

Cardiac pacemaker business essay sample

[Business](#), [Company](#)



Cardiac Pacemaker Business

The legacy of Medtronic Corporation, the company that created the cardiac pacemaker industry, is a proud one. Starting from its earliest pacemakers, which had to be carried outside the body, Medtronic had achieved dramatic improvements in the functionality, size and reliability of these devices. In 50 years it had extended the lives, and improved the quality of life, for hundreds of thousands of people in whom pacemakers had been implanted. The pacemaker has been designated as one of the ten most outstanding engineering achievements in the world over the past 50 years, along with the digital computer and the Apollo 11 moon landing. Medtronic, which in 1995 booked operating profit of \$300 million on revenues of \$1.7 billion, had been founded in 1957 in Minneapolis, Minnesota by Earl Bakken, a researcher and inventor who had to his credit patents on several of the crucial technologies that led to the modern heart pacemaker.

Pacemakers were small, battery-powered devices which, when implanted within a patient, helped a malfunctioning heart to beat in a steady, fixed rhythm. Because Medtronic was the first entrant into the pacemaker field and built a strong technological lead, it enjoyed a substantial portion (over 70%) of the market share for cardiac pacemakers through the 1960s. Building upon Medtronic's legacy and leadership was not easy, however. In the face of increasing competition, rapid technological change and tightening market and regulatory demands for product quality, Medtronic saw its market share cut by more than half between 1970 and 1986. Though it had invested heavily in technology and product development over this period, much of that investment had been unproductive.

Many projects failed to produce product designs that could be launched competitively, and the features and functionality of most of the products the company was able to launch, lagged the competition. Several key employees left the company, seeing greater opportunity to develop their new pacemaker product ideas in new start-ups rather than within Medtronic. These competitors proved much faster than Medtronic at developing new products that advanced the state-of-the-art in pacemaking. Medtronic was also pummeled by two major product recalls related to product quality problems. Observers felt the company would have lost even more of the market during this period, were it not for its strong worldwide salesforce and the lingering legacy of its brand reputation amongst surgeons, the primary customer group.

This citation was made by the National Society of Professional Engineers in 1984. Professor Clayton Christensen, MIT Sloan School of Management, is the basis for this discussion. The author is grateful to the Sloan School of Management for its support of this research. Some of the data and names in this case (UVC PLC) disguised the proprietary information of the company.

Copyright © 1997 by the President and Fellows of Harvard College. To order copies or request permission to reproduce materials, call 1-800-545-7685, write Harvard Business School Publishing, Boston, MA 02163, or go to <http://www.hbsp.harvard.edu>. No part of this publication may be reproduced, stored in a retrieval system, used in a spreadsheet, or transmitted in any

form or by any means—electronic, mechanical, photocopying, recording, or otherwise—without the permission of Harvard Business School. 1

698-004

We've Got Rhythm! Medtronic Corporation's Cardiac Pacemaker Business

Management changes which were initiated in the late 1980s, however, had sparked a dramatic reversal in the company's fortunes, and by 1996 the company had regained its position of product and market leadership. By all accounts, it was in front and pulling away from its competitors. On a pleasant Minneapolis spring afternoon in 1996, several members of the team that managed this turn-around — Steve MaNe, president of the Brady Pacing Business; Mike Stevens, general manager of the Pulse Generator & Programming Systems (PGPS) Division; Bill Murray, general manager of the MicroRel component manufacturing subsidiary; Director of Marketing Paula Skjefte (pronounced Sheftee); and Director of Product Development Technology Don Deyo — gathered to assess the progress they had made since they had taken the helm of the troubled division in the late 1980s. They were all anxious to understand whether the management structure and the processes, values, and resources they had created to achieve this turn-around, were capable of maintaining the company's successful momentum in the future. This case recounts their achievements and concerns.

Medtronic's Brady Pacing Business

Medtronic's Brady Business Unit designed and built pacemakers that

<https://assignbuster.com/cardiac-pacemaker-business-essay-sample/>

delivered a rhythm of electrical impulses, to remedy a disorder called Bradycardia, in which the heart's electrical system does not generate pulses to cause the heart to beat rapidly enough to sustain the body's normal activity, as described in Appendix L 2. Amongst its other businesses, Medtronic also had a Tachycardia Business Unit, whose products addressed the opposite malfunction – when the heart's electrical system generated too many beats. Because of the prevalence of Bradycardia relative to other disorders in cardiac patients, the Brady Business Unit historically had delivered most of Medtronic's revenues, and an even larger share of its profits. Consequently, the health and vitality of the Brady Business strongly affected the corporation's overall financial performance.

The Brady Business Unit worked hand-in-glove with the component divisions of Medtronic. The Promeon Division, for example, developed new technologies to power pacemakers. In the early years of the industry's history in particular, battery technology had been a pivotal selling point because the battery could not be replaced: once it was depleted, a new pacemaker had to be implanted. Another division, MicroRel, designed and fabricated the critical hybrid microelectronic circuits in Medtronic's portfolio. Medtronic, PGPS focused on developing new products for Bradycardia pacing, by translating customer and market-based inputs into product designs, and then worked closely with manufacturing to produce the final products.

This involved design and assembly of the pacemaker as well as the programming unit, which typically sat on a table in the cath lab or operating

room where the implantation was performed. Programming units allowed physicians to tailor the firmware in the pacemaker so that the frequency of the pulses it generated and a number of other attributes of the device matched the needs of each individual patient. It was to try and get decisions to be made by the functional leadership — they only had minor authority to make decisions themselves. “Planning new products is actually a lot more difficult in a business like ours than it looks,” reflected another experienced executive. “In some businesses the problem is a lack of great ideas.

But in our situation — with rapidly changing technological possibilities, some darned good competitors and thousands of cardiologists out there with ideas for all kinds of new features, the opposite is true: We’ve always had too many ideas for new products. In our functional organization, without a single, coordinated process or person to articulate a product plan or strategy, development projects just started everywhere. When you had a good idea, you’d mock up something — either a real prototype or something on paper — and carry it around with you. Then when you’d run into Earl Bakken or another powerful manager in the hall, you’d corner him, pull your idea out of your pocket, and try to get him to support it. If his reaction seemed positive, then you would use that leverage, to get a few friends to help you push it along. At some point you’d go to the engineering manager to get formal resources.

“The problem with this system was not that we were working on bad ideas. Most of them were technically sound and made market sense,” commented Don Deyo, an experienced engineer and currently Director of Product

Development and Technology. “ We were trying to do too many things, and no project got the focus and attention needed to get it done right. It was taking too long to get anything to market. We never got good at releasing new products, because you only get good at things you do a lot. Those that we did introduce often followed the lead of competitors. That’s what happens when you continually try to respond to every new idea to come along.”

The problem then fed on itself,” reflected Mike Stevens, general manager. “ The development people would tell me that they could never get anything to market because marketing kept changing the product description in the middle of the projects. And the marketing people would say that it took so long for engineering to get anything done, that by the time they got around to completing something, the market demands would have changed. When customer requirements evolve faster than you can develop products, it becomes a vicious spiral. ” In environments like that, it is very difficult to plan product families.” Stevens continued. “ If the company launched a product that subsequently could be modified or extended to create derivative models, it was a stroke of luck .” Because of the way in which new product development projects were conceived, Medtronic’s project pipeline was made up of incongruous development cycles. Projects were separated according to whether they were single or dual-chamber platforms. Each new model had largely its own unique circuitry, components, testing programs, casing, and battery . Due to the high costs of developing all these parts of the pacemaker, project managers battled each

other for resources. Although the company's reputation and strong salesforce relationships with surgeons kept disaster at bay, the company's performance suffered as a result of its disabilities in development. Between 1970 and 1986, it was almost always a competitor, not Medtronic, that introduced major new improvements to the market. For example, Cordis introduced the world's first programmable pacemaker in 1972; Medtronic followed in 1980.

Cardiac Pacemakers Inc., a Medtronic spin-off, pioneered the first pacemaker with a long-life lithium battery in 1974. Even though the technology was available from a third-party supplier, Medtronic did not get its lithium battery-powered product out the door until 1978. Although Medtronic introduced its first dual-chamber pacemaker during this period, it did not follow it with an improved dual chamber device for another eight years. Deyo explained, " We were working on next-generation dual chamber products during all of those eight years. The problem was that just as we'd get ready to announce a new product, a competitor would come out with something better. So we'd force the funnel open again to allow for their new input, re-scope the project, and try to leap ahead of the competitor. Then just as we'd get ready with the improved version, a competitor would come in ahead of us with an even better product; and so on."

" I got so that I just didn't want to answer the phone because I was afraid there would be a salesman on the line wanting to know when we were going to come out with a product that was comparable to something a competitor had introduced," recalled Paula Skjefte, director of marketing. " 1

It couldn't give him an answer." Field product failures compounded the problems caused by Medtronic's long development cycle. Its Xytron pacemaker line was recalled in 1976 after several units failed following implantation. And a few years later, physicians found that the leads on some pacemakers they had implanted had disintegrated, so that the pacemaker's output was not getting transmitted to their patients' hearts. In total, Medtronic was forced to issue four different product advisories to Wall Street that certain models were susceptible to malfunction.

The result of these factors was a massive loss of share, from 70% in 1970 to 29% in 1986, as shown in Exhibit 2. Still, however, due to significant growth in the market, the company continued to report record sales and profits over this period, and "for many in the company there was no cause for alarm." "Medtronic was a really nice Minneapolis company," Don Deyo noted. This reflected in many ways the values of Medtronic's founder, who had a genuine reverence for every employee's contributions to the company's success. "But somehow in the mid-1970s, Deyo noted, "This attitude got out of hand. We dominated the market, and were very profitable. Because there was so little pressure on the business, we lost our intensity and willingness to focus our efforts."

A Home Run Saves the Day

The company's decline was arrested in 1986 — more by good fortune than any change in management practice, however. In the early 1980s a project leader, Ken Anderson, championed an idea for a "rate-responsive" pacemaker — a device which could sense when changes in body activity

required the heart to beat faster or slower, and stimulated the heart to beat accordingly. Although most cardiologists Anderson spoke to thought the idea was impractical, and despite the indifference of most of Medtronic's staff Anderson won the support of the general manager, and the two of them set up a dedicated team to pursue the idea. Its product, dubbed Activitmx, worked — technologically and in the marketplace.

Cardiologists found its single-chamber design easy to implant, and its effect was nearly as good for patients as a dual chamber pacemaker. Patients reported feeling stronger, because it would cause their hearts to beat more rapidly when they were working hard or exercising. And they reported feeling more rested in the morning, because Activitrx paced their hearts to beat more slowly when they were asleep. The dramatic Activitrx therapeutic breakthrough literally saved Medtronic, because no other new platform products were ready for introduction until 1992. It did not, however, “alter the way the company developed products.

The Turnaround in Product Development

Though Medtronic's market position was helped by the success of Activitrx and by a serious product recall suffered by a principal competitor, the most dramatic changes in the company's market position were instigated when Mike Stevens was assigned to be vice president for product development of the PGPS Division in 1987. Stevens' career with Medtronic had begun in 1973, when Motorola decided to shut down its hybrid circuit manufacturing operation near Phoenix. Stevens and several other employees of the Motorola facility decided to continue the operation and obtained financing

from Medtronic, which had been a major customer. Stevens had watched Medtronic's struggles in product development from a supplier's viewpoint.

“ Though I didn't have a background in product development, I saw much of Medtronic's problem as Management 101. We had very strong functional roles. People were being measured by cost centers, and there was no accountability for the delay or failure of a new product. I felt the basic values and structures of the company were still really strong. But what needed work were its processes. I felt if we could get those straightened out, then we could bring the Brady business back to its past glory.” Stevens summarized key elements of his management philosophy as follows:

Commitments are sacred. The more responsibility you give to people to control their destiny, the more you can and must hold them accountable.

Create a sense of urgency by contrasting the excitement of bringing new therapy to patients, versus the consequences if your competitors are there first with better solutions. Don't waste time with excess travel or off-site meetings

Are happy employees productive, or are productive employees happy? Stevens believed the latter, whereas Medtronic management had been acting as if the former were true.

-lo

Do nothing that separates management and employees. Management means responsibility, not status.

You only get what you measure.

Focus on gaining market share. Over time, this is the most accurate measure of your success.

Managers in the PGPS Division got a taste of Stevens' belief that commitments are sacred when, shortly after arriving at Medtronic, he held management to the project milestones they had agreed upon at the beginning of fiscal year 1988. Their incentive compensation was tied to these objectives, and 1988 was the first year in memory that management did not receive year-end bonuses that were tied to objectives.

Measuring Product Development Performance

Stevens implemented his measurement philosophy by focusing on four measures of product development performance, which corresponded to the achievements he wanted the organization to focus upon. These are described in the following table.

698-004

We've Got Rhythm! Medtronic Corporation's Cardiac Pacemaker Business

Focus

Measure

Speed

Cycle time

Stevens' Comments

“Time is the time required to get a new product into the market. If I measure this, there isn't much else I need to measure. It forces you to do the other things right in product development, because you can't make mistakes, and you can't waste time.”

Fully allocated unit product costs

“The reason we focus on fully allocated costs, rather than just viewing functional costs as direct product costs, is that it gets you thinking about market share, and the impact that unit volumes can have on your financial success. This is healthy thinking.”

Innovativeness

Product performance relative to competitors

“This translates into market share, pure and simple.”

Product Quality

Field performance defects per million

“In our business, you can't afford a field failure — because our patients count on us, and doctors can choose to go elsewhere.”

Most people in PGPS welcomed Stevens' attitude. One commented, “I was just getting started as a project manager, and Mike was a breath of fresh air. His priorities were clear; I knew where he stood. He had a very different

management style: very firm, assertive, thoughtful and focused. He was execution-oriented, and really held people accountable.

Processes and Practices

“It isn’t a story about great management,” Stevens emphasized. “It’s a story about putting into place a set of processes that helped a great team of people be as productive as they could be.” The processes Stevens instituted had the following features:

1. Speed “Being fast to market eliminates 50 many other problems,” commented Steve Mahle, who took over as president of the Brady Pacing Business in 1990. “The slowest part of our process was actually in deciding what needed to be done. We used to spend lots of time debating what we should do. One of Mike’s greatest achievements was in cleaning up the front end. He did this by articulating very clearly what our strategy was, so that there was a well-defined criteria that could guide these decisions. Then he created a process to get those decisions made.” Exhibit 3 describes the process by which new products were defined.

An assessment of the competitive and customer environment was combined with a technology assessment, to define the business objectives of each new product, and to clarify what the financial and competitive contributions of the new product needed to be. Stevens, who by 1991 had become division general manager, reviewed new product ideas according to their potential for meeting those business objectives. His staff, comprised of the managers of the division’s marketing, research, development, technology, finance,

human resources and manufacturing functions, participated in this review with Stevens.

2. Platform Strategy Since product ideas in the earlier regime had originated in disparate parts of the organization and were approved and funded in independent decisions, it was quite common that products that required significant investments of time and money were not leveraged with derivative products that could extend their life and market reach. The highly successful Activitrac model, for example, did not spawn a single derivative product that offered different features, performance, or price points to the market. To devise an effective product line architecture built around product platforms, Mahle established a product planning team comprised of himself, Mike Stevens, Paula Skjefte, Don Deya and Stan Myrum, Vice president and general manager of the business unit's leads division. This team defined a platform strategy around three key elements.

The first element was that the initial platform product had to be designed to accommodate the full range of derivative models from it, without significant redesign. "In other words," Stevens explained, "We designed the highest-performance, most fully featured version of the product at the outset."

Medtronic then created derivatives by de-features and de-rating certain elements of that design, so that it could address other tiers of the market as well. The second element of the platform strategy was enabled by the first. Historically, Medtronic had introduced new pacemaker features on its single-chamber models first, because they were technologically simpler to design and build. Once the features were accepted and the technology perfected in

the single-chamber platform, the features were then moved up-market onto the dual chamber platform. “ The effect of this,” Paula Skjefte noted, “ Was to force a lot of our lead physicians to continue focusing on single-chamber devices just so they could utilize our newest features.

Once we began designing the platform to accommodate the full range of derivative models we planned to spin off from it, we didn’t face the same constraint – it was just as easy to put the most advanced features on the dual chamber model. This gave us a much clearer progression from basic, simple devices for the low-end of the market to high-performance, fully featured models at the high end. Skjefte continued, “ The way we used to play in the low-end of the market was to discount the price of our old model, after we had introduced a new one. This was ironic. Because we were reducing the cost of our products with each generation, we sold our high-cost models at the lowest prices, and our low-cost, newest models at the highest prices.” The result was that there was little incentive to maintain a strong presence in lower tiers of the market.

Under the new strategy, Medtronic addressed lower price points in its market with the simplest versions of its new lower-cost platforms. Hence, even as Medtronic was assuming a leadership role in features and functionality in higher tiers of the market, it strengthened its position in the low end as well. The third aspect of Medtronic’s platform strategy was to change the way platforms were defined. Formerly, Medtronic had thought of platforms in terms of physical architecture. Hence, it was inconceivable that a dual-chamber device could have been levered off of a single-chamber device

platform. The projects were executed by completely different teams, and their designs therefore diverged from the very beginning. Under the new strategy, advances in microelectronics technology enabled many of the most important capabilities to be designed into the hybrid circuit, that the circuit design constituted the platform.

This circuit could then be modified quite readily, often through firmware modifications, to enable or disable particular features in the design of derivative products. “I couldn’t say whether Medtronic’s decision to integrate backward into hybrid circuit production by starting MicroRel was good luck or good management,” Stevens reflected. “But at this point the expertise we have developed in circuit design and production is an enormous advantage. Our competitors outsource their hybrid circuits. But we have found that the hybrid is so integral to our functionality and our standards in quality and specifications, that suppliers just can’t meet what we need. We can outsource things that are a little bit more modular — things that aren’t so integral to the essence of our product. And being vertically integrated helps with speed. We can go down to MicroRel and shift priorities if something needs to be done quickly. We are so vertically integrated with our battery development and manufacturing.”

Medtronic faced many particular challenges in implementing its platform strategy, Stevens reflected. “First, we learned that we needed to have the technology building blocks in place, before we could begin a platform project. Product development is not technology development — you can’t have the uncertainties of advanced technology development on the critical path of a

rhythmically executed product development project. Technology takes time to put into place, and it requires consistency in strategy and management methods, to tie advanced technology development with product development in a consistent, useful way. The second challenge we encountered was that platform projects required much more interaction and coordination amongst various individuals and groups in the company – within engineering, and across engineering, manufacturing, marketing and finance — than other projects. You can't have a 'one-size-fits-all' habit for R&D or CT development teams, if you're really serious about a platform strategy."

Indeed, Stevens' decision to vest platform development teams with much greater decision making authority — essentially making project managers the peers of functional managers — had a pervasive and some times disruptive impact on many in the organization. He assigned eight project managers with dedicated teams — from research, development and marketing — to oversee the development of every platform. Other project managers, working under the supervision of the platform manager, took responsibility for derivative projects extending off of each platform. This represented a significant shift in the job of the company's functional managers. Their charge became providing trained, capable people to staff projects, and developing new technology platforms. "It became very clear, very quickly," observed Bill Murray, an electrical engineer-turned-project manager, "That project management was the path for career advancement. Even some of the functional managers left their positions to become project managers."

3. Project Documentation Previous agreements to initiate a project were often made verbally. “ It was amazing how many misunderstandings and disagreements seemed to survive those verbal contracts,” Don Deya recalled. “ You could leave a meeting thinking you had agreed on something, and learn a few months later that you hadn’t. Then when we had to change something, the marketing and engineering people were always accusing each other of violating an earlier agreement. It’s amazing in a set-up like that, how easy it is legitimately and honestly to find someone else at fault.” One way Stevens implemented his credo that commitments are sacred was to require key documents to be written at the start of the development phase of each project: A Product Description document, written by marketing, which detailed the customer requirements, product definition and clinical performance expectations of the product; and the Product Specification document, written by engineering.

This detailed the technical and cost specifications that the product would have to meet, in order to meet the Product Description. Stevens required marketing to sign off on the Product Specification, certifying that there was a technical specification corresponding to each requirement in the Product Description. Similarly, Engineering had to sign off on the Product Description, as a double-check that marketing and engineering were synchronized.

4. Phase Definition Stevens and Mahle defined a system Df phases and project reviews, to which all projects would be subject. Projects started in a Preliminary analysis phase, in which the Product Description was written and the financial benefits of the project to Medtronic were estimated. Following

review of the business case, the project would enter the development phase. Here, the technological feasibility of the project was probed, to avoid putting the necessity of inventing something on the critical path of a development program. Rapid prototyping was emphasized in this phase, to identify problems and possible solutions as quickly as possible. If a product idea required a technology that was not well developed, Medtronic would shelve the idea, preferring to wait until the approach had been developed and proven in other markets. The Product Specification was prepared during this phase, and consistency with the Product Description was verified.

The major executive review came after the demonstration phase, where the proposed product's technological potential, competitive activity and market needs, and its volume, profit and return on investment projections were rigorously reviewed. "I call this our commitment review," noted Mahle. "I believe that language conveys intent. We had been plagued by waffling and compromise, and weren't doing what we said we would do." At one commitment review on a critical product, in fact, Mahle asked the team to stand up and make a verbal pledge to deliver to the customers and patients what they had said they would. "I believe in the power of personal commitment. Management tools are important, but tools alone won't do it." Following the commitment review, projects went into the development phase. "In the first two phases we have a lot of product ideas falling out or getting canceled, because we decide the market or technology just isn't there," Stevens commented. "But once projects enter the commitment phase, we expect

100% of them to be technically and commercially successful. There is no narrowing of the funnel after that.”

The Product Planning Team, which as noted above was responsible for establishing the product line architecture, also had responsibility for conducting the major phase reviews for each project. 5. Rhythm “ There’s a lot of uncertainty in new product development,” noted Stevens. “ You don’t want to create additional uncertainty by the way you manage. The more predictability you can build into the development environment, the more productive your efforts will be.” Stevens implemented this philosophy in two steps. First, he and Mahle fixed a date each month, a year in advance, when phase reviews would be held. Project teams approaching a review milestone thus could always count on Mahle and Stevens being available, to review their progress. Second, the management team established a schedule, far into the future, according to which new products would be developed and launched.

“ Of course we don’t know now what these specific products will be,” said Stevens. “ But we know the technology will always change, and we know the competition will always be trying to get ahead. It’s like publishing a train schedule. It helps people to know when the next projects are scheduled to leave the station.” In retrospect, one benefit of setting a “ train schedule” in advance was that there was less clamoring amongst Medtronic’s marketers to revise objectives to include additional functionality or features after projects had begun. “ In our troubled days,” recalled Mahle, “ No one knew when the next project was going to be started, let alone finished. Because of

this, whenever a competitor came out with something, or an important physician came up with an important new idea, our marketing people were desperate to revise the charter of the product currently under development, to include that feature. If they didn't get it on this train, when would they ever get it?

Once we had a train schedule, they could relax. If we froze the spec and their feature or idea didn't make it on this one, they knew that in another 18-24 months, all other trains would be leaving the station, and they could get their idea on that one." 6. Market Inputs Medtronic also systematized the ways in which the company got input from customers, by revitalizing two eight-person physician review boards which had previously been functioning but which had lost their impact on company policy, for each of Medtronic's pacemaker lines. These boards met twice each year to give inputs on the performance of existing models, and suggest what functionality and features the company might incorporate in new models.

"A big challenge with these boards," noted Paula Skjefte, was that "There is a strong tendency just to have experts on our boards. Life would be easier if we did that, but we wouldn't be getting the whole picture. Joe Average Cardiologist only spends about 2% of his practice on pacemakers. He's just not interested in spending a whole day on our board advising us about pacemakers. We want to be able to satisfy all the customers, from the experts who want to do their own programming, to the cardiologists who just want to get the pacemaker going with no hassle. Taking the pulse of the less demanding end of the market is actually a huge challenge." Once these

boards were properly constituted and functioning, they became critical to Medtronic's ability to define the right pacing systems to meet clinical and customer needs.

Results To Date

The result of the Medtronic team's efforts to put discipline into the Brady Pacing Division's product development operations have been remarkable, as summarized in Exhibits 2 and 4. The time required to develop new platform products was reduced by 75% between 1986 and 1996. Fully allocated product cost per unit fell 30%. Manufacturing defects per million units dropped by a factor of 4; and the number of field failures over the life of an implant dropped by 90%. And the company's share of the Brady Pacemaker market increased from Medtronic was the leader in every segment of the market.

29% in 1986, to 51% in 1996.

From July 1995 to July 1996, Medtronic replaced 100% of its products with new models. It was able to access every segment of the market, and became the highest-volume competitor in each-with ten derivative products built around a single platform technology. "What's interesting," Paula Skjefte observed, "is now to see some of our competitors doing the same thing as we did in the past. There is a vicious cycle that almost got us, and is starting to hurt them. It looks like this: 1. When their share starts to decline, they start arguing over what needs to be done and how to do it. They start more and more projects in to the system, to placate these diverse opinions. 2. Because they aren't focused, it causes delays, and Medtronic gets its

product out first. 3. They have to redirect their project to respond to our product, which slows them down. 4. They panic because we are getting way ahead, and try to make sure that the flagship product they are trying to launch has all the features and functions that will boost it ahead of the competition.

5. This takes even longer — forcing the manufacturer to introduce products that are not functionally competitive, or to rush something into the market that is potentially faulty, just to get something out there. 6. The effect of this is that they spend all the money required to develop and launch products, but it is wasted because it does not generate profitable revenue.” Stevens added, “ People ask us what the secret is, to make a development organization work effectively. I tell them there aren’t any magic bullets that kill the problems. It’s just discipline. You need to do what you say needs to be done. You need to be in it for the long haul, There are no quick fixes. It’s interesting how many people leave these conversations and then go off in search of an easier answer from some guru somewhere. It’s amazing that the obvious isn’t so obvious.”

Challenges for the Future

Success brought a new set of challenges to the Medtronic team, however. Internally, it was becoming clear that the job of changing company practices and culture would never be finished. Stevens noted, for example, that Medtronic’s career path system constituted one of the most vexing challenges to implementing improvements. “ When your best people are moving on every two or three years, you can never just sit

back and say, 'It's working.' Because we're always losing the people we've trained, the understanding of what we're doing and why we're doing it has a very short half-life. We have to keep training and teaching and coaching. I suppose that someday these values and processes will become so ingrained that working this way will just be a part of our culture. But we sure aren't there yet. And probably by the time it gets deeply ingrained here, we'll need to unlearn this because something even better has come along."

"The new marketing challenges are formidable as well," Skjette remarked. "We've always measured the performance of our products in terms of their therapeutic benefit — the extent to which the pacemaker can mimic the normal functioning of the heart's electrical system. Now we have dual chamber pacemakers whose rate varies with the patient's activity, whose batteries have a life far longer than the life expectancy of most implant recipients. Fifteen years ago pacemakers were not programmable. Today, our most advanced models have 200 parameters, which can be reprogrammed non-invasively using RF (radio frequency) technology. Today our models can sense and store all kinds of data about irregularities and other abnormal events in a patient's heart. Doctors can download this data with RF technology, simply by placing device near the patient's chest. How much more do we need? I worry that we're getting to the point that "better" will no longer be valued as "better" by the mainstream cardiologists. How do you develop a stream of improved products if customers are genuinely happy with the performance and features in the

products that they have today? In the future we'll need to change the rules of the game. We've got to figure out how to add value in different ways."

"Catching up to competitors was a very different challenge than it is now, to stay a generation ahead of them — because now we're the ones needing to define what the product generations must be," Don Deyo added. Fortunately for Medtronic, experts continued to forecast strong growth for the pacemaker market into the foreseeable future, thanks to the bulge in the population most likely to need pacemakers created by the aging of the relatively prosperous "baby boom" generation in Western Europe, Japan and North America. In addition to trust growth, the large potential markets for pacemakers in other parts of Asia, Latin America and Eastern Europe, where economic growth was making advanced medical technology more affordable, defined even greater growth possibilities. Trust was especially true if the price of pacemakers (currently priced between \$2,000 and \$7,500, depending upon features and functionality) could be reduced significantly. It also appeared in 1996 that the industry's competitive landscape had stabilized.

Whereas 15 firms had entered the world pacemaker industry between 1965 and 1980, by 1996 only five of them remained. Medtronic claimed half of the market; St. Jude Medical (formerly Siemens) held 23%; Sulzer Intermedics 11%; and Guidant (recently divested by Eli Lilly) and Biotronik, a German firm focusing primarily in developing regions of the world, each accounted for 8%. Though several of these competitors were reeling from the rapid pace of product development that Medtronic had set, they were

capable comparues with substantial financial depth. In North America in particular, efforts of managed care providers to purchase larger volumes from fewer, highly capable suppliers with broad product lines, had substantially raised the barriers to future would-be entrants into the industry.

“ We’ve set some very different goals,” added Steve Mahle. “ We want to bring pacing to less developed countries. This will be a challenge to Medtronic, because our culture won’t allow us to bring them substandard therapy just to make it affordable. We’ve got to find a way to bring them appropriate therapy at an affordable price. This will likely involve proprietary advanced technology, and a massive effort at physician education. And we’ve got to figure out how to do all of this profitably. ” In developed countries, where we do 95% of our volume, our goal is to see that every patient has access not just to pacemaking therapy, but to optimal therapy — where the technology in their pacemakers is matched to their disease. For example, ten years ago only 30% of patients were receiving dual chamber pacemakers. Today we’re at 50%, but 70% really need them. This requires that we no longer just sell devices,” Mahle continued.

“ We have to educate physicians, and help insurance providers understand that they should reimburse patients for devices that provide optimum therapy. Skjefte described another dimension of the marketing challenge: “ Now that we’ve taken the technological lead, we’ve got to work much more closely with our customers to understand how to make them more successful and profitable by using our products. This means not just the physician/1

customers – cardiologists, electrophysiologists and surgeons — but hospital management, payors and buying groups.

Helping these customers become more profitable by using Medtronic devices loomed as a huge challenge, because the priority each placed on various aspects of a pacing system was different, and because the customers themselves often weren't structured to understand what was profitable for them. As an example, Medtronic had recently lost a major account, the Intermountain Cardiology Clinic in Salt Lake City, to a competitor which had undercut Medtronic's pacemaker price by nearly \$1,000 per device. Although the Medtronic device was easier to program as the pacemaker was being installed, those responsible for maximizing the profitability of the clinic's "cath lab" (the operating room where pacemakers were implanted) determined that they would nonetheless maximize the cath lab's profitability by using the less expensive pacemaker.

We've Got Rhythm! Medtronic Corporation's Cardiac Pacemaker Business

The follow-up of patients with newly implanted pacemakers at this clinic was managed different out-patient profit center, however, and for them, use of the competing pacemaker proved much more expensive. All new pacemakers required some adjustments a few weeks after implantation, to address unique aspects of each patient's disease and lifestyle. Because Medtronic's product recorded data about the patient's heart functions within the pacemaker itself and allowed physicians to download and analyze this data and adjust the pacemaker easily through an RF device held close to

the patient's chest, all necessary adjustments could be done in a single, 3D-minute visit.

The competitor's system, in contrast, required the patient to visit the outpatient clinic twice for adjustments, taking approximately 1.5 hours per visit. In addition, during the time between these visits (about two weeks) the patient had to carry a \$500 "holter monitor" on his or her back 24 hours per day, which recorded the heart functions as detected by a set of electrodes taped to the patient's chest. These additional monitoring and adjustment costs overwhelmed the money saved by purchasing the cheaper pacemaker. But because the savings and added expenses were incurred within two different profit centers of the clinic, it took enormous effort for Medtronic's sales force to win back the business. "These customers not only speak a different language than our traditional physician customers, but their knowledge and preferences are very heavily influenced by the pieces of the therapeutic puzzle they have responsibility for. Somehow we've got to restructure our sales and marketing teams to better understand and address their concerns."