its patient assistance program. For patients accustomed to zero out-of-pocket costs for a branded medication, the sudden introduction of a high-cost specialty co-pay for a generic version can be a significant shock to patients. By offering co–pay assistance on our rare disease generics, we bridge this gap and ensure that the transition to a lower–cost medication does not create a new financial barrier for the patient.

While there is an administrative requirement to maintain separate PBM and Medicaid agreements for each business, these documents are fundamentally similar. Our strategy is to focus on one, finalize the framework, and then replicate it across the other businesses to ensure our agreements remain consistent.

With the Inflation Reduction Act (IRA) and Most Favoured Nation (MFN) at the forefront of many headlines, how do you perceive the industry’s reaction to current US policy discussions around affordability and pricing?

Affordability is a topic on which virtually everyone in the healthcare ecosystem can agree. However, a significant issue is the lack of transparency. While list prices are visible, net prices remain opaque. Even as a manufacturer, it is difficult to track the final destination of rebates or determine how they ultimately influence a patient’s out–of–pocket costs. In this regard, I view market initiatives like Mark Cuban’s Cost Plus Drugs Company or Trump RX as positive developments. They offer clear cash prices at significant

discounts to list prices, and providing patients with more affordable options is always a constructive step.

Regarding certain specific policies, the IRA's provision for price negotiations after a set period is designed to lower costs. While we are still waiting to see the ultimate outcome, its intention is positive. On the other hand, the MFN is far more difficult to implement in the US. From a global perspective, the suggestion that other markets should artificially raise their prices to align with the US is a rather disconnected from economic realities of the world.

Beyond price controls at the point of market, meaningful change for affordability must also happen from the beginning of the therapeutic life cycle. The FDA's move toward requiring only one pivotal trial with confirmatory evidence as the new default standard for marketing authorization is a significant step in reducing the capital and time required to bring new drugs to market. Lowering these upfront costs will lower the hurdles for companies to launch products and therefore increase competition. This is inherently beneficial for exerting downward pressure on pricing. We are currently seeing this dynamic play out within the GLP-1 class.

One discussion which is key but also particularly complex is regarding PBMs. While they provide a necessary service to their clients, there is a clear need for greater transparency concerning rebate structures and the extent to which those savings actually reach the patient. These are complicated dynamics that will take time to resolve, but anything that increases competition and choice for providers and patients is a step in the right direction.

In your view, how can a balance be struck between ensuring long-term sustainability for manufacturers to drive innovation while providing equitable, affordable access for patients?

Finding this balance is a central challenge, particularly as many pharmaceutical companies are publicly traded and must satisfy shareholder expectations for financial returns. One of the most effective ways to manage this is by reducing the cost of bringing a drug to market. By utilizing tools like AI to compress development and regulatory review windows, we can lower the initial capital investment. When upfront costs are reduced, achieving long-term sustainability becomes significantly more attainable.

Furthermore, sustainability requires a long-term perspective that extends beyond the initial period of exclusivity. For example, DPG's integrated model includes launching our own authorized generics. By maintaining our own generic operations, we can continue to utilize our manufacturing capacity and recoup investments over a much longer horizon. We do not cease production when a molecule loses exclusivity, instead, we retain a strategic share of the market. This ensures that we can support our portfolio while maintaining reliable access for patients.

How does DPG’s status as a privately held group influence its long–term strategic perspective and approach to growth compared to publicly traded companies?

There are two sides to that dynamic. While we do not have the same immediate access to capital markets as a publicly traded company, this necessitates a trade–off where we must independently secure the financing for our business. This constraint makes it even more important that we think long and hard about every investment we make, whether we are developing a new therapy or acquiring an existing product.

However, the primary benefit of being privately held is the ability to maintain a long–term strategic vision. We do not have to chase the dragon of rapid turnarounds or superficial changes just to satisfy quarterly market demands. Instead, our structure allows us to focus on value–driven, sustainable growth and development that aligns with our core identity.

How is DPG navigating the current geopolitical climate, specifically regarding supply chain security and the impact of US tariffs?

Our primary commitment is to ensure that our medicines remain accessible to US patients without facing dramatic cost increases. To achieve this, we have implemented a targeted inventory expansion as a short-term solution while we develop longer-term structural responses to the evolving trade landscape.

For the products we manufacture internally, we have significantly increased our inventory levels within the US. However, for products produced by third parties globally, the process is more complex due to longer lead times. We conduct rigorous risk assessments with our suppliers to understand how specific duties like the recently implemented Section 122 tariffs might apply to certain drugs.

The current regulatory environment is exceptionally fluid. For example, recent announcements regarding global tariffs raise immediate questions for a company like ours: do they apply to pharmaceutical products? And for our Canadian operations, does the United States–Mexico–Canada Agreement (USMCA) supersede these new measures? We are constantly analyzing new data as it becomes available to quickly develop and execute action plans. Our proactive approach to inventory and supply chain resilience is a clear indicator of our long-term commitment to the US market and the patients who rely on our therapies.

Looking forward to the next two to three years, what does success look like for DPG in the US, and what are your primary growth priorities?

Success is defined by our continued growth in the US through both internal product development and strategic partnerships. Our objective is to broaden our pipeline and maintain a consistent rhythm of new product launches.

We see a significant opportunity in the women's health sector, which has been historically neglected and lacks novel therapeutic innovation. While many firms have pivoted toward the highly competitive rare disease market. This has made acquisitions and in-licensing more challenging. However, women's health remains an area where we can lead by applying a unique strategic lens.

Simultaneously, we are strategically expanding our generic portfolio. Within the next 15 to 18 months, we will launch several additional generics, including authorized versions and independently developed products not previously in our portfolio. This ensures we can provide competitive pricing and added value as our own proprietary assets face loss of exclusivity.

Ultimately, we are looking to scale across all three pillars of women's health, rare disease, and generics not only in the US and Canada but globally. When we evaluate new assets for development or in-licensing, we prefer to secure global rights. This allows us to commercialize directly in the North American markets while leveraging our network of partners to bring essential treatments to patients throughout the rest of the world.

We have seen a surge in rare disease approvals – nearly 50 percent of novel FDA approvals last year. Does this “boom” create a risk of neglected innovation in non-rare therapeutic areas?

The market dynamics we have discussed are highly applicable to the rare disease space. We are seeing a significant shift where conditions that lacked research for decades now have two or three competing treatments. As I mentioned, I consider this to be a positive development since competition within a market is a powerful tool for increasing both accessibility and affordability. Generally, the more drugs available for a condition, the easier it is for patients to access them and the more likely prices are to decrease.

However, maintaining a fine balance is essential. While the surge in orphan drug development addresses critical unmet needs, we must ensure the industry's focus does not shift so exclusively that other non-rare areas where innovation is just as vital— like women's health—are neglected. This is why DPG remains committed to a diversified strategy, ensuring we drive innovation in sectors like women's health alongside our rare disease and generic portfolios.

How do you integrate Duchesnay's Canadian heritage with your own US leadership perspective to navigate the realities of the US market?

The influence is reciprocal. The Canadian perspective encourages us to be exceptionally judicious regarding pricing. Because the Canadian market is far more transparent and prices are generally lower, it keeps patient affordability at the forefront of our minds. This helps us remain disciplined in our pricing strategies, ensuring we focus not just on the list price but on the ultimate cost to the patient.

On the other hand, the US brings an entrepreneurial spirit and a fast-paced, problem-solving culture that permeates back to Canada. Our generic business is a prime example of this back-and-forth exchange. We initially launched our generic company in the US to address the loss of exclusivity on our products. Its success there prompted us to replicate the model in Canada which has not been part of the original thought process.

At its core, however, our culture is driven by the Canadian emphasis on employee well-being, flexibility, and a sense of family. This is particularly strong because we are an emerging company headquartered in Quebec. We firmly believe that by prioritizing the well-being of our people and our patients, we are making a meaningful contribution to society.

Do you have a final message you would like to deliver to the healthcare and life science community on behalf of DPG?

Our most important message is to reiterate that we are global in reach and deeply dedicated to our three core pillars of women's health, rare disease, and generics. We collaborate with a diverse range of partners worldwide and are eager to continue that level of cooperation. We aspire to be the partner of choice, particularly for companies seeking to bring innovative products to the Canadian and US markets.

Beyond our commercial goals, we firmly believe that by promoting the well-being of our patients, we are contributing to the betterment of society. While this is the fundamental purpose of the pharmaceutical industry, it is the driving force behind everything we do at Duchesnay Pharmaceutical Group. We remain dedicated to our current business segments and are focused on growing our footprint to bring essential healthcare solutions to patients across the globe.

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