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Erik Peterson at Biometra (A)

Erik Peterson hung up the phone, exhaled slowly, and noted the date: March 10. In nine months as general manager of Biometra, a subsidiary of Scientific Materials (SciMat), Peterson had spent most of his time troubleshooting for Biometra's first product launch. The phone call had come from Chip Knight, who had recently joined SciMat as vice president of product operations for peripheral vascular devices. Knight was planning a two-day visit to meet Peterson, see Biometra's operations firsthand, and review Peterson's ideas for dealing with several major issues the organization had been experiencing.

SciMat had acquired Biometra, a small company based in the Boston suburb of Woburn, two years earlier to deepen its portfolio in vascular medical devices, which were used to treat medical conditions involving blood vessels. Biometra focused chiefly on catheters, or tubes used to drain or inject fluids or to allow access of surgical instruments for medical procedures. Using innovative engineering techniques, the young company had produced a plastic composite catheter that was thinner, more flexible, and easier to maneuver than existing catheters. The catheter would be the first product ever launched by Biometra.

The original sales and distribution launch target date, February 1, had proved impossible due to internal and external obstacles. Peterson had submitted a revised launch date of April 1 to SciMat headquarters. With such a short time remaining, Knight thought they should meet in person to go over Peterson's plans for achieving the new target date. Peterson checked the calendar again, and realized he had roughly two weeks to prepare for Knight's arrival, and less than a week after that until the new launch date.

Peterson's Path to Biometra

A native of Colorado, Erik Peterson was 29 years old, married, and the father of one child. He had completed his MBA the previous May. Before that, he had earned his B.S. and Master's degrees in biological engineering from MIT and then spent three years as a management consultant in the pharmaceutical and telecommunications sectors. Peterson was well-liked and respected by colleagues and classmates, and had a reputation for thoughtfulness, maturity, and collaboration. He spent the

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summer between his two years at business school working as a marketing intern at a major medical device company. He enjoyed the work and was impressed by the industry's growth potential, so he focused his job search activities mainly on that sector. Among several attractive offers, Peterson settled upon Scientific Materials, in part because of his positive interviewing experience with Richard Jenkins, the charismatic president of SciMat's medical devices group.

When Jenkins offered Peterson a job as product manager in charge of sales and marketing of Biometra's catheter, he explained that the product had a number of serious launch problems that had made it a high profile situation for SciMat. The situation would undoubtedly be challenging, but Jenkins emphasized that Peterson would be reporting directly to the vice president of peripheral vascular devices, who was an extremely seasoned executive known for his mentoring skills. Jenkins added that he personally planned to spend a significant portion of his time on the launch as well. Peterson felt fortunate to have an important management role right out of business school. He also appreciated the chance to work with SciMat's senior team early in his tenure at the company.

Shortly after graduating in May, Peterson had gone through a two-month orientation at SciMat, which consisted of visiting SciMat subsidiaries around the United States and cycling through the corporate functions at SciMat's headquarters in Los Angeles. In an impromptu meeting with Jenkins toward the end of orientation, Peterson learned that the vice president who would have overseen the catheter product launch had left abruptly to join a startup device company. A number of key Biometra managers had departed as well. With many other SciMat product launches in progress and heavy competition for talent in the medical device industry, it was unlikely SciMat would find anyone to take the vice president's place for several months. Due to the urgency of the situation, Jenkins told Peterson that he had been promoted to acting general manager (GM) with overall authority for Biometra's operations. Jenkins added that he himself would be even more closely involved with the launch. Peterson was both excited and daunted by this opportunity to have general management experience so early in his career.

SciMat and Richard Jenkins

Known as an innovative company with deep expertise in materials science research, SciMat had traditionally competed in the consumer and industrial segments with a wide range of products including adhesives, insulation, alloys, plastics and composites. However, rising competition and slowing market growth in these segments had driven SciMat's management team to pursue new arenas where the company could leverage its strengths. The medical device industry's high margins, attractive growth rate, and reliance on engineering innovation seemed a natural fit. SciMat had moved quickly, acquiring five small companies with innovative vascular technologies over the past three years. The management team expected to launch a number of medical device products in the coming months, the first of which would be Biometra's catheter.

Peterson had been very impressed with both SciMat and Richard Jenkins, who as a cofounder had helped build the firm from a narrowly focused startup into a diversified, publicly held company with over \$1 billion in revenues. Jenkins had a reputation for toughness and an aggressive, entrepreneurial drive that had taken him from modest beginnings in a small Indiana town to considerable success and influence. Though he had no prior experience in medical devices, industry competitors admired Jenkins' track record in leading SciMat to enter and quickly dominate other new industry segments. It was widely believed that he would succeed cofounder Marshall Chang as CEO of SciMat within two to three years.

Peterson had heard that Jenkins was a demanding task master who would not hesitate to intervene swiftly once he had lost faith in a manager. When initial sales for a launch of an industrial product had

failed to meet his expectations, Jenkins immediately replaced the former product manager and had the new manager report directly to him until the sales targets had been achieved. The industrial product had been the first entry by SciMat into a particularly important market niche. Jenkins had hoped to use the event to build SciMat's reputation and credibility, and had instead been embarrassed by the cost and schedule overruns plaguing the launch. It was clear to everyone that Jenkins would not tolerate a similar situation in launching SciMat's first medical device.

Early Challenges

The past months had been both difficult and frustrating for Erik Peterson. He regularly worked 60 to 80 hours a week, and at times the challenges of the product launch seemed so overwhelming that he woke up in the middle of the night thinking about them. The general management opportunity that had seemed so promising at first now threatened to consume him, and he often tried to figure out when all the problems had begun.

Upon arriving at Biometra in early August, Peterson discovered that instead of reporting directly to Jenkins he was assigned to Jeff Hardy, vice president of planning and control for the peripheral vascular division. (**Exhibit 1** charts SciMat's organization at the time Peterson took the general manager position.) Hardy had received his MBA three years before Peterson, but had no product launch experience. As a result, Peterson found that Hardy was unable to offer him any initial advice or guidance that was specific or helpful. The nature of their relationship was also awkward and ambiguous from the outset, because neither Jenkins nor Hardy had formally told Peterson of the new reporting structure. It just seemed to have occurred.

On the bright side, the Biometra catheter was similar enough to existing products on the market that it qualified for an accelerated approval process by the US Food & Drug Administration (FDA) known as a 510(k) clearance. This process avoided lengthy and costly clinical trials but required the company to demonstrate that its product had comparable safety and efficacy to that of competitors. Much of this work had already been completed by the time Peterson arrived, allowing him to focus on preparing for the global manufacturing and supply chain, sales and marketing, and customer service aspects of the launch.

The Biometra Team

Peterson's direct reports included five key managers, as shown in the organization chart in **Exhibit 2**. Jim Wescott, a 44-year-old former medical supplies sales representative, managed a sales force of twenty representatives and had joined Biometra around the same time as Peterson. Wescott had a reputation for being a high-performing sales representative, though he was also described as an aggressive "gunslinger" who often rubbed people the wrong way, particularly the technical professionals, with his confrontational style. Peterson also discovered that Jim Wescott's communications to sales reps were sometimes not detailed or clear enough, and that they required careful review. Unfortunately, as Biometra's technical problems mounted, Peterson found himself with less and less time to track Wescott's communications trail. But on the whole he found Wescott to be competent, if sometimes abrasive.

Stephanie Hanes, a 41-year-old registered nurse practitioner with a master's degree in cardiovascular nursing, ran the clinical training department, including all aspects of teaching interested vascular clinicians how to use the Biometra catheter. This entailed developing and continually updating a training manual, scheduling and coordinating training trips for in-house medical specialists as well as external experts, and following up with previously trained doctors to check on their

experience and gauge the need for further training. Peterson thought Hanes had done an excellent job in organizing the department around a mission-critical priority for the company. Hanes also seemed to get along quite well with most of the staff. By late winter, Peterson had come to respect and trust her judgment a great deal.

Trevor Burns was a 28-year-old college graduate Peterson had hired in the fall to run the marketing department. In the absence of a product manager, Burns reported to Peterson. Burns had previously been a marketer at a mid-sized consumer goods company. He had hands-on marketing knowledge but no prior experience in the medical device industry. A member of a prominent and wealthy Massachusetts family, Burns seemed to Peterson to be bright, knowledgeable, and enthusiastic. However, Trevor Burns and Jim Wescott soon developed problems working together, even though Wescott himself had suggested hiring Burns. Peterson believed that some of these difficulties stemmed from the many suggestions that Burns made about sales strategies and approaches during pre-launch meetings. Some of Burns' ideas were excellent; others were impractical. Eventually, the constant flow of new ideas became distracting for everyone, including Peterson himself. It became such a problem by January that Peterson had to talk to Burns about it. The relationship between Burns and Wescott had become quite strained by then. Peterson suspected that some of the difficulties arose from Wescott's resentment of Burns' privileged family background as well as his annoyance at Burns' constant criticisms and suggestions.

Curt Andrews, Biometra's director of operations, had worked his way up from senior technician to director of operations for SciMat's consumer adhesives unit in San Diego before transferring to Biometra the previous spring. The adhesives line was well established and used locally based manufacturing processes. It had gained a reputation within SciMat for being technically superb. However, after a few months Peterson came to believe that Andrews lacked the flexibility and resourcefulness needed to serve as director of operations in startup mode at Biometra. Andrews seemed easily frustrated by the constant ups and downs and the uncertainty of the pre-launch process. Peterson felt this limitation quite keenly, because he himself had limited experience in the medical device industry and needed someone he could rely on in the director of operations job.

Melissa Miczek, the 45-year-old manager of regulatory affairs, had many years of experience in the pharmaceutical, biotechnology, and medical device industries. Shortly after Peterson's arrival at Biometra, Miczek had come to his office to let him know she had been offered a comparable position at a competitor with a significantly higher salary than she was receiving at Biometra. Given the tight labor market for Miczek's special expertise and the disruption to launch that her departure would cause, Peterson offered a premium over the competitor's package to retain Miczek. However, SciMat's head of human resources (HR) in Los Angeles thought that the resulting increase was excessive. Eventually, HR approved an increase that was 15% less than the amount Peterson had offered and slightly below the competing offer. Though Miczek decided to remain at Biometra, Peterson noticed that her general enthusiasm and the quality of her work had waned over time.

Peterson had encountered another salary problem with Jim Wescott. Peterson's predecessor had offered Wescott the sales management job at a salary substantially higher than those of the rest of the Biometra management team, including Peterson himself. After somehow learning the amount of Wescott's salary, Miczek made an offhand remark about the disparity in earshot of Andrews and Hanes, both of whom quickly made their displeasure known to Peterson. Peterson felt uncomfortable about the situation, given that other managers at Biometra had similar or more medical device experience compared to Wescott. He met with Wescott to let him know that his salary had become public knowledge. Although Wescott would not agree to a salary cut, he did allow for a greater proportion of his compensation to be shifted from a guaranteed base to a commission-based bonus.

Peterson believed that this would help smooth things over with the rest of the team and suggested to Wescott that his original baseline compensation would be restored in six months, subject to the outcome of Wescott's first performance evaluation at Biometra.

Peterson also suspected that Andrews and Miczek might have resented Peterson's rapid promotion to General Manager by Jenkins. Peterson's initial hiring into the product manager role had been announced upon his acceptance of the offer, and so the Biometra team was well aware that the scope of his original role was far more limited than the role he now had. He hoped that any such resentment would subside as he earned his colleagues' confidence over the course of the product launch.

Despite these problems, Peterson believed that he had built a good organization considering the circumstances. It mattered to him that his people worked as a team and that Biometra be managed with as much participation and collaboration as possible. Peterson had instituted weekly, companywide pre-launch meetings to discuss problems various departments were having and to maximize the exchange and flow of ideas among Biometra's staff. Many employees had remarked that they found the weekly meetings very effective, and that they believed that his approach had raised morale and improved employee understanding of the company's key challenges. Peterson was also convinced that the meetings prevented the spread of rumors and anxiety about pre-launch issues by keeping everyone equally informed about what was going on.

Gaining Support from Key Opinion Leaders

A successful medical device company needed to build strong relationships with doctors who were leading experts in the medical fields relevant to its products. These doctors, referred to as *key opinion leaders (KOL)*, not only provided important feedback and advice to engineers during the product development process but often also conducted clinical trials of new products and recommended products to peers at medical conferences. Biometra's launch plan targeted one hundred of the leading peripheral vascular surgeons in the world, with the goal of convincing 20% of them to try the catheter by product launch and another 40% within three months after launch.

Though the promise of Biometra's composite technology had attracted interest from physicians, the recent management turnover in SciMat's medical devices division had created uneasiness among the doctors targeted as potential early adopters. Because KOLs put their own reputations on the line when collaborating with or supporting the development of new technologies, they tended to be wary of any situation that hinted of potential issues with an upcoming product.

Most troubling to Peterson, five particularly prominent KOLs had recently indicated that they would prefer to delay trying out Biometra catheters until after launch, when other doctors had reported their initial experiences. Peterson feared that any hesitation from these five prominent KOLs could trigger a downward spiral in which other doctors began delaying Biometra trials as well, ultimately putting the tryout targets beyond reach.

Peterson responded by offering the five linchpin KOLs more support, such as flying in a dedicated technician and additional trainers for the KOL's clinical staff in advance of the product trials. The KOLs appreciated Peterson's suggestion and took it as a sign of partnership and good faith. However, at SciMat headquarters, Hardy was unwilling to sign off on the new support agreements that Peterson had drawn up. To Peterson, the funds needed were insignificant given the importance of firming up KOL support well in advance of the launch date, but Hardy avoided making a decision every time Peterson raised the matter with him. Because he got no definite answer from Hardy, Peterson found that he had to equivocate with the KOLs regarding what the company would be able to offer, only

furthering their discomfort and increasing the likelihood that they would withdraw from working relationships with Biometra.

Peterson thought that Hardy had a very unrealistic picture of what was at stake, and that Hardy's only concern was the effect that providing extra KOL support would have on the near-term financials. Peterson was afraid that if news of Biometra's equivocation began to circulate among KOLs, it might damage the company's reputation and relations with other clinicians. Eventually, it might even spill over into KOLs relationships for SciMat's other medical device subsidiaries. These issues were major problems for Peterson because he did not have the time to become involved with discussions with each KOL, as well as with hospital administrators and other interested parties.

Fortunately Peterson found some relief from these pressures when two people from Los Angeles headquarters joined the launch team in mid December (see **Exhibit 1** for SciMat's organization prior to February 28). Dr. Scott Green, group vice president of clinical and regulatory affairs for medical devices, and Karen Cantor, an attorney and his special projects assistant, took on active roles in the KOL negotiating activities. Cantor considered her involvement a priority project. Peterson felt relieved that she was handling the details, and wondered whether he should ask Green to have her report directly to him because of the project's importance. Full KOL support was essential to the launch, and Peterson felt uneasy about not being directly involved in making sure the key doctors were on board. On the other hand, Peterson could barely manage the many other issues facing Biometra, and ultimately welcomed the relief of not having to supervise the KOL negotiations.

Although Cantor and Green offered welcome help with his workload, Peterson felt somewhat uncomfortable with both of them because of clashes he'd had with them during his summer orientation at SciMat. These encounters had left him so taken aback that he was eager not to tangle with either of them again. For example, Peterson had been asked to shadow the general manager of SciMat's neurovascular coil devices and write a report on his observations. In this report, Peterson had criticized the product line's chief engineer, who he felt was technically brilliant but did not sufficiently incorporate customer and market feedback into the design process.

When Peterson subsequently visited headquarters, Green asked him for his reflections on the neurovascular coil product line. Peterson gave Green an oral summary of his impressions. After he finished, Green attacked him for criticizing what Green perceived to be one of the best run units within SciMat. Peterson was surprised by Green's hostile reaction, and during the ensuing exchange, Green asked Peterson what his background was. When Peterson explained that he had just finished his MBA, Green lectured him on how much more he needed to learn about medical devices. Green, who was only thirty-seven, was recognized by many as a "wunderkind" of the industry and had a reputation for being a sharp, smooth operator. Peterson resented what he perceived to be Green's condescending attitude, and ended up avoiding him for the rest of the orientation period.

Just before his tangle with Green, Peterson had met with Karen Cantor, Green's project assistant. Cantor had told him in no uncertain terms what she thought he needed to do at Biometra. Several of her suggestions struck Peterson as being misinformed or even blatantly incorrect based on his previous internship experience. When he challenged some of her statements, she became argumentative and was visibly upset by the time Green arrived. As a result of these two exchanges, he was not inclined to interfere with their work in the KOL problem, particularly since he sensed that Cantor would resent reporting to him on the project.

Addressing Other Pre-Launch Problems

Another significant challenge for Peterson was launching Biometra's commercial manufacturing operations. As was typical with many medical device startups, Biometra had designed its manufacturing process in-house and set up a small local facility in Woburn to create prototypes for product development and testing. This had been sufficient for the pilot manufacturing runs to meet Biometra's needs in gathering evidence and data for its FDA approval filing. However, scaling up manufacturing operations in Woburn to satisfy commercial demand would be very expensive due to local real estate and labor costs. As a result, Jenkins had decided to locate Biometra's commercial manufacturing facilities in Costa Rica to take advantage of that country's relatively lower operational costs. While Costa Rica had become a growing hotspot for "nearshoring" of medical device manufacturing by other firms, this would be the first time that SciMat set up facilities there although other SciMat business units had experience outsourcing production to neighboring Latin American countries.

Jenkins had chosen the Costa Rican manufacturer because it had several FDA-certified production facilities and enough experience to scale up the catheter manufacturing process that had been tested and refined in Woburn. When Jenkins briefed Peterson during the orientation in Los Angeles, he had assured Peterson that the Costa Rican contractor would closely manage the installation and validation of the manufacturing equipment so that Peterson could focus on the other aspects of the launch. But soon after starting at Biometra, Peterson was surprised to discover that the validation of Biometra's production lines had fallen seriously behind schedule. Devices coming off the production lines failed to consistently meet specifications, and the contractor's technicians were at a loss to explain why. Knowing how quickly this issue could derail the launch process, Peterson immediately flew to Costa Rica to meet with the contractor in person. He was accompanied by Biometra's director of operations, Curt Andrews, and Andrews' direct report Todd Jones, the manager of quality control.

Peterson felt somewhat better after his initial tour of the manufacturing facility. The production lines were gleaming and modern, and the workers seemed focused and competent at their tasks. However, he started to worry again as he and his team met with the facility director late in the day. Though the director seemed to listen to his concerns, Peterson could not help feeling that important points were getting lost due to the language barrier. From what he could gather from the translator, this type of issue in launching a new production line was not uncommon and the contractors expected to isolate and resolve the problem quickly. Peterson emphasized that further delays would be unacceptable and that he expected daily updates from the contractor until the manufacturing quality issues were resolved.

Peterson felt a particular sense of urgency in resolving the validation issues, because he knew that Green and Cantor were negotiating specific service agreements with KOLs for pre-launch product trials. If Biometra could not deliver catheters to the KOLs on the specified dates, Green's and Cantor's efforts could end up proving fruitless. Already insecure about his lack of involvement with the KOL negotiations, Peterson did not want to further aggravate his relationships with Green and Cantor by failing to deliver on his responsibilities.

As he debriefed with Andrews and Jones in the airport waiting lounge, he was bothered by their different but equally troubling reactions to the facility visit. Andrews seemed almost cavalier about the situation, remarking on the high quality of the other working production lines that they had seen and stating that it would only be a matter of time before the contractor sorted things out. In contrast, Jones was deeply pessimistic about the contractor's capabilities and complained loudly and repeatedly that he had objected strongly to outsourcing production to Costa Rica in the first place. Peterson's

concern grew over the next two weeks as the contractor continued to have issues in validating the catheter manufacturing process while the facility director could only offer excuses.

Management Issues

As Peterson learned more about the manufacturer, he realized that Biometra's expected orders in the coming year were a very small proportion of the facility's total capacity. He believed that as a result the director might not be prioritizing Biometra's needs and deploying sufficient technical resources to fix the validation issues.

Peterson became increasingly convinced that the operations team would need to partner more directly with the Costa Rican technicians to complete the validation. However, it seemed that Andrews could barely keep up with the other difficulties of pre-launch operations, particularly the constant churn of new and changing information. Peterson discussed the problem with Hardy several times to no avail. During one of his visits to Los Angeles, Peterson raised the possibility that Andrews be replaced or at least supplemented by a person who had more pre-launch and start-up experience. He was told that because of the company's rapid expansion and the industry's demand for talent with such skills, these people were in short supply. SciMat had just relocated Andrews and his family from San Diego to Woburn, and Peterson suspected that the company did not want to put him through a move again so soon. In addition, the corporate team in Los Angeles insisted that Andrews had the technical excellence to drive a successful launch; he simply needed more coaching and support from Peterson.

Peterson tried to help by working with Andrews to set up better tracking systems for operations data and to be more hands-on in meeting with and managing the operations team. However, Peterson found Andrews resistant to suggestions and suspected that he was resentful that Peterson did not trust him to get the work done. Peterson also believed that Andrews resented having been passed over for the GM job, especially given Peterson's inexperience in the medical device industry. Peterson continued to have difficulty in getting operations reports from Andrews completed accurately and on time. Despite his attempts to keep his feedback constructive and upbeat, Peterson sensed that Andrews was angered by the implied criticism but that he was "bottling it up" rather than surfacing the issue directly. Peterson discussed these problems with Hardy and again raised the possibility of having Andrews transferred and replaced with someone more suitable to Biometra's needs. Hardy was reluctant to take any action, saying that neither Peterson nor he had the authority to make such a request and that it would only result in both of them being perceived badly by headquarters.

These problems were further complicated by tensions between Andrews and Todd Jones, the manager of quality control. Andrews and Jones had several conflicts over how best to manage the production issues in Costa Rica. In particular, they disagreed strongly on which quality metrics to use in the sample run analyses. Their differences over these issues had become so frequent that Jones told Peterson on several occasions that he felt he was smarter and more qualified than Andrews and that he deserved to have Andrews' job.

Despite Andrews' limitations, Peterson did not share Jones's view. Though Jones was quite capable, he had a tendency to focus on the negatives of a situation rather than think through potential solutions. He had also chafed at Peterson's suggestion that he spend at least two days a week in Costa Rica until the process validation had been completed. Peterson thought the quality issues at the Costa Rica facility should unquestionably be Jones's top priority, and wondered whether Jones was trying to distance himself from the decision to manufacture in Costa Rica given his resistance to the idea from the outset.

Convinced that his team would not be able to resolve the situation in Costa Rica on their own, Peterson shifted some funds from his marketing budget to hire manufacturing consultants to work on-site with the Costa Rican technicians full-time. Despite receiving recommendations on consultants that SciMat had used before, Peterson chose a firm that he had encountered during his MBA summer internship. He believed this firm had more relevant expertise in medical device manufacturing, although it had never worked with SciMat before. Peterson's decision was not well received at SciMat headquarters, where there was much more familiarity with other consultants who had done extensive work with multiple business units within the company. Nevertheless, given the urgency of the situation Peterson felt that his choice was justified. He succeeded in convincing Hardy and headquarters that the change was necessary. Jones would manage the consultants on a daily basis, with oversight from Andrews and Peterson.

Equipment Selection and Specification Issues

SciMat's home office had further complicated Peterson's first few months in Woburn by delaying key decisions or making significant changes to the equipment originally specified. For example, Jenkins delayed the decision whether to use laser micromachines (which Los Angeles had promised to resolve by mid-summer) until October. Laser micromachining allowed for more precise cutting of catheters than the mechanical drills and cutting blades typically used, resulting in fewer manufacturing defects. Because the laser micromachines required significant capital investment, Jenkins had deferred the decision as long as possible to acquire more information. As a result, the timeline for ordering the equipment for the Costa Rican facilities had fallen behind by several months, perhaps contributing to the process validation issues.

In addition, headquarters had required Biometra to change its supplier of a key composite material in December due to a corporate-wide SciMat purchasing initiative. Though this decision had no effect on the catheter manufacturing process itself, the FDA had required Biometra to run tests demonstrating that the materials from the two vendors were equivalent. The switch in suppliers had also required the operations team to spend precious time negotiating a new contract and arranging for shipment of the material from the new vendor. Peterson fought hard for an exemption to the policy, but was unsuccessful in influencing Hardy to reverse the decision as it applied to Biometra.

Peterson had felt consistently hampered by his inability to get either support or clear direction from Hardy. Hardy's monthly visits to Woburn consisted mainly of what Peterson called "nit-picking," such as fussing over a proposed color scheme for medical journal advertisements, without resolving the major problems that Peterson felt he had to deal with. Peterson suspected that some of Hardy's indecisiveness stemmed from Hardy's uncertain relationship with his own boss, Richard Jenkins. Peterson had sensed from the beginning that Hardy was somewhat insecure and anxious regarding his standing with Jenkins. It was easy for Peterson to understand why that might be the case, given Hardy's lack of operating experience and his tendency to avoid conflict.

The equipment selection issues also exacerbated tensions in the working relationship between Curt Andrews and Melissa Miczek. Any changes to the manufacturing process required the company to interact with the FDA, ranging from basic additional testing and paperwork for minor changes to a complete re-filing for clearance followed by a 90-day review period for significant modifications. However, the FDA left it up to each company to use its own judgment in deciding which approach was warranted. In response to Andrews's inquiries regarding operational issues, Miczek often took up to a week to develop a recommendation as she reviewed reams of reference documents. She typically argued for the least risky option in terms of FDA approval, which caused further operational delays of the launch date. Peterson found himself increasingly caught between Andrews's desire for immediate

clarity on the regulatory aspects of operational questions and Miczek's methodical approach to determining their resolution.

Sales and Marketing Issues

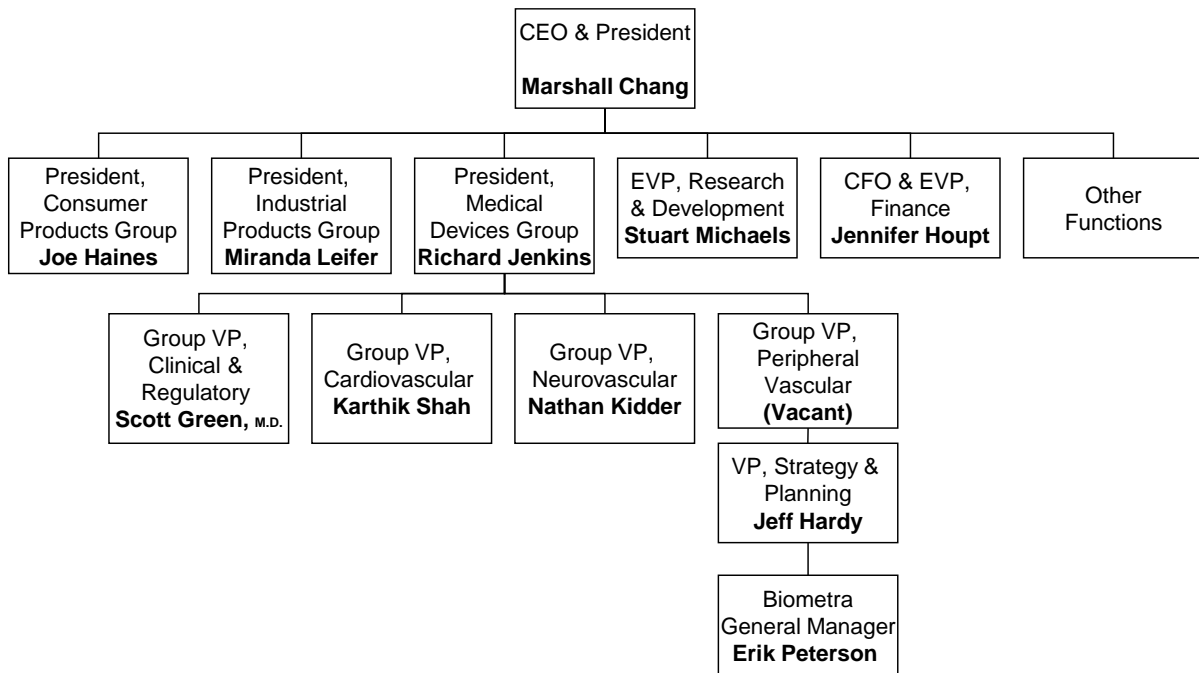
Peterson saw another major problem in the tension that had recently worsened between James Wescott and Trevor Burns. As Biometra approached the product launch date, the marketing function (Burns' area) and sales function (Wescott's focus) became increasingly important as did the level of coordination between the two men. The most recent conflict between Burns and Wescott had been over the amount of funding Burns planned to allocate to advertisements in vascular medical journals. Burns, whose experience was from the consumer packaged goods industry, planned significant investment in print ads in journals most popular with KOLs, where most of the current market leaders advertised. Wescott argued that print advertisements were not a relevant channel in the launch phase, particularly for such a new and unfamiliar technology, and that the marketing funds would be better used to send top sales representatives to major upcoming vascular device conferences and trade shows. Peterson settled the issue by allocating 60% of the marketing budget to print ads with the remainder for conference and trade show attendance by sales reps. But the conflict between Burns and Wescott had increased the tension at Biometra, and Peterson felt that he would need to intervene further to help them work together better.

Chip Knight and the Reorganization at SciMat

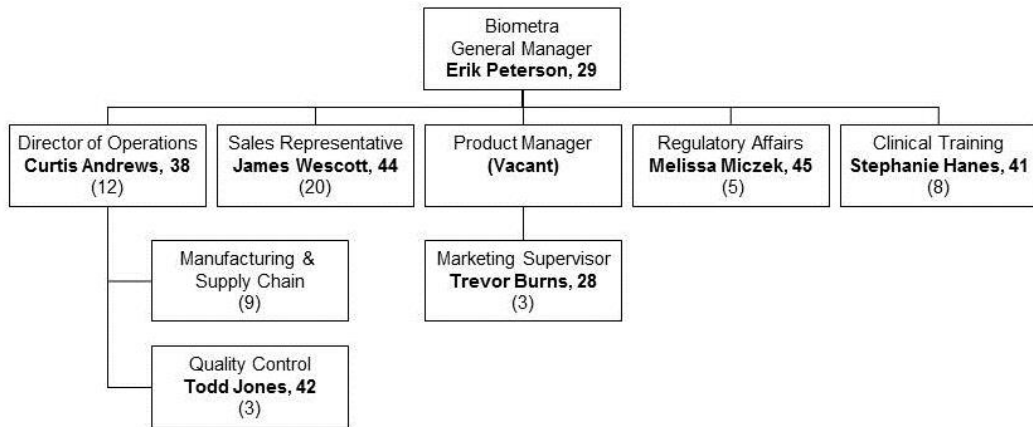
Peterson had not yet met Knight in person. He was looking forward to laying out his plan for driving Biometra through the remaining obstacles to a successful launch and getting Knight's reaction. Knight, like several other new SciMat executives, had been brought into the company as part of a reorganization recently implemented by the new group VP of peripheral vascular devices, Dashiell Harper (see **Exhibit 3** for the revised SciMat organization). "Dash," as Harper was known within the industry, had previously been in charge of peripheral vascular devices at a large, global healthcare conglomerate. Before that, Dash (who had both an MD and PhD) had pursued a successful career in academic medicine, ultimately serving as head of a prominent cardiovascular research center. Knight, like several other executives Dash had brought in, had previously worked at a large West Coast bioengineering firm.

Peterson expected that the infusion of professional managers with relevant healthcare and medical device experience at the top ranks of the SciMat organization would greatly improve the situation. Peterson had been very impressed by Dash Harper during a recent visit from Harper and Hardy at Biometra, as well as by the recommendations Harper had made. Harper had asked many questions that day, taken voluminous notes, and in Peterson's eyes, seemed generally satisfied with the way things were going. Hardy had remained relatively silent during their visit.

Although he was not yet sure whether he would ultimately report directly to Knight or to Hardy (whose new title was assistant vice president of product operations), Peterson felt that the situation could only improve. Hardy had told Peterson that he was quite upset by his appointment to his new position, which he viewed as a demotion.

Exhibit 1 SciMat Organization Chart (prior to February 28)

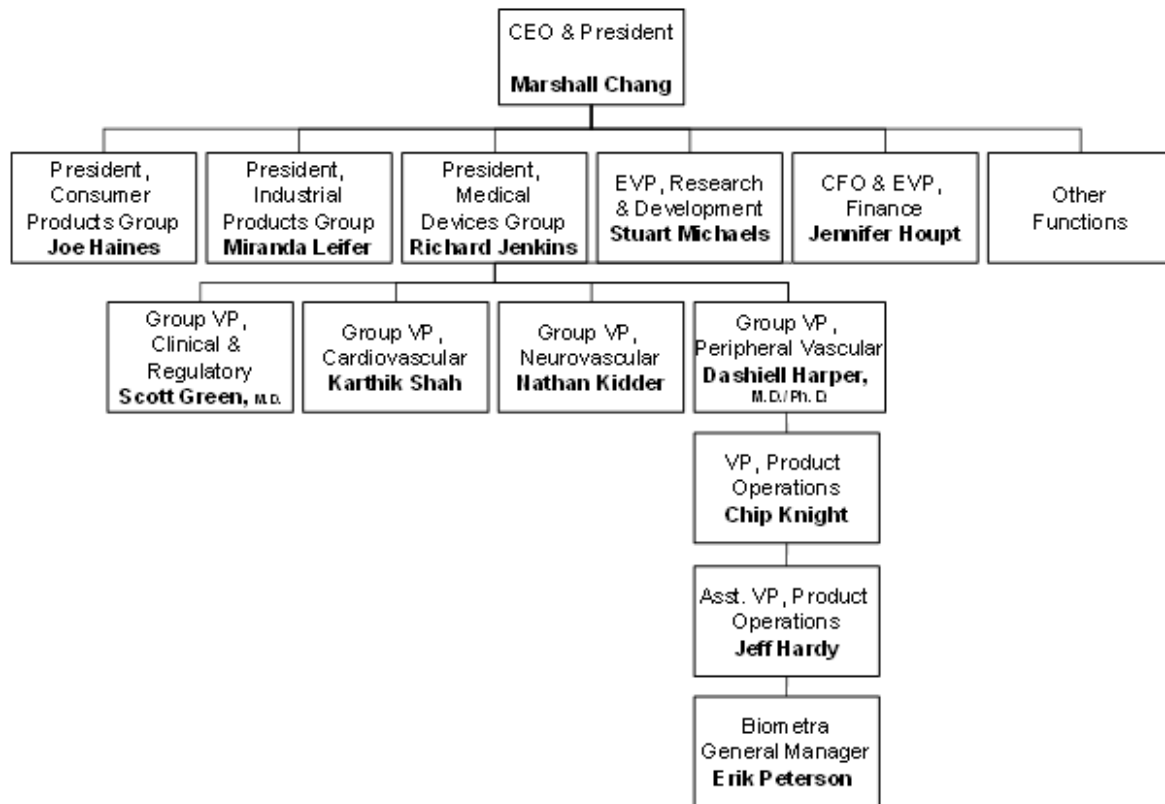
Source: Casewriter.

Exhibit 2 Biometra Organization Chart

Source: Casewriter.

Notes: Number of people in each function given in parentheses under the department head.

Organization chart includes only Woburn location, excludes Costa Rica contractors.

Exhibit 3 SciMat's New Organization Chart (after February 28)

Source: Casewriter.

Note: Reorganization implemented on February 28