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Techniques in Vascular and Interventional Radiology

Innovation Best Practices in the Medical Device Industry

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Advances in patient care often germinate from keen clinical insights and a needs-based approach to innovation. Although there is an important role for incremental improvements to existing solutions, transformational innovation is what truly drives real shifts in clinical outcomes and subsequently patient satisfaction, market access, and economic value. A good example of this is the evolution of the coronary stent market. The best innovation programs are focused on unmet needs rather than solutions, call for a careful articulation of the specific problems to be solved, involve a deep dive within a clinical area, and seek to prioritize research and development investments into areas where the greatest impact can be expected. To enhance its ability to pursue breakthrough innovation, Johnson and Johnson (J&J) has organized itself along priority disease areas, created the global J&J Innovation organization to pursue external technology and know-how, and continues to partner closely with clinical practitioners. The process undertaken at J&J to acquire a microwave ablation technology and enter the interventional oncology space is a recent case study of these innovation principles and organizational focus in action.

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The Criticality of Breakthrough Innovation

Innovation has long played a central role in the evolution of patient care. From the pioneering work of Dr Charles Dotter in angioplasty to Dr Thomas Fogarty's development of the balloon embolectomy catheter, breakthroughs in patient care have come from keen observation and application of clinical insights. The development and dissemination of new therapies is characterized by a complex interaction between physicians and industry. Articulating clinical insights as unmet needs, (co)inventing and refining new technologies to address those needs, generating clinical evidence in close collaboration with academia, and developing markets for those new treatment modalities are some of the ways that the medical device industry advances patient care.

A good example is Johnson & Johnson's (J&J) role in developing the coronary stent. Having observed the rapid growth in angioplasty, J&J investigators identified the important constraints in the procedure at that time: vessel recoil and restenosis. Armed with this knowledge, J&J sought out and licensed the stent technology invented by Drs Julio Palmaz and Richard Schatz, which addressed these critical issues. This resulted in a 7-year product and clinical development process, leading to FDA approval of the Palmaz-Schatz stent in 1994. In its first year on the market, this stent was placed in more than 100,000 US patients. The market grew dramatically after that, with 2.6 million stent placements and sales of $3.59 billion in 2003. Further growth was driven by incremental yet important innovations such as drug-eluting stents, which J&J's Cordis business unit introduced in 2003.

As the market matured, however, the value of such incremental innovations diminished. This is a well-documented phenomenon in which, once products reach a certain level of performance, the "good-enough" stage, customers will still welcome incremental innovations but

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are no longer willing to pay a higher price for them. Once a technology reaches the point where it cannot be significantly enhanced, at least without outsized R&D spending, companies must consider whether investments would be better directed to more clinically meaningful unmet needs which also hold the potential promise of a greater return on investment. For this reason, among others, J&J exited the stent business and eventually divested its Cordis business unit in 2015, freeing up funds for reinvestment toward more breakthrough innovations.

The coronary stent experience at J&J demonstrates the importance of breakthrough innovation and novel treatments for sustaining growth in today's increasingly competitive and cost-constrained health care market. Organizing the corporation to identify and act on such innovations has been a major imperative at J&J. Paul Stoffels, Chief Scientific Officer of J&J, has been championing this strategy for years across the enterprise. Dr Stoffels states[1]: "The answer to economic pressure is innovation. If you bring innovative new drugs into the market, society will be prepared to pay for it. We need to produce more and more significant innovation to be reimbursed by the payors in the world. It is a scientific, technical, and global development challenge to develop the best drugs [and] pick up the best technology."

A Needs-Based Approach to Innovation

Dotter and Fogarty, both physician-innovators, were acutely aware of unmet patient needs and these inspired their search and development of novel technologic solutions, exemplifying the fundamental concept of needs-based innovation. The natural tendency of most innovators is to build upon an existing solution, for example, a drug-coated stent or balloon. But the true breakthroughs come from a disciplined focus on clinical needs, not solutions, and the rigorous characterization of those needs, often leading to a fundamental change in the understanding of the disease state and a shift in the treatment paradigm.

The Biodesign innovation process developed at Stanford University has codified this needs-based approach.[2] The core of this process involves the creation of a need statement, which carefully articulates a specific problem to be solved in a specific patient population, by a specific provider type, at a specific setting, to achieve a specific outcome. For coronary angioplasty, the need statement could have been "a way to nonsurgically increase blood flow in the narrowed epicardial coronary vessels of coronary artery disease patients to reduce angina symptoms, the risk of myocardial infarction, and morbidity related to open coronary artery bypass surgery."

Another key element of needs-driven innovation is clinical focus and the notion of establishing a deep knowledge of all aspects of a defined clinical area—from prevention and diagnosis to treatment and posttreatment care. This imperative is selfevident for a clinical specialist, but not necessarily for most broad-based health care companies or aspiring individual innovators. To address this potential gap, J&J Medical Devices has refocused its efforts from a product-based platform approach, which seeks to gain new markets for existing technologies, to a disease and specialty-based approach. Today, J&J has several clearly defined clinical areas of focus, for example, cardiovascular and oncology.

Disease area focus allows for concentrating on the discovery of unmet needs within a given area and encourages one to consider all aspects of the disease process from interception to advanced treatment. The process, therefore, is agnostic to existing technologies but instead seeks to identify the critical needs that will meaningfully effect treatment outcomes. As not all needs are created equal, prioritization proves to be essential. The Biodesign innovation process outlines an approach for making potential needs "compete" against one another, against a series of defined screening filters, to determine which show the greatest overall promise to take forward into invention. For instance, J&J uses filters to identify which needs, if solved, would improve clinical outcomes known to have a significant disease burden, increase patient satisfaction, improve access and reduce health care costs. These tenets are aligned with the Institute for Healthcare Improvement's Triple Aim Initiative[3,4] and are shared by most global health care systems, payors, and regulators today as they struggle to meet increasing patient demand with diminishing health care budgets. Indeed, medical therapies that withstood the test of time, including advances in, for example, interventional cardiology and laparoscopic surgery, were successful precisely because they meet these criteria.

Specialty Orientation and Flexible Development Models

Like most large medical companies, J&J has traditionally been organized by product or technology platforms rather than need area. Within Ethicon Inc, a J&J company and one of the largest surgical device companies in the world, most initiatives, budgets and staff are organized in 4 core platforms: wound closure, energy, endomechanical, and biosurgery. Naturally, this has meant that innovation activities have historically been focused on incremental improvements to existing products. In such a structure, innovation tends to be solution—rather than need-driven. This model builds on the company's core competencies and delivers a pipeline of products that continually improves the products' performance and safety; allowing for system solutions and global scale. It does not, however, lend itself to transformational, disruptive innovation that requires unconstrained design and a total absence of preconceived notions of what the solution(s) should entail.

To counteract this, J&J has increasingly organized its innovation organization and activities (and in some cases commercial activities) by disease state, allowing for deeper focus in priority areas. For instance, in oncology, this has