For UBC’s Patrick Lindsay, providing decision support across the full product life cycle is no stretch goal—it’s today’s fact of life

By William Looney, Editor-in-Chief

The strategic uncertainty confronting big Pharma today has put a premium on generating new ideas from outside sources—it’s the fresh wind that lifts the sales. CROs and other biopharma vendors with a business mission to guide the industry through an era of rapid change are under intense pressure to keep up, with service offerings that bind strategy to execution and are global and cross-functional in scope. In the following interview, part of our “CEO Snapshot” series, Pharm Exec sits down with Patrick Lindsay, President of UBC [United BioSource], a scientific, medical affairs, and risk management advisory firm geared to meeting industry needs at every stage of the product life-cycle. Jamaican-born Lindsay, 53, and a co-founder of UBC, offers an update on the company’s recent merger with drug distribution giant Express Scripts, which puts him and UBC at the center of what is now the nation’s largest supply chain on medicines, filling nearly a third of all prescriptions written in the US.

PE: The acquisition of Medco Health Solutions [of which you were a key part] by Express Scripts in April 2012 has placed UBC in a unique position as a leading provider of research evidence, access expertise, brand loyalty and safety management—all of it within the orbit of the largest pharmacy benefits manager in the US. How has this new combination changed UBC’s basic business proposition to clients?

Lindsay: Our capabilities are much more extensive because today we are part of a truly integrated business, with competitive scale and reach. We do not see ourselves as a traditional vendor or CRO. UBC is instead a full strategic partner, and the level of engagement that we are able to achieve through the Express Scripts family gives us access to the most senior levels of the entire pharma and biotech community. In addition, it allows us to align UBC’s business model with Express Scripts specialty pharmacy unit, Accredo, to create a unique...
and differentiated service offering geared to the specific needs of specialty drugs, a high-profile segment of the trade. Our work goes further than project execution: we provide strategic advice on every aspect of the portfolio, at every stage of the product life cycle, in a way that helps companies save time and money, root out waste, and drive results through demonstrable outcomes. We refined this integrated service delivery model by choosing deliberately to work with the mid-tier companies in the industry; based on that record of success, we are now bringing the big Pharma 10 into our orbit too.

**PE:** UBC is a service organization, which requires a keen awareness of the external trends and challenges that confront the biopharmaceutical industry, particularly those that come from adjacent sectors or are otherwise “outside the box.” Can you identify the issues that are most prominent in shaping the future path of the industry and which also affect the ability of UBC to perform its basic mission for clients?

**Lindsay:** We see the US Affordable Care Act as having a profound impact on the current business model in biopharma. Those of us who are strategic partners to biopharma must adapt as well. Reform will change the way many health interventions are funded, and how success is measured—the Act wants to put the emphasis on metrics that drive system outcomes, not service income. But no one at this point can easily form a coherent and consistent operating plan based on how all the new mandates will shape incentives in the marketplace.

The only truth is that market change is a constant. I spend much of my time observing and investigating business options with players outside the traditional health care sector. The key influencers in health are changing and strategic service organizations like UBC have to keep up.

**PE:** Is there an example where you believe Big Pharma has to be more proactive in adapting to these induced market changes?

**Lindsay:** UBC is devoting a significant amount of time to analyzing the implications of a surge of enrollees in health insurance programs, many of whom will be obtaining coverage for the first time. The structure of benefits under these plans will vary considerably. Drug companies must think carefully about meeting the expectations of all these additional patients as well as providers and regulators under the new structure. For example, what adjustments will be required to the Patient Assistance Programs (PAP) that most Big Pharma companies operate to provide medicines to low income or uninsured patients? Some changes are due because our analysis indicates the key demographic going forward will be the under-insured, rather than the uninsured. We will see much more complexity in the management of PAP programs as the level of drug benefit coverage becomes apparent in the new Health Care Marketplace exchange plans. If a patient has some level of access but still cannot afford the co-pays or co-insurance charges, then you might say that patient is actually worse off than not having insurance at all. It is important that uncertainty around the regulatory framework for the PAP programs in health reform is resolved so that they can remain a vital link in helping patients obtain their meds.

**PE:** Won’t adherence to medication increase in importance if more under-insured patients fail to initiate a course of treatment due to concerns about cost?

There are many other issues like this, because the ACA legislation is replete with gaps and unintended consequences—where patients are literally being left to fall between the dock and the boat. In the last six months, UBC has held several senior-level meetings with the major pharmaceutical companies, looking at ways to ensure this does not happen. Doing nothing could end up damaging company reputations.

**PE:** How is UBC adapting to the increasing complexity in reading market signals? Is greater market insights the rationale for the merger with Express Scripts?

**Lindsay:** Getting a better handle on adherence is definitely a priority in adapting to health reform. It’s a big part of our business. One of the advantages from the combination with Express Scripts is we gain access to their enormous data retrieval capabilities in key areas like safety and side-effect concerns. We can easily track for clients how patient adherence is affected by these two critical drivers. This complements UBC’s capabilities in supporting the rapid market uptake of new medicines.

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span every stage of the product life cycle, from proof of concept to registration to post marketing surveillance and then to loss of exclusivity (LOE) —and beyond. There are three basic platforms for this work: Safety, covering activities around clinical development, regulatory approval, and post approval commitments like REMS, and pharmacovigilance; Loyalty, which includes brand reimbursement strategy, PAP and adherence programming, and benefit program management and analytics; and Access, which includes our growing business in specialty pharmacy solutions as well as logistics and management along the drug distribution chain. Issues like adherence show how we bring all three platforms—the triad—together. An adherent patient is one who is using the drug safely, he/she stays loyal because the drug is working for him, and it enhances access by avoiding the excess cost and waste to the system when a patient develops complications by not being adherent.

Express Scripts brings its enormous on-the-ground operational strength, assets we can leverage through state-of-the-art data and analytics. Express Scripts is responsible for filling nearly a third of all prescriptions written in the US today. If you believe, as I do, that waste is a huge drag on productivity in health care, then having Express Scripts as part of the team is a real differentiator in terms of competitive advantage—it knows precisely where all the spending is.

PE: Isn’t it a conflict of interest that UBC consults extensively with Big Pharma companies on strategies that might be of competitive interest to a big drug distributor and PBM like Express Scripts?

Lindsay: We have a strict internal firewall in place that prevents us from sharing research results with our new parent company. The legal strictures are quite tight; our combination was contingent on having these guidelines operative from day one. For example, no one at UBC is exposed to any information relating to formulary activities or the operation of P&T committees linked to Express Scripts. Likewise, it is not permitted access to the research and advice we give to companies on benefit design, brand or risk management. Training in standard operating procedures is conducted for every employee several times a year. This way our commitment is reinforced, especially for new employees or those who are being reassigned to a new role. You cannot desesel yourself out of this process.

PE: Evidence is the basic product that UBC generates for its clients. A question that must be important for you is the direction the US is taking on standards to evaluate the cost effectiveness of new medicines. Will the federal government move toward formal requirements or is this process more likely to be driven by the private sector, with multiple varying standards to assess value?

Lindsay: Diversity is an ingrained feature of the US health care system. There are still numerous private payers and many of them define value in different ways. Thus, the prospects are remote we will be adopting a formal QALY-driven system like exists now in the UK. At UBC, we specialize in the analytics of what we call value demonstration. The centerpiece here is we look at every product as a unique proposition to patients, clinicians and payers. We evaluate the product against its peer group of competitors. We spend a lot of time on patient perceptions and how they believe a therapy might affect them. And we work with manufacturers to help them build the case to payers about the product’s unique value, which should be rooted in hard clinical outcomes data.

PE: Do you believe your Big Pharma clients are ready for a world that insists on their proving positive health outcomes as a condition for gaining access to the market?

Lindsay: Senior leaders in the industry acknowledge we are in a different environment today than even five years ago. Most companies have restructured their clinical activities around what we call parallel development: where once there was no consideration of the commercial prospects for a drug candidate until just prior to registration, we now see this being considered as early as the start of Phase II. In addition, commercial staff are incorporating genetic profiling and other sophisticated clinically-based data from the development teams to assess how to lengthen the life span of brands well past LOE. External partnerships are also part of the mix. All of the changes make it more likely that new products will lead to better health outcomes, regardless of whether this was the original intent.

PE: What about the contrarian view on early-stage consultations with payers—that it can actually inhibit innovation by terminating that great idea from left field before it has a chance to prove its merit as a therapy? It is worth recalling that some of the biggest drug blockbusters of the past might not have made it to market under these narrow parameters. Is it possible to prove a compound’s market potential while it is still being tested?

Lindsay: Chance is inherently a part of the research enterprise. There is always risk, and the impact of miscalculation around a candidate can be costly in terms of future revenues foregone. But it is equally true that the industry is getting a lot better at linking their science to the needs of the patient and clinician, which in turn drives market success. There is a clear strategy, which I describe this way: “the new big is a lot of small.” Companies we work with are pinpointing their development dollars toward uniquely differentiated niche
products that target smaller sub-sets of the affected patient population. This way, the risks of miscalculating your ROI are lower. UBC’s analytical and advisory expertise is increasingly focused on the orphan drug space, because this is where our clients are placing their R&D bets. It may no longer be feasible to run up the charts with a single $15 billion drug, but you can generate the same amount of revenue with nine or ten highly differentiated orphan therapies which justify high price points precisely because there are few treatment alternatives.

**PE:** Are you positioning UBC as a leader in the development of personalized medicine?

**Lindsay:** The UBC business concentrates in areas where we have unrivaled expertise. There are other companies out there with strong capabilities in personalized medicine, so we have chosen not to make this business segment a priority. Our focus is on the analytics and advisory services required to develop and commercialize products, in real world settings. It’s real-world evidence applied to actual clinical settings that distinguishes UBC from the competition. The big challenge for drug makers is that moment when they have to switch: from a carefully controlled, restricted world—one where they must prove the clinical attributes of their research to a small cohort of regulators—to the messy world of patients, providers and patients, when that new drug is actually out circulating in the market, being dispensed. More and more effort is required to succeed in this post-marketing phase. We build the case for the uptake of these products in an environment where it is harder than ever to stand out. This is precisely the area where we shine.

**PE:** Can you identify the next disruptive “shot from the dark” that UBC and others in the industry need to prepare for?

**Lindsay:** The one issue that is going to be a game changer is the health of your IT assets and capabilities. The biopharmaceutical industry is an information industry. Information technology, done well, connects all the moving parts of the product lifecycle, from discovery and development to approval, commercialization, market acceptance and LOE. UBC looks at it as a new information highway, speeding our work with patients, pharmacists, and providers. The vital accelerant on that highway is data. The Affordable Care Act and other reforms will facilitate the aggregation of data so that it can be applied productively to find better ways to treat patients and compensate providers, at lower cost to the health system overall. In that regard, the combination with Express Scripts presents us with rich opportunities to leverage information: our parent manages the prescription benefit plans of nearly 100 million people—one third of the total US population.

What we can do for our customers with that data, subject to the appropriate legal safeguards, is nothing less than revolutionary. UBC is making this central to our service offerings in the specialty pharmacy segment, which is becoming the most important single segment of drug spend. Express Scripts forecasts that by 2015, eight of the top 10 selling drugs in the US will be specialty biologics. UBC is determined to be the lead expert service provider in this space, going forward.

A second example of a “shot from the dark” is what I see as the ultimate legacy of US health reform: the necessity to prove outcomes on the basis of clear, transparent metrics on drug performance. Here, we are helping to advance that objective through the development of decision-support prescribing models for physicians.

Building on this outcomes theme is the increasing sophistication of tools designed to track patient safety once we move beyond the prescribed regimen of the clinical trial. Patient registries are a key part of our business, which provide an extra margin of assurance in evaluating the safety of a product in the marketplace. But there is another advantage as well. Such registries are vital to guaranteeing a fair hearing from regulators when companies start seeking new indications for the same approved product. We tell our clients it’s wrong to see these new evidentiary requirements as a drain on productivity and innovation; instead, they serve as the foundation for additional product claims that will extend the life cycle of the product. However, it can be a tough task to manage these programs on a global scale, which is what the market requires. This is where UBC comes in; it aligns perfectly to where we want to be.

Finally, evidence is beside the point if patients cannot access your drug. Access, as I noted, is the third part of our service triad. We provide a range of patient support services that initiate and then help keep patients adherent to their therapy. We apply this knowledge to design the benefit programs to ensure there is a patient-centric perspective.

**PE:** What is your perspective on the patient’s role in health care. Is the “empowered patient” still more of an aspiration than a practical reality?

**Lindsay:** Patients—and the caregiver—are becoming educated. They are much less passive in decisions on treatment. We find this particularly true among caregivers; our clients are asking us to look more carefully as to how this cohort drives decisions on care and treatment. Technology, and the accessibility it provides, is allowing patients to ask the right questions to providers. We believe this is a positive trend because it represents the confluence of the same forces that have helped expand our business.

**PE:** UBC is an organization built on evidence. Compiling and interpreting data is central to your skill
set. How do you believe the current debate on the disclosure of biopharmaceutical clinical trial data is going to play out? Is there a downside to the goal of full transparency in public access to this data?

Lindsay: I have only a personal perspective to share. It is very early in the debate; there is room for evolution from both sides on the issue. We know how the business model works: companies sponsor and fund their own controlled trials based on an approved design and retain the rights to disclosure beyond the regulatory dossier as proprietary, commercially sensitive information. This data is compiled to support a product submission. It is also used to establish the core components that will help differentiate that product in the market.

With so much on the line commercially, one has to wonder what the incentive is to share that data in an uncontrolled manner, with outside groups. Will the data be useful in answering key questions that relate to public health and safety while preserving individual privacy? When groups are unfamiliar with the details on how that data has been amassed, there is the potential that conclusions can be rendered based on facts that are misconstrued – the “big picture” gets obscured in pursuit of the small. So I think careful ground rules—a better term might be guardrails—must be in place before we venture down this road.

I would also add that we already have a great deal of shared data in the form of publications that compile study results from various complementary, contemporary sources—the meta-analyses. What seems to be motivating those who want more transparency is the ability to get access to very raw data rather than an overview of results. I don’t think we have devised a method to do that without creating privacy, confidentiality and intellectual property bottlenecks. The responsible course is to retain confidence in the entire trial system by allaying these concerns, but we’re not there yet.

PE: As a senior manager, what are the behaviors you believe to be most critical to achieving your business mission as a leading strategic service provider to biopharma?

Lindsay: What distinguishes the biopharmaceutical industry today is the imperative to be global. My biggest priority has been to transform a structure geared to doing business in one area to doing business without boundaries—on a global scale. Today, we have 18 offices around the world. At every hour of the day, someone is awake and working for UBC. The challenge is how to ensure that the colleagues in Germany and the US or the UK are working seamlessly in one area to doing business with out boundaries—on a global scale. This brings me to a related point: as a service business, our greatest asset is people. I spend a good part of every waking moment thinking how do I attract the top talent in our field? How do I ensure that I keep the talent we have energized and engaged, with a strong learning curve? What are the structures UBC needs to create leaders able to deliver consistently high performance against the competition?

My response is to focus on values—I should cite Express Scripts values of integrity, mutual respect and passion—that foster collaboration across the organization. Values are a way of overcoming the distractions imposed by geography, language, local standards and cultures. We make these values central to the business mission we have laid out, in a variety of formats, to our approximately 2,000 employees worldwide. The values are embedded in every manager’s annual performance goals. For example, each of my direct reports has an annual objective centered on hiring the best people and limiting group turnover. These two levers must work in tandem, because if you attract talent but then fail to keep it, the business won’t grow.

PE: What about the potential of individual initiative, as opposed to “group think”? Is it possible in a large organization for a single person to make a difference?

We tell our clients it’s wrong to see these new evidentiary requirements as a drain on productivity and innovation; instead, they serve as the foundation for additional product claims that will extend the life cycle of the product.

Lindsay: You will hear this from everyone you talk to at UBC: if we want to make a difference for this industry, we have to act differently. Every individual we employ should feel empowered to make another individual—our customer—happy. When we go out and decide we are going to work for a biopharma client, that client has a right to expect he or she will get knowledge, expertise, awareness, discretion, follow through and proactive communication. Each and every one of these capabilities will be designed and implemented by an individual, acting either alone or more likely as part of a team. They will be individuals we have in-house; we don’t do pass-through projects reliant on hired help or freelancers. As I said, we try to hire for keeps. We strive for a balance among people with strategic insight and people with technical skills. Added to that is a commitment
to diversity, including the active recruitment of staff with different geographic backgrounds.

**PE:** Although UBC has long positioned itself as a global entity, your new parent company is heavily focused on the US market. Do you have a mandate to extend UBC’s global orientation to the rest of the Express Scripts family?

**Lindsay:** I have expanded the operation to where we now have a ground presence in 25 countries. It is true that Express Scripts has focused primarily on the US. It is a PBM; that business model was designed here for a multi-payer system. It may not be appropriate for other countries with a different payer base. But I am part of the Express Scripts leadership team. I spend part of every month with the CEO, George Paz, and his senior leadership team in direct discussions on ways to help grow their business. I can say it is readily acknowledged that potential activities outside the US are necessary to keep the overall business growing. UBC has a significant role in recommending what the combined organization can do to stay flexible about new opportunities in global markets.

**PE:** Any learnings you can highlight to date from the integration process with Express Scripts?

**Lindsay:** UBC started out as an entrepreneurial enterprise. I was a founding Board member. We were fortunate to grow beyond that and benefited as well from a gradual transition to the marriage with a big partner. We did it in two stages: first we became part of Medco. That gave us the experience to handle the still larger merger with Express Scripts.

In any merger, communications is critical. But what is even more important is to approach the integration with the conviction that the sum is going to be better—not just bigger—than its parts. You don’t want to put the focus on the organizational fit while failing to facilitate changes that will actually grow the combined business. I had to accept and understand the fact that UBC would benefit from being part of a bigger platform. For example, I have been surprised to learn how Express Scripts is really a very strong technology company—like many people, I thought it was a distributor and pharmacy claims processor. UBC is now leveraging that strength.

**PE:** How do you define success in your position in three years time?

**Lindsay:** I have three items on my list of performance objectives. The first is growing our talent base. Next, I intend to demonstrate on the basis of clear metrics that the combination with Express Scripts has contributed to a reduction of waste in the use of medications in the health care system. Finally, I have committed to meet specific revenue growth targets—in the double digit range.

**PE:** You have been active in this industry for 25 years, moving steadily up the ladder toward the CEO suite. What might you say to a younger colleague interested in learning from your experience?

**Lindsay:** What has worked for me is recognizing that you can learn a great deal from other people, especially if you consider that each encounter is unique. One of my early mentors taught me how to listen. Another showed by example that the benefit of teamwork comes not from striving to be the person in charge but from learning how to navigate through conflicts, build consensus and make everyone else look good first. My predecessor at UBC gave me a firm financial grounding—metrics and numbers count; they define goals, and serve as a rigorous benchmark of success. And I would have to cite my own mother for insisting that everyone should be treated with respect, regardless of their standing in the organization.

What a striver has to do is to seek—and in seeking you shall find, not necessarily from one individual but from the collective legacy of all those who pass through your life. Such encounters take place for a reason because, if you discover positive traits from others that you can make your own, they will advance your potential as a successful contributor to society. Appreciation for diversity and individual differences helps make our culture whole. I point to myself as an example: An immigrant, I came to this country as a child, from Jamaica, and I found education to be the ultimate integrative experience. I have made education my key external commitment and am proud to be a co-founder of the Reach One Child Foundation, which provides schooling and mentoring support for disadvantaged children in Jamaica.

**PE:** Who is your competition today—and tomorrow?

**Lindsay:** We’re in an industry that changes every day—so I do keep an eye on all the players. Today, I believe that un-integrated models are not what pharma needs, so we’re watching other companies that understand this.

The word of tomorrow is “specialty,” our competitors will align their services around the unique needs of specialty therapies, just as we’ve already done. The market will change as development and niche providers integrate in the name of parallel evidence development. Along with the maturation of technology offerings, certain providers should be able to grow with potentially less intense capital investment. Market-leading commercial solutions that influence drug price, delivery, utilization, administration, position, promotional mix, and prescriber loyalty will grow exponentially.

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