



**Innovation in Medical Device and Consumer Health Products:
The Role of Patients and Medical Professionals**

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It's common to think that inventions, including medical devices and other healthcare products begin with a cry of 'Eureka!' as the lone inventor has a flash of inspiration and races to the lab to tinker through the night to create a product ready for market. In reality, medical innovation occurs in response to a happy combination of practical need, insight, idea, technology, process, infrastructure, commitment, problem or possibility. It usually takes a team of people to research, develop, test, fund, manufacture, market and deliver a viable device or product.

The history of medical product innovation begins with the history of research and development. While the great thinkers of the Renaissance such as Leonardo Da Vinci rediscovered the scientific method and were the first systematic practitioners of research and development, the following centuries caused R & D to evolve into its current industrial form.

In nineteenth century United States research was managed by scientists who selected projects and conducted research that provided many essential breakthroughs and contributed to important and profitable products. An example is the lab lead by Dupont. This is considered first generation R & D. Second generation R & D began when corporate managers rather than scientist managers, realized that they had to focus their labs on projects critical to the success of their companies and applied project management practices developed during WWII.

Third generation R & D saw the practice of technology management in the context of financial risk, strategic planning and technology roadmaps take hold. As noted in the influential book Fourth Generation R & D by Miller and Morris, the traditional innovation system described by 3rd generation R & D divided the responsibility for knowledge acquisition between marketing and R & D. The limitations of this arrangement are many, including the problem that patient need is defined as that which is explicit or the visible tip of the iceberg. The larger mass of need tends to be invisible or latent and "will probably not be discovered, or satisfied, in a practice that fragments critical knowledge." As a result, changes to existing medical devices and products tend to be incremental and, over all, few truly innovative devices are brought to market.

Advances in information technology have enabled the development of 4th generation R & D where patient needs and technological capabilities coevolve in a process of "mutually dependent" learning, in which technological enabled capabilities and concepts are assessed and refined in the context of real need.

Fourth generation R & D is driven by the synthesis of new knowledge extracted from transdisciplinary sources. A key source of new knowledge is the end user. In the case of medical devices and health care products, the end users are the patient and medical professionals who use or recommend them. In health care, tapping into the knowledge of

medical professionals and patients allows discontinuous and unbounded innovation because it is driven by the discovery of unmet, tacit clinical needs.

The integration of the insight and observation of the end users into the front end of new product development has been called open innovation. A number of models of open innovation exist including the more traditional joint development efforts, alliances, and consortia. An example might be the medical device companies that work with University faculty to identify and develop promising technology. The problem with these models is the limited reach that is provided. Reach is defined as the ability to connect globally with the thousands of potential providers of basic science, clinical services and emerging technology.

Newer models include the subscription model and the open network model. The subscription model requires a device company to pay for access to a limited network of experts to consult with regarding unmet clinical need or potential solutions to clinical problems. The open network model provides a structured process for developing requests for clinical, technology or innovation solutions and distributing them to the global clinical and research community.

Medical device and consumer health product companies invest in innovation to drive new product development because new products create profit. Yet companies spend the bulk of their R & D dollars on incremental improvements to existing products. This is because, despite the increasing awareness of the need for medical professional and patient involvement in new product design and development, access to end-users is difficult. As medical professionals we are busy caring for our patients and the traditional methods of engaging with device and pharmaceutical companies through sponsored research or speaking engagements is coming under scrutiny for conflict of interest reasons.

Balan Biomedical, Inc. is developed on the open innovation model and is dedicated to bringing critical insights of medical professionals and patients to new product development in medical devices and consumer health industries. Balan is a physician-owned company with extensive medical professional and patient networks. Balan works directly with the R & D divisions of the large medical device and consumer health product companies to identify unmet clinical needs through tapping medical professionals and patient experience and insight. Examples of areas of discovery include new consumer products to support diabetic patients, sleep-disordered breathing patients, and patients with osteoporosis as well as improvements in the power source for neurostimulators and design improvements in cardiac catheters.

Medical professional insight is tremendously valued by new product development companies. Finding a way to bring those insights without burdening already busy professionals is the goal of Balan Biomedical.

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