A LEADERSHIP BRIEFING:

The U.S. Pharmaceutical Market Outlook: The Path to Recovery and the New Normal

ASK THE EXPERTS:

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What are the "re-invented" or innovative commercial models that you think have the greatest likelihood of success in the future?

JIM LANG: We have seen a shift in the industry of pharma companies turning away from traditional launch and commercialization approaches and looking for ways to streamline cost, mitigate risk and, ultimately, improve patient outcomes. The "re-invented" model must be one that truly addresses ALL of the challenges our industry faces and not a few at a time. Especially at a time of patient-centred, value-based care, the integration and flow of data is no longer an optional nice-to-have; it is a must-have in any commercial model. As you evaluate models, look for those that address fluctuation of resources, operational excellence to address market and product complexity, and the challenge of data integration and use of analytics to make informed decisions.

Candidly, we believe large pharma learned to structurally overspend, during the "sales and marketing era" of drug differentiation over the last few decades. Middle managers associated with brands sought to consume as much budget as they could to ensure their area of responsibility was successful … so they could be associated with that success and move up the career ladder. For many good reasons, this old model is being shattered now.

JOE JIMENEZ: The pharma industry must interface with physicians in ways that are consistent with how this new generation of physicians consumes information and learns about new therapies. As an industry, this means transitioning from large field forces, where associates are essentially gross rating points, to digital methods of communication – conducted when the physician is ready and willing to accept this information.

Secondly, we need to move to outcomes-based pricing to ensure the sustainability of healthcare systems that continue to struggle to pay for new therapies. Today, for example, we estimate that we can eliminate 20-30% of waste in the system by accepting payment only for those patients who respond to a given therapy. Granted, there are well-documented barriers to outcomes-based pricing; however, we must overcome these challenges to ensure the sustainability of the system upon which we rely.

KABIR NATH: I think the key will be a gradual move away from the "one-size-fits-all" share of voice model on the sales side. Both more specialized functions (e.g., medical, patient support) and potentially new, broader roles more able to have value-based discussions with providers and systems will emerge. Models will vary by geography, disease area and system/provider nature. The ability to allow providers and payers to "pull" information and data, rather than the industry to push, will be critical.

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Do you believe that data-driven drug development, especially genetic data, will dominate R&D in the pharma industry? Is the lack of standardized data in the U.S. a barrier to adopt this model?

KABIR NATH: Genetic data will be important to some disease areas but not others; for instance, in psychiatry, where Otsuka focuses, yet another attempt to identify a singular genetic basis for depression has just announced failure. I think frameworks and regulations will move slowly to allow disparate data sets to be brought together and that disruptive private sector companies will be the first to establish inter-operability on a scaled basis.

JIM LANG: Understanding what patients, providers and payers need from data – and articulating WHY it matters – is a significant barrier in the industry. With our recent partnerships with Symphony and Compile, we can solve global pricing, access, reimbursement, real-world evidence, adherence and product delivery challenges at any stage of the product life cycle. We believe utilizing this data to inform commercialization strategies will drive upfront success for not only chronic disease medications but also innovative therapies like cell and gene and digital therapeutics.

It was unfortunate that we as taxpayers funded the deployment of the EHRs, yet our policy makers did not demand secure data interoperability. That "mistake" probably cost us a decade in getting valuable insight from the data collected by EHR systems, and the ability to link to other relevant sources (labs, claims, etc.). The good news is that leading companies (Datavant is one of several great examples) are creating compliant connectivity, allowing companies like EVERSANA to make use of this data to improve patient success. There will be a massive shift in the industry over this next decade that we all should be excited about.

JOE JIMENEZ: I believe opportunities in digital healthcare go far beyond back-end processes and extend from the digitalization of R&D to digital therapeutics. For example, Aditum Bio's companies deploy a "clinical therapy + digital therapy" approach to patient treatment, providing patients with apps and other tools that help them to change behaviours, track progress and symptoms, and address other behavioral factors that contribute to a disease or condition.

Our goal at Aditum Bio is to make data-driven drug development and clinical trials as inclusive as possible. Of course, we recognize that, in pursuit of this mission, lack of data standardization can be often a barrier to progress, which is why we're continuing to think "outside the box" in order to reach as many people as possible. For example, by leveraging Trial Spark's innovative digital infrastructure, Aditum Bio can create FDA-compliant clinical trial sites that are unobstructed by geographic restrictions. As a result, Aditum Bio can tap into the 95% of patients that don't typically participate in clinical trials.

How can manufacturers shape the market to smooth the introduction of cell/gene therapies for chronic metabolic diseases like congestive heart failure, chronic kidney disease, etc.? How can they prove value? How can manufacturers, payers and governments partner to advance development of these curative therapies and keep prices sustainable?

KABIR NATH: There is appetite for risk sharing in industry for new products; by contrast, it's very hard to turn the existing revenue base (and rebate-based agreements) into value-based agreements. I think commercial insurers and health systems will move more quickly than government in this space, though there may be exceptions. For instance, companies working on RNA technologies with prophylactic potential in areas like raised cholesterol or hypertension may be able to negotiate success-based vaccine-like models.

JOE JIMENEZ: It's clear that cell and gene therapies will move into more prevalent diseases once less toxic conditioning methods are developed (e.g., antibody conditioning). When this happens, it will no doubt be great for patients but will unfortunately be a problem for healthcare systems that will struggle to pay for these therapies.

To ensure the sustainability of the payer system, we need to develop creative new models for therapeutic funding, such as outcomes-based pricing or instalment payments. Of course, while there are admittedly limiting factors for outcomes-based pricing, given the short time that any one individual in the U.S. can stay with a particular payer, we must find ways around these hurdles. Why? Because we must enable promising therapies to reach the patients who need them.

JIM LANG: Over the next decade, we are definitely going to see cell and gene therapies become more curative across various therapeutic areas. We need to be prepared to articulate a compelling narrative about the holistic benefits of these therapies and how they (albeit expensive) will ultimately save the healthcare system millions of dollars.

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The next generation of product launches demands integrated data and analytics across the patient journey to model value-based care. However, measuring product value is highly subjective because each audience values different data points:

- Regulators and clinicians want to know a product is safe and effective.
- Patients want to improve their health without significant financial burdens.
- Payers want to understand how a product performs both within clinical trials and in actual practice compared to current standards of care.

Leveraging data and analytics to measure and illustrate clinical and economic outcomes is going to be key to framing the brand story and educating all stakeholders. In the U.S., we can also use this information to drive the industry insurance reform we need for our country to be sustainable in the midst of new science and innovations.

The life sciences industry is prepared to be held accountable to value-based contracts (we are working with leading firms doing just that). Moreover, CGT does not have to be expensive when applied to large patient populations. We did an analysis recently looking at all classes of branded drug products' net prices times their volume and saw a surprising clustering. This essentially means the life sciences industry is pricing at essentially what is needed to recover significant R&D and commercialization costs rather than "gouging" payers and patients, which is too often the false perception. This bodes well for the long term, as both clinical and commercial models are undergoing significant model transformations. This will ultimately continue to lower drug prices on average.

I would be remiss to not point out that drug prices, as received by drug manufactures (called the net price), continue to decline. We still have a very inefficient system with many middlemen between the manufacture of the drug and the patient (wholesalers, distributors, pharmacies on the physical side, and PBMs on the financial side).

Another major hurdle is the risk/reward disconnect between payers and providers. This is why we see more innovative value-based contracts in integrated payer/provider systems (Kaiser, Geisinger, etc.) than elsewhere. Until we effectively backstop or re-insure payers with a national stop-gap or equivalent, innovations around pricing and contracting, whether for CGT or elsewhere, will be slowed.

Do you believe that bringing U.S. and global pricing more in line will decrease U.S. prices or increase global prices? Would it reduce access to drugs outside the U.S.? How is this likely to affect R&D and commercialization?

JIM LANG: The fight around drug prices is an easy political lighting rod, but is a complete misframing of the situation of why U.S. healthcare costs are greater than twice per capita vs. other developed nations. Meanwhile, all major research studies show we drop every year in healthcare outcomes as measured by life expectancy, infant mortality and access to care.

We need a more comprehensive solution that addresses the behavioural challenges of U.S. health. Our obesity rates are now double that of other developed nations and rising at twice the rate. This is a macro driver of many co-morbid chronic conditions (diabetes, cardiovascular, respiratory, cancer, etc.). While the life sciences industry has delivered many therapeutic solutions to all of these categories, they cannot overcome behavioural choices that the U.S. population is making relative to many other nations.

Secondly, we need continued structural reform that fosters innovation and competition to bring down costs. U.S. healthcare is the largest cottage industry on the planet, with structural fragmentation that is preserving outdated revenue models. Only policy change can facilitate that.

I remain optimistic that the life sciences industry is filled with passionate people who are trying to make medicines more affordable. It's actually much easier to launch a product in some of the international markets, where there's an alignment between payers and providers, because those who face the cost see the benefit of an innovation. Here in the United States, we've got to get that more aligned.

JOE JIMENEZ: I believe it will do both. It will lower pricing in the U.S. and raise pricing outside the U.S. While I do not believe these changes will materially affect R&D, it may affect commercialization. With this in mind, to earn an acceptable return on the risk incurred during drug discovery, the pharma industry may be forced to avoid or delay commercialization in certain geographies. This will be very unfortunate for the patients who need these therapies.

KABIR NATH: Bringing U.S. and global pricing for drugs more in line by lowering U.S. prices through reference pricing or Most Favoured Nation policies is a fundamentally misguided approach to the problem of high out-of-pocket expenditures for drugs in the U.S. All costs in the healthcare system in the U.S. are extremely high – HCP salaries, hospital costs, etc. The focus needs to be on fundamental reform, including benefit redesign, the rebate system, etc. A significant drop in U.S. pricing and profitability would certainly lead to fewer risks being taken in discovery and development.

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With more and more companies engaging in patient-centric approaches, why isn't there more of an initiative to move to a more "direct to patient" distribution approach with some of these rare disease treatments?

JOE JIMENEZ: As a result of slow clinical trial processes, high clinical trial expenses and recruitment barriers, some drug candidates, both for rare and large patient population diseases, are simply never developed – and consequently fail to reach patients who could benefit from them. This is where Aditum Bio comes in.

Through our partnership with Trial Spark, Aditum Bio is able to usher in promising assets through Phase II by using data, software and technologies to streamline clinical trials and improve patient centricity. We believe the future of R&D is growing increasingly digital and are guided by a pursuit of bringing drug development processes as close to the patient as possible. By leveraging digital technologies to track progress and symptoms, we believe that we're well-positioned to employ a direct-to-patient approach that's both more efficient and more effective.

KABIR NATH: There are, appropriately, stringent laws and regulations in place governing the relationships between industry and individual patients. But you do already see much more tailored provision of appropriate information and education to patients with rare diseases. The fact that distribution of drugs has not been disintermediated at all by technology (most prescriptions are still picked up at retail) is something that will likely change over time, not just for rare diseases.

JIM LANG: At EVERSANA, we are starting to see a shift in how rare disease therapies are distributed. In working with companies like Vineti and Cryoport, we are helping cell and gene therapy innovators bring their products to patients in a faster, more effective and data-driven supply chain. Many of these therapies require unique temperature-controlled storage and transportation, so the traditional model just doesn't work. When you fully integrate patient care and support with streamlined product distribution, you improve the patient experience and their overall adherence.

We are working with leading life sciences companies on innovative, direct-to-patient delivery through e-commerce channels. A silver lining of COVID-19 is the acceleration of delivery models we see in many other industries now being applied to healthcare.

There's a large push in the U.S. to move infused/injected treatments for chronic conditions (and even some cancers) away from hospital infusion centers into physician offices and, increasingly, into the home. How are pharmaceutical leaders thinking about this shift in terms of the support required for physicians and patients, as well as about ideal methods of administration?

KABIR NATH: We recognize this trend and indeed have invested heavily to make it more convenient for patients to access our long-acting injections at multiple different centers, not just physician offices. Often with the U.S. system, however, what may be best for patients – e.g., home dialysis, SC injections for home administration – is bedevilled by misaligned incentives and other profit-seekers within the system who resist these changes. It behoves the industry to put patients first and seek ways to ensure that more patients can access medicines in the manner of their choosing.

JOE JIMENEZ: For many years, we in the pharmaceutical industry have witnessed a distinct transition away from treatments in hospital infusion centers and toward treatments in physician offices and even everyday residences. It's a fact of life: Patients today are looking for therapeutic regimens that don't interfere with their day-to-day responsibilities and are open to using digital tools that help bring convenience to otherwise costly and time-consuming processes.

In order to capitalize on these shifting sentiments, pharmaceutical leaders today should consider leveraging new and innovative digital tools that support patients with at-home care. Aditum Bio, for example, aims to combine behavioural modification though digital devices (e.g., mobile apps) with pharmaceuticals in order to support patient treatment, improve adherence and, ultimately, create better patient outcomes. I believe this is the future of patient treatment.

JIM LANG: At the height of pandemic this summer, the Centers for Medicaid and Medicare (CMS) issued a new rule to allow patients to receive in-home infusions. This rule immediately accelerated the volume of patients receiving therapy in the safety of their homes, and I truly believe this motion saved

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lives. CMS, healthcare providers, nurses, manufacturers and patients worked tirelessly to figure out administration schedules, product distribution (often shipped to the patient home or the nurse transported it to their home), documentation, outcomes reporting, etc. These efforts paved the path for future therapies as new protocols were developed and patients/providers became more comfortable with the process and procedures. I think this is a great case study for other infused/injected therapies. We've seen that this type of high-touch patient support provides a smooth on-boarding process, identifies barriers of access and improves overall patient care. Manufacturers should really consider how their patients can benefit from this option.

How would you rate the preparedness of the pharma industry to travel side-by-side with both the vast medical (health) and digital industries?

JIM LANG: Patients, providers and payers are expecting healthcare to be more accessible, intuitive and adaptable to their needs. Barriers that have held back innovation in digital medicine and telemedicine have been blasted apart with the recent relaxing of requirements by CMS and HHS, continuing advances within the FDA's Digital Health program and additional reimbursement opportunities that are emerging globally. Momentum is rapidly building, so I think we'll see many new therapies and strategies within the next few years.

KABIR NATH: The industry knows that it must engage both with wellness (if that's what's meant by health) and digital technology. Successful leverage of digital technology within pharma will require collaboration with the tech industry.

JOE JIMENEZ: Now more than ever before, I believe the pharma industry is primed for innovation. Against the backdrop of the COVID-19 pandemic, the past few months have served as the catalyst for profound transformations in the way we live and work. Seemingly overnight, pharmaceutical companies have had to adapt to new operating models, taking advantage of digital-first infrastructures in order to continue delivering innovative therapies to patients who need them. In the face of such disruption, I anticipate that pharmaceutical companies will grow in tandem with both the medical and digital industries – bringing existing processes into the digital age and addressing significant unmet patient needs along the way.

About EVERSANA™

EVERSANA is the leading independent provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through LinkedIn and Twitter.