



New Voices, New Opportunities:

Toward a Patient-Centric Biopharmaceutical Commercialization Model



Few industry narratives are as prevalent today as the need for biopharmaceutical companies to re-engineer their R&D model. Amid declining productivity, increasing costs, decreasing pipelines, lower earnings and a host of other challenges, the call has gone out for urgent action to transform and re-energize the drug development process. The biopharmaceutical industry is indeed entering into a New Health landscape, and success will certainly be determined by how well biopharma navigates the new risks of this landscape, learns to interact with new stakeholders such as health technology assessment (HTA) groups, payers and patients and as a result embraces the need for convergent thinking from the commercial and clinical domains within the clinical development process.

The reason for change is clear: The current model simply isn't working any longer. Clinical and commercial success, for example, is rare, with the U.S. Food and Drug Administration (FDA) approving only 25 first-of-a-kind drugs in 2009. Meanwhile, there is an increasing gap between regulatory and commercial success while development time and costs continue to rise, reaching between \$800 million and \$1.2 billion over eight or more years. As a result, the days when biopharmaceutical companies could look to a "predictable" stream of blockbuster products to fuel sales and support large, fixed-cost infrastructures appear to be over.

But beyond clinical failure and cost constraints, an entirely different basket of challenges awaits innovative biopharmaceutical companies. As the blockbuster model disappears, it is only logical that the research and commercial systems that have supported these models become just as obsolete. According to a recent study by the Tufts Center for the Study of Drug Development, more than 30% of compounds that make it to Phase III trials are withdrawn from development for marketing reasons. Further, 71 of 91 products that have been submitted to the FDA over the last 24 months missed initial sales forecasts. Additionally there are an increasing number of drugs that are subject to pay for performance deals from payers requiring that the marketing company commits to build upon health economic value data generated within the clinical phase, soon after launch and beyond.

Therefore, a new way forward in bringing innovation to market must be found. A new commercialization model is necessary, one that takes into account the new decision makers and, most importantly, the new decision requirements needed to have a successful commercial product.

That this change is to be accomplished against a backdrop of the shifting relationships between stakeholders, a growing need to maximize revenues, new distribution interactions and against the ever increasing cost-consciousness of payers, adds to the challenge of renewing commercialization success. Despite these hurdles, however, biopharmaceutical companies must identify and implement transformational change in their market access, sales and commercialization strategies, or risk becoming a dinosaur by failing to adapt to the New Health landscape and its future market realities. Only by developing the right communication and interventional channels to multiple stakeholders, particularly payers, HTAs and patients, will pharma be able to gather the much-needed outcomes data to drive market access. More importantly, they must use this market access knowledge to drive the successful clinical development of compounds, based upon not only safety and efficacy considerations, but also commercial considerations. This is what we mean when we talk about the convergence of the clinical and commercial domains.

Tomorrow's Vision, Needed Today

Today, many biopharmaceutical companies are struggling to make sense of the future, during a period of significant and rapid change. As a result, developing an effective commercialization strategy can be difficult, as it has to take into account the potential future paradigms defined by new technology, new competitors and new outcomes requirement and a rigorous assessment of the hurdles to overcome for their own compounds in development.

Many of the overarching trends driving this change are well known. Amid a growing demand for health care services and medication, for example, costs are outstripping economic growth, leading to an intensification of cost containment efforts and the shifting of health care cost and risk dynamics. However, it is not only the cost to the institutional payers but the cost to the patients that needs to be taken into consideration. Although pharmaceuticals only represent less than 10% of the overall health care budget in the U.S., they consume a much larger part of a patients' disposable income. A lack of patient compliance continues to lead to suboptimal outcomes with medicines and drives health care costs upwards. Additionally, pharmaceutical companies are experiencing declining returns on investment (ROI) even as they become better at cost and risk management and continue to expand into emerging markets.

Taken as a whole, then, the landscape biopharma must market to will look different tomorrow than it does today, and will continue to evolve. Within the realm of all possible scenarios, however, a smaller number of likely environmental commonalities can be identified – each with the potential to come to fruition in competition or in concert with each other. These outcomes can be labeled as:

- **Incrementalism and compromise**, in which multiple health care reform efforts lead to uneasy compromises between health care stakeholders,
- **Focus on cost**, in which deteriorating macroeconomics causes an extreme focus on immediate health care budget containment,
- **Focus on value**, in which a consensus forms that a focus on health outcomes and value is the best long term approach to manage cost,
- **Focus on the patient**, in which patients demand and receive a new level of control over their treatment, and
- **Technology leap**, in which new diagnostic, device and drug technology combinations precipitate a major health care ecosystem shift.

Changing Relationships, Changing Value

Within these buckets – taken singly or in various combinations – three factors can be seen as driving a successfully re-engineered commercialization model: The changing relationship between patients, physicians and payers and the coincident shift in relative influence; increased patient decision-making and power; and the need to demonstrate value effectively within a treatment paradigm.

For example, common to all of these environmental scenarios is the increasing potential for physicians to lose importance in prescribing decisions and health care choices, while patient influence increases and payer mandates against health care inflation continue to drive decision making. Further, even if the issue of “patient power” fails to gain critical political mass at any point, patients are likely to seek a greater role regardless of environmental outcome as the narrative around change in health care continues to take center stage. Equally, the need for modes of communication (whether they are educational or interventional) with patients to educate them on the value of compliance and gather much needed outcomes data to support product value propositions will increase. Likewise, even in a scenario dominated by technological leaps, patients are likely to continue to become more involved in their treatment to lobby for further innovation. In any scenario, a pharmaceutical company must understand the decision criteria of patients, payers and physicians.

Perhaps even more vital, a focus on value – as identified through metrics such as Comparative Effectiveness Research (CER) and Health Technology Assessment (HTA) – underpins the entire range of these scenarios as long term patient health outcomes move to the forefront of the debate. Going forward, each of these factors is likely to become increasingly important in influencing commercialization strategies and outcomes.

The Need to Re-balance Resources

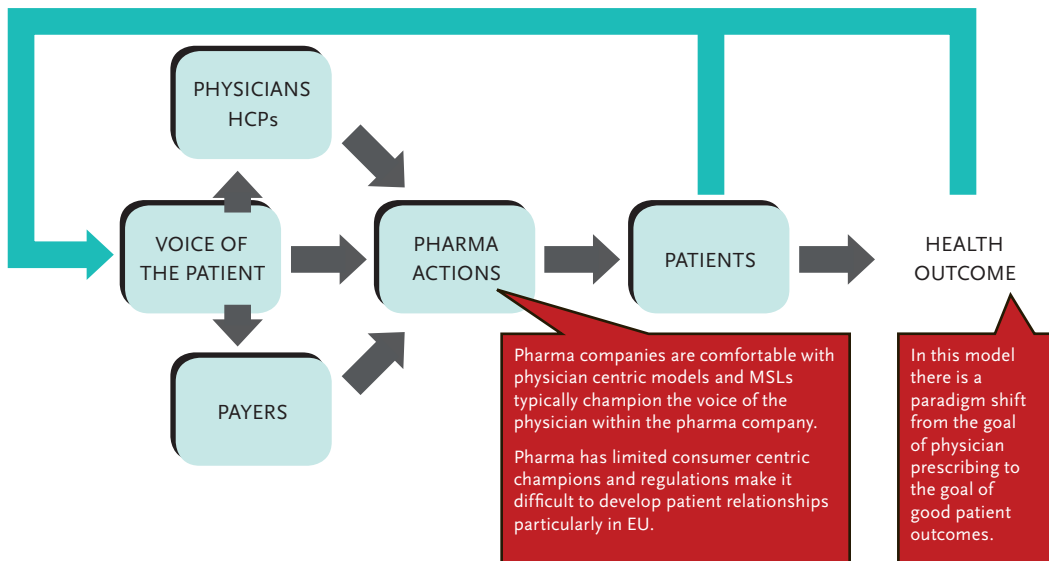
Regrettably, for many biopharmaceutical marketing and sales operations, questions of patient power, long-term health outcomes and patient-centric data analytics are only beginning to come into view in product and brand management strategies – if they’ve arrived at all.

Instead, a continued focus on physician detail continues to absorb the lion’s share of resources – by some measures, as much as 80% to 90% of commercial resources are still poured into physician detailing despite rapidly diminishing returns. Such strategic deployment of resources belies a recent survey by Oliver Wyman which found that only 56% of physicians are willing to meet with pharmaceutical sales representatives, and only 24% are willing to spend more than two minutes with a sales professional¹.

Besides continuing to saturate an already overfilled marketing channel, this misalignment of resources also fails to address the eroding position of physicians at the nexus of the treatment decision making process. Today, physicians are seeing their influence over prescribing and health care choices challenged by better informed and more empowered patients, along with public and private payers who are imposing increasingly restrictive formularies. Add into the mix the movement of physicians to larger group practices; or joining practices as employees, in which decisions of sales professional access is made on an administrative level, and a stakeholder mix develops that is unlikely to be effectively served by current promotional methodologies.

¹ *A Prescription for Change: The New Go-To-Market Strategy for the Pharmaceutical Industry.* Oliver Wyman. 2009.
http://www.oliverwyman.com/de/pdf-files/OW_EN_HLS_2009_Go_to_Market_final.pdf

Good Patient Outcomes: a Key Sales Goal



Modified from a presentation by Reinhard Anglemar; given at the *Sales Force Effectiveness Europe 2009* conference. See also: *The empowered patient - what it means for pharma*. May 14, 2009. <http://social.eyeforpharma.com/story/empowered-patient-what-it-means-pharma>

As patients are asked to carry directly an increasing proportion of their health care costs, they are likely to demand a greater say in what treatment they receive and how it is delivered. This means that biopharma companies must gain a much better understanding of the decision process of patients. Even in an environment where physicians continue to play the dominant role of treatment initiation choice, it is still the patient who ultimately decides whether to stay on that treatment. From a pharmaceutical commercialization perspective, such a paradigm shift presents both challenges and opportunities.

Within the New Health landscape that results from this shift, patients will increasingly seek new settings and ways of obtaining health care that fits in better with their lifestyle and economic situation. "Self service" primary care and home health care will gain new adherents and importance. Where patient choice of prescription medication (where medically appropriate) becomes commonplace, managed care organizations and the Centers for Medicare & Medicaid Services are likely to support these choices with increased patient medical education, much of it industry sponsored. This means biopharma sales and marketing programs will need to open communication channels directly to the patient and find optimal communication vehicles that balance educational and promotional messaging effectively.

Therefore, a new model of commercialization that focuses on patient influence and decision making must move to the forefront, recognizing the patient as a key stakeholder and requiring the direct communication of evidence-based value messages. While traditional patient-centric programs focus on driving compliance and persistence, in this model the sales goal of physician prescribing transforms into the goal of communicating good patient outcomes and demonstrating effectively

the overall value of the biopharmaceutical product. This reality presents further challenges to sales and marketing efforts, however, as many biopharma companies are currently more comfortable with physician-centric models and have developed few internal champions for the patient as decision-maker or appropriate approaches to communicate with patients.

Patients' Voice, Patients' Power

In order to deliver the value messaging necessary for success effectively, developing a patient-centric commercialization model may well require a better understanding of consumers. This involves adopting a mindset not unlike the consumer-driven models prevalent in other industries, without actually adopting consumer model promotional approaches. Where the voice of the patient has an impact on physicians or pharma behavior, it must be accessed and acted upon, whether it's in a hospital, physician's office or a home. And to access and act upon that voice, effective communication mechanisms must replace the interactions currently employed in physician detailing.

The centerpiece of this new commercialization model is the ability to access the data necessary to understand patient behavior better – to listen to the voice of the patient with more sophistication than previously employed. Taken as a whole, this data can be broken down into a range of constituent parts²:

- **Information** – What drives the patient to the doctor?
- **Advocacy** – Will the 'political' voice of the patient support access to therapy?
- **Experience** – Which patient pathway allows optimal access to therapy?
- **Satisfaction** – What are the specific therapy issues relating to treatment satisfaction that need to be addressed?
- **Behavior** – What will increase the level of adherence?

Naturally, collecting this data is incredibly complex, as, unlike a physician, the patient is often a moving target, open to a number of potential channels for messaging and data retrieval. As direct sales representative interaction with patients is out of the question, alternate channels must be employed. These can include call centers, interviewing, clinical education, homecare providers, expert patients and other vehicles that can be operated within an appropriate regulatory framework.


Home care stands as an effective example, whereby a physician makes a prescribing decision while a nurse from a pharma company delivers the drug in the home environment. This presents an excellent opportunity for focused data collection, as the nurse makes measurements, takes checks, asks questions, gathers outcome data and talks to the patient. Opportunities like these can help a more appropriate commercialization approach focusing on outcomes of various therapies and help identify data requirements for the positioning of a new product. In any commercialization model, this collection of outcomes data is critical for success, as demonstrating product value vis-à-vis real-world patient outcomes is a centerpiece of the realities of the New Health landscape.

² *The empowered patient - what it means for pharma*. May 14, 2009.
<http://social.eyeforpharma.com/story/empowered-patient-what-it-means-pharma>

New Metrics for New Realities

The basis of value creation is shifting

Current State			Future State Determinants of Value		
Salesforce	Stakeholder focus	Marketing Approach	Salesforce	Stakeholder focus	Marketing Approach
Downsizing traditional GP sales forces	Focus on prescribers Accepted patient attrition as long as new patient acquisition drives sales	Organized around and focused on brands	Refocused to key account managers	Multiple stakeholders Focused on patients; reduce patient attrition	Blend of brand and customer-centric approaches



In order to prove successful, a renewed commercialization model must also adhere to a further critical component: recognition that the basis of value creation within the biopharmaceutical industry is shifting.

In the current model, a sales force focuses primarily on detailing prescribers about safety and efficacy data, mostly generated during clinical trials and compared to placebo. Usually it is organized around brands, therapeutic areas and patient specialties.

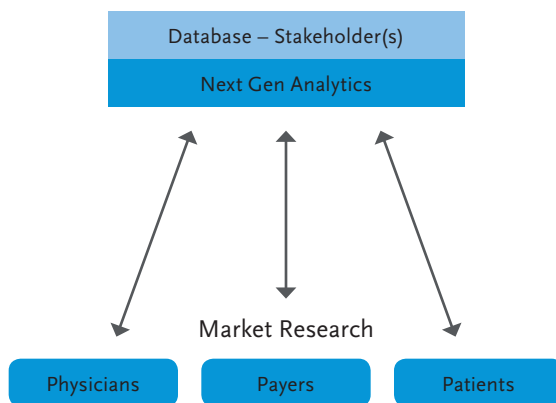
Pharmaceutical companies have traditionally ignored patient attrition as a ‘cost of doing business,’ as long as new patient acquisition helped to drive sales growth. This was mostly driven by the fact that despite significant efforts, health care systems never were able to consistently initiate impactful compliance systems. The danger with this system is that inappropriate utilization further undermines the Brand value proposition. In a re-engineered model, sales teams are refocused on key account managers who work multiple stakeholders with a blend of brand and customer-centric approaches to help communicate the value of good patient outcomes.

In this model, industry needs to demonstrate the benefits of its products in meaningful terms for varied stakeholders and audiences. High-value innovation is not merely to introduce new medicines, but to introduce better ones – proven to provide greater therapeutic benefit, safety, improved quality of life or convenience for patients or providers. By this measure, the overall treatment process or outcome of a particular product must be shown to be an acceptable improvement over the current standard of care for commercial viability.

One way to demonstrate the relative value of products is Comparative Effectiveness Research (CER), an approach in which products are evaluated in a true-to-life setting against the current standard of care. As short term “cost containment” actions fail to produce long term economic or health results, the concept of value based on a product’s evidence of comparative effectiveness – an incremental improvement in treatment process or outcome conferred to patients compared with the current standard of care in a real world setting – continues to gain currency.

Currently, the concept of CER has limited metrics, such as explicit measures of effectiveness and implicit measures of cost containment. Nevertheless, as payers embrace health care value and look to longer term patient outcomes collected in real world settings for determination of that value, CER stands to gain increased importance in reimbursement decisions. Under an evidence-based market paradigm, then, payers will base their recommendations of value in areas such as safety, effectiveness, quality of life and convenience, and can be expected to price accordingly. These factors need to be considered early on in the development cycle, and a closed-loop system of reporting data and altering development strategy based on that data must be an ongoing process throughout the product's lifecycle.

Patient Data Drives Success



With patient behavior linked to treatment outcomes occupying greater importance in a re-engineered biopharmaceutical commercialization model, robust database management and insightful data analytics represent key drivers of success for manufacturers.

To influence patient and payer behavior through communication of outcomes as part of an effective commercialization strategy, a feedback loop of value creation developed by a manufacturer or trusted partner needs to be developed and implemented. To develop an appropriate product-specific strategy, such a program requires:

- A database that builds in value over time, so techniques such as segmentation of patients and outcomes analysis become increasingly powerful.
- Data that allows for organizational flexibility – brand-centric and customer-centric based approaches (e.g., looking for commonalities of patient characteristics across brands).
- Sophisticated analysis using principles of consumer analytics to create unique guidance for strategy development.
- Longitudinal and real-life outcome analysis to create an ability to guarantee outcomes.

The ability to access the necessary data to ‘decode’ patient behavior – with greater precision than previously required – creates the capability to support market access and drive patient acquisition and adherence strategies.

A Ready Partner for Change

As biopharmaceutical manufacturers struggle to make sense of the future during this period of significant and rapid change, the rules governing successful commercialization of new and existing products are changing. As the rules change and the New Health landscape becomes a reality, so too must the business models biopharmaceutical companies need to move forward.

At Quintiles, we must also ensure we are positioned for success in the New Health landscape. Given the significant interaction Quintiles has with patients in multiple therapeutic categories, the company feels the same responsibility as its biopharmaceutical companies, physicians, government agencies, and private payers to find a solution for the benefit of the patients we all serve. In light of this rapidly changing environment, we are shifting our focus better to provide comprehensive solutions and transforming our core business to respond to the changing needs of our customers and the industry alike.

As with all successful companies, we must both run our business today and enact a new strategy to serve the needs of our customers and the industry tomorrow. In preparing for the future, we have embarked on extensive market analysis and solicited direct customer input to help us develop solutions for our partners. Our vision is to be the global comprehensive commercial solutions ally for the New Health landscape – the fundamental, intense change the biopharmaceutical industry is undergoing today.

Whether employing our expertise in pre- and post-launch Product and Brand Solutions; expanding market access capabilities; using patient-centric data and analytics to help drive commercialization strategies; leveraging our power to in-license or acquire commercial rights to products; or helping engage and manage the right type of pharmaceutical sales team or develop alternative communication channels, our goal is provide effective commercial solutions even as we continually evolve our focus and capabilities.

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Michael Ackermann, Ph.D., serves as the Senior Vice President of Global Commercial Strategy and Alliance, Global Commercial Solutions at Quintiles, a position he has held since May of 2009. Prior to joining Quintiles, Dr. Ackermann founded and acted as President of Laurus, LLC, a business accelerator for start-up life sciences companies. Dr. Ackermann also spent 18 years at Eli Lilly and Company where he held numerous executive positions as a Business Unit leader, executive sales leadership positions as well as corporate strategic pricing and market research.

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