PAYBACK II: MEDICAL DEVICES RIDE THE CASH CURVE

Device companies have been able to innovate and generate cash returns, but will the good times last?

The medical device industry has generated returns over the past decade that exceed pharmaceuticals and many other sectors. These returns have been driven by payback on innovation, which the authors define as generating cash returns from new ideas. Device executives have generated payback by deftly managing the four S-Factors: start-up costs, speed-to-market, support costs, and scale operations. The challenge for device companies will be maintaining these returns in the face of increased investment in this sector and the threat of health care spending constraints.

While the pharmaceutical industry publicly struggles against payers and public opinion to preserve payback in a business model that has generated unprecedented advances in human health, the medical device sector goes quietly about its business. And what a business it is—total shareholder returns for the past decade averaged 15.3%, easily outpacing the S&P 500 Pharmaceutical Index and just about all other comers. The secrets to device success are a unique blend of marketing channel structure, medical ingenuity, and cash flows that allow innovation – and payback – to thrive. Nevertheless, devices are not immune to the very real pressures facing health care, and industry executives must keep their business models in step as medical device cash curves respond to the current environment.

PAYBACK REVISITED

As outlined in the January 2007 issue of IN VIVO, a simple notion rests at the heart of the payback concept: all innovations need to generate returns over a reasonable period of time in order to fund ongoing operations, fuel future growth and compensate shareholders for putting their capital at risk. (See “Payback: Making Innovation Count in Uncertain Times,” IN VIVO, January 2007.) In their new book, Payback: Reaping the Rewards of Innovation (Harvard Business School Press, 2007), BCG senior partners Jim Andrew and Hal Sirkin profile the stories and inner workings of some of the world’s most innovative companies as they set about that task. Payback is all about drawing the “cash curve” as innovations wend their way through the stages of idea generation to commercialization and, ultimately, to realization of a cash return on investment (see Exhibit 1).

What is surprising, however, is that the book and The Boston Consulting Group’s annual Innovation Survey, conducted in conjunction with BusinessWeek, identify relatively few health care companies among the world leaders in innovation and payback – and no pure-play medical device companies. And yet, based on sector results at least, device companies would appear to have some mastery of the art.

As outlined in the first article in this series, successful payback in both devices and biopharma rests on achieving innovation based on the four “S-Factors”.

S1. Start-up costs determine how large a financial down payment the innovation entails. A Premarket Approval (PMA) generally has a much deeper trough to climb out of than does a 510(k).

S2. Speed-to-market dictates how
quickly companies begin to register sales for their new product ideas. Medical devices generally hit the market quickly—often as little as a year from conceptualization for a 510(k), and as quickly as 2-3 years for a PMA.

53. Scale operations imply that the idea has passed the initial build phase and cash flows have reached an equilibrium state. For device companies, this may be a short-lived cycle as competitors continue to churn out incremental innovations that shorten product life spans.

54. Support costs include COGS, sales & marketing support, G&A and any ongoing R&D requirements. The high-touch sales model used by most device companies engenders loyalty but causes support costs to skyrocket.

The device industry has indeed shown itself to be a deft manager of the 4 S-Factors, evidenced by the sector’s very strong returns. Nevertheless, even successful companies have some projects that never quite live up to their potential. “To the extent that these projects continue to attract investment, they run the risk of turning into cash traps that never generate payback.” (See Sidebar: Seven Tips for Riding the Cash Curve.)

**BEST IN SHOW**

The device sector has been on an extraordinary bull run for the past decade, easily outpacing close cousins in the pharmaceutical sector and the broader S&P 500. No other sector has performed as consistently or as well, as measured by Total Shareholder Return (TSR). TSR takes into account changes in stock price plus the sum of dividends paid over time (see Exhibit 2).

The device sector’s strong track record has drawn a raft of attention from investors. Device companies grew their aggregate top line at an annual rate of 11% in the decade leading up to 2005. During this time period, device executives boosted R&D funding by 16.4% per year—to the point where device R&D expense as a percent of sales now hovers at 10.3%. To understand how this investment will achieve payback, it is useful to examine medical device cash curves.

**GETTING TO PAYBACK IN THE DEVICE INDUSTRY**

Device cash curves are not as easily derived or as definitive as their counterparts in the pharmaceutical industry. After all, a device can be something as simple as a suture needle or as complex as a bi-valve pacing device. Given the vast differences in criticality, clinical evidence required for approval, and the associated costs to develop and launch such products, the cash curves for devices are highly divergent. A large swath of the device world, including most Class I and some Class II devices, fall under FDA exemptions that require no formal regulatory approval. These products have cash curves that differ little from those observed in the industrial technology sector, where quality, speed to market and setting the standard are of critical importance.

For the sake of simplicity, the balance of the device world may be divided into two segments based the products’ FDA regulatory pathways: those that require a 510(k) Premarket Notification and those that need a PMA to be sold on the US market. In 2006, the FDA issued a total of...
3,210 510(k) notifications, versus 39 PMAs. (See Sidebar: Sunset for 510(k)s?) The ratio, almost 100-to-1, reflects the difference in the sheer size and complexity of the bets placed when considering one type of investment versus the other.

Medical device companies routinely use the 510(k) route for enhancements to products that are substantially equivalent to a marketed device deemed safe by the FDA for its intended use. As such, the requirements for approval are considerably less stringent and the approval process is far faster than it would be for a PMA. However, even within the 510(k) designation, the size and nature of bets can be widely divergent.

Exhibit 3 traces two hypothetical cash curves for medical products that require 510(k) clearance:

- Product A incurs total design and development costs of $250,000, most of it over a 9-month time period leading to regulatory submission. The 510(k) is filed, receiving clearance in 12 months, and the product reaches the market 3 months later. The product achieves cumulative sales of $1.6 million and generates an operating margin of 20% over a 2-year useful life.
- Product B costs a total of $2 million to design and develop over an 18-month period pre-regulatory period. The 510(k) is cleared 3 months later and the product reaches the market after the initial concept is floated. The product achieves peak sales of $5.35 million per year after 2 years and generates a 20% operating profit over its 6-year market life cycle.

Average total time from receipt to final FDA decision for 510(k)s reduced to 69 days

SOURCE: The Boston Consulting Group

As different as these two economic profiles are, they have one thing in common: both generate an internal rate of return, or payback, of 15%. Such returns might be a typical 510(k) success story, but clearly not every investment achieves this level. As indicated in a BCG medical technology benchmarking study, most companies face difficulties with the process discipline required to keep costs and timelines under a firm grip. (See “High Science: A Best-Practice Formula for Driving Innovation” IN VIVO, April 2004.) This is especially true for the long tail of development projects that do not garner sufficient management support to move forward, yet no effective consensus is sought to terminate them. As a result, they continue to divert time, resources and management attention from more productive innovations that can achieve payback.

The challenges for PMAs tend to be somewhat different. With only a few dozen approved each year, the number of truly innovative device launches (i.e., Original PMAs) is roughly equivalent to the number of New Drug Approvals (NDAs) reaching the market each year. Though the timeframes and investment levels for PMA devices do not often reach pharmaceutical levels, the half-billion dollar gambles by Johnson & Johnson and Boston Scientific Corp. to

---

**SEVEN TIPS FOR RIDING THE CASH CURVE**

Best practices in medical device innovation and payback can be summed up in seven simple steps:

1. **Start with a defined ideation process.** Scour the market to extract ideas from users and add a robust portfolio management process to prioritize ideas for further investment.
2. **Balance technical breakthroughs with market need.** While it is possible to achieve payback with technologies that create markets, it is a far surer path to serve a known or clearly discernable customer need.
3. **Go to market quickly.** Time is money—and a product that is slow to market may miss the wave and generate little payback. Even if the product catches the wave, early delays increase start-up costs and push the point of peak sales into the future.
4. **Chop the tail.** Too many companies waste time and expense on projects that will never see the light of day—which decreases productivity and payback.
5. **Support continuous innovation.** Medical device product lifespan is determined by updated versions and functional innovations that refresh successful products in an inexpensive manner. Such incremental innovation is not a bad thing; in fact, it is often the fastest way to turn good ideas into cash.
6. **Understand customer incentives.** The highly regulated and complex nature of device reimbursement creates a thicket of payer and user incentives that must be untangled in order to price and market products effectively.
7. **Watch the support costs.** The standard device sales model requires an extremely “high-touch” selling system that can cause a financial drag on the company as products age and become more commoditized.
bring their Cypher and Taxus drug-eluting stents to the market were more sizable than many drug development efforts. A more typical example PMA cash curve—for a hypothetical Class III product—is shown in Exhibit 4.

In this example:
- Product ideation, development, and prototyping takes 2-1/2 years
- Annual design and development costs run $32 million per year, reaching a total of $80 million by the time the PMA is filed
- FDA review time, from receipt to final decision takes 270 days and the product reaches market 6 months after approval. This phase incurs a cost of $20 million that covers pre-launch set-up cost, infrastructure build-up and associated training at surgery sites
- The product reaches peak sales of $215 million per year after 2-1/2 years, during which time it generates a 30% operating margin over an 8-year lifespan

The device described above achieves a payback of 20%, as measured by its internal rate of return. However, the cost of failure is sufficiently high—in our hypothetical example it reaches $100 million—that device companies need the prospect of a rosy future to spur continued investment in innovation. Hence, the question: will the good times last for medical device companies?

There is no shortage of good ideas, and the device sector is extremely well positioned to take advantage of them. For instance, the parallel and mutually-reinforcing trends of miniaturization, faster IT processing speed, and biological discovery provide opportunities for technological convergence that are only just being imagined today. Similarly, the rise of networking ushers in the very real possibility of continuous health monitoring—which would boost economic productivity by getting the worried well out of waiting rooms and prod those who are ill but unaware to seek treatment. These and other developments will require nurturing and investment over the coming years and there is reason to believe the investment will be forthcoming.

**THREE REASONS TO INVEST IN DEVICE COMPANIES (AT LEAST FOR NOW)**

What is it that sets devices apart? Ultimately, it comes down to adoption issues: who controls product selection; and what factors decision-makers consider. Three characteristics of the device business combine to provide insulation—at least in the near-term—to aid and abet growth and margins:

1. **The role of the physician.** For higher-end medical devices, the physician’s ability to perform a particular medical procedure is often linked to the device itself. Skilled surgeons and other interventionists will speak of the “feel” they get from one device or another. The pharmaceutical equivalent, say, finding just the right choice and titration of clot busters for a stroke victim or the optimal cocktail of drugs for a diabetic, is an intellectual challenge for physicians.

---

**Exhibit 4**

**PAYBACK FOR PMA CLASS III DEVICE REQUIRES HIGH DOWNSTREAM CASH FLOWS**

**Cash Curve: PMA**

![Graph](https://via.placeholder.com/150)

SOURCE: The Boston Consulting Group

---

**Exhibit 5**

**PRIVATE EQUITY – A RISING FORCE IN M&A**

![Graph](https://via.placeholder.com/150)

Note: Any buyout or financial sponsor involvement, both sell and buy side world wide (Financial sponsors are companies that engage in private equity or venture capital transactions using capital raised by investors. A company is considered a financial sponsor when it engages in non-strategic acquisitions acting as a financial buyer).

(1) Accumulated excess capital for all PE funds in US and Europe; Levered at 4.5x

Source: Thomson One Banker, The Boston Consulting Group Analysis
However, the outcome may have more to do with the specific morphology and habits of the patient and less to do with the drug itself.

For evidence of the difference, look no further than the role of the device representative versus that of a drug detail rep. The former routinely scrubs in for procedures, offering real-time advice to physicians about technique and product selection. Meanwhile, drug detail reps spend a good portion of the day in the doctor’s waiting room, hoping to catch a few minutes with the decision-maker to go over key talking points, drop off some literature or samples, but above all, to get the doctor’s signature as evidence that the call took place.

2. The role of the medical center. Medical devices are used in procedures that take place, by and large, in a hospital or ambulatory care center – but overwhelmingly under the care and guidance of a skilled clinician. The more sophisticated the device, the more likely it is to be used in a high-acuity setting. For instance, an FDA Class II ostomy system will be available for home use by patients after training by a skilled wound ostomy care nurse – but an implantable defibrillator will only find its way into a patient’s chest through the cardiac center and under the guidance of an electrophysiologist.

Higher end devices require a certain level of health care infrastructure to be effective. Take the case of India, which has a booming pharmaceutical R&D sector and local companies pump out products that are chemically identical to their Western counterparts. Yet India – with a population of over a billion people – counts just 400 cath labs compared to 2000 in the US. While the price per cardiac procedure may be only a tenth of the cost in Western markets, without a substantial indigenous outlet for their products and a reasonably price-elastic Western market, it can be difficult for low-cost producers to challenge the supremacy of the US market leaders for higher end devices. Nevertheless, the pressure will surely grow, especially as China and India expand their local health care infrastructure to meet the demands of their rapidly expanding middle class. (See Sidebar: The Gathering Wave.)

3. The role of payers. To be sure, expensive medical devices are not welcomed with open arms by payers. On the other hand, because of the comparative market sizes, the device sector simply doesn’t register in payers’ cross-hairs to the same extent as the pharmaceutical industry. While 2005 worldwide biopharmaceutical sales were roughly $660 billion, medical devices registered only about $87 billion in revenues. More importantly, while the selection of devices often rests with the physician, the direct payer in the US market is most often a medical center. As a result, even expensive medical devices can engender payer support by reducing hospital length of stay. Endovascular stents, for instance, permit patients with aortic aneurysms to leave the hospital within 4 days compared to spending 7-12 days with a 15-25% chance of complication from the more traditional and extremely invasive procedure, which requires a large abdominal incision.

Nevertheless, the US market—which accounts for roughly 60% of worldwide sales—is changing in two important ways. First, Medicare is beginning to experiment with variable co-payments that give patients an economic stake in medical decisions. For instance, a few years ago Medicare would not cover a presbyopia-correcting intra-ocular lens (IOL), which was deemed an unnecessary indulgence. As of 2005, however, Medicare patients have the option of paying the difference for advanced devices, opening up a broader market with built-in demand-side discipline.

The second change involves the enormous growth of ambulatory surgery. When physicians perform procedures in hospitals, they tend to be paid on the basis of a procedure code—which is separate from the DRG payment received by the site. However, an ambulatory surgery center (ASC) receives a single payment that covers infrastructure, materials and clinical care. The same holds true for office-based surgery. Because physicians often own a portion of the ASCs and offices where they practice, the owner-physician’s clinical decisions can have a substantial impact on his or her pocketbook. To thrive in this setting, device companies will need to be armed with cost-benefit calculations that satisfy a buyer whose interests include both clinical and economic factors.

For the reasons outlined above, the medical device industry enjoys at least a modicum of insulation from the pressures experienced by the pharmaceutical industry. But there is another major phenom-

---

SUNSET FOR 510(k)s?

The conventional wisdom is that medical technology advances continue at a blistering pace. This is certainly true of medical technology R&D investment, which has risen at a compound annual rate of 11.1% in the past decade. Meanwhile, the number of PMA has gone sideways since 1997 and 510(k) clearances have plummeted from a high of 4,327 ten years ago to only 3,210 by the end of last year. The rising stakes and inherent complexity of investing in a PMA have conspired to keep their numbers in check. But what in the world explains the drop in 510(k)s?

In fact, there are several explanations. First, the FDA issued new guidelines in February 1998 that exempted a large swath of Class I and II devices from the need to receive 510(k) clearance. With a typical 2-year lifecycle for 510(k) products, the reclassification would have taken until the end of 1999 to work its way through the system. This timeframe corresponds with an 18% drop in the number of 510(k) clearances.

By 2002, the number of 510(k)s had once again begun to increase. However, the FDA announced a user fee program that added $3,000 to the average 510(k) submission. Despite the modest fees, the program may have sparked a drop in the number of 510(k) submissions – at a rate of roughly 3.5% per year.

Applying the logic of a 2-year lifecycle, any user-fee inspired decline should have run its course by the end of 2004. So why the continued downward trend in 2005? Perhaps because the FDA exempted another 122 categories from 510(k) requirements in 2005, bringing the total number of exempt device types to 572. Still, the flow of new ideas on this smaller base of core products proves to be persistent—as evidenced by the small rise in 510(k) notifications last year. As long as there is payback, innovation will take root.
PRIVATE EQUITY MATH

Private equity has discovered the medical device world and things may never be the same. Unlike so-called “strategic buyers,” who make their living in the sector, private equity (PE) players are “financial buyers” who make their living by generating high returns for their investors. To this end, they bring three formidable advantages: they have the ability to move vast sums very quickly; they can get a good portion of investor returns by taking special dividends in the early years; and, they are not afraid of very high debt loads.

Exhibit 6
Doing the Math

Even with a premium on a high-multiple deal, PE generates strong returns

Once a private equity player controls the device company, several things begin to happen. First, the investor takes stock of incremental profit improvements available within a 2-3 year timeframe. For a company with an operating margin of 20%, each percentage point that drops to the bottom line increases valuation by 5% (at a constant multiple). Similarly, excess working capital will be targeted for conversion to cash that can be used to pay down debt and boost the value of the investor’s equity. Most often, the company’s management team is given a portion of the upside from operating improvements and working capital management to ensure alignment of interests. Lastly, the private equity player will look for the “take-out” or “liquidity event” that allows the firm to cash in on its investment. Typically, this would occur after 3 years or so, but it can happen sooner.

As the above example demonstrates, even device companies trading at high multiples exert a powerful draw to the fund managers in PE firms. With some modest assumptions—a 3% reduction in operating costs, 10% revenue growth, and aggressive working capital management, fund managers can net a stellar 50% IRR. The example assumes buyers pay a 25% premium for the device company, fund managers take a 10% equity stake, and the property is resold 3 years later at the pre-deal trading multiple. For larger PE funds, however, it is not unusual to see the fund managers’ equity participation below the 5% level. The additional leverage on the same deal would yield an IRR of more than 100% for the fund managers.

The story is very different for the PE investors—typically institutions and high net worth individuals. In this example, PE investors end up with a return of 14%. While that is still quite a bit better than the S&P 500 average, the risk is proportionally higher.

If all works out according to plan, everyone gets rich(er). However, given the debt load assumed by companies, gains and losses are multiplied for equity holders. Thus, a 2-point decrease in the exit multiple leads to an 8% decrease in return for PE investors and an 18% decrease for fund managers. Conversely, a 2% increase in growth corresponds to a 3% swing for investors and a 7% change in the fund manager’s return, and so forth.

So why do they do it? Presumably because (a) the upside is attractive; (b) PE represents an alternative asset class; and (c) the fund manager has a powerful incentive to chase these deals. To ensure that the manager doesn’t play fast and loose with investors’ money, many firms distribute gains equally until total returns reach 9% per year. Beyond that point, the bulk of the abnormal return is skimmed off by the fund managers and PE investors are brought along for the ride.

Still, if sector returns continue to run at 15% or more, a PE investor might be better off investing directly in a publicly traded device company.
enon underway that is likely to fuel the sector: the ascendance of financial investors. Financial investors—including private equity and venture funds—had taken their stake of all M&A transactions from around 8% to 21% by 2005. Meanwhile, these groups have a staggering $250 billion of excess cash available for investment. When multiplied by a typical private equity debt load of 3-4 times equity, the funds available for investment come to over $1 trillion.

Gambro AB, Molnlycke Health Care Group and the Transfusion Therapies business of Baxter International Inc. have all been recent targets of Private Equity (PE) investors. With relatively strong cash flow, moderate growth and reasonably predictable R&D requirements, such properties make excellent targets for financial investors to work their magic.

But what of high-growth, high-margin and heavy cash-consuming Class III device makers? These too are beginning to attract the gaze of PE firms – if only because the sheer volume of non-invested capital presents a challenge for money managers. Thus, the recent acquisition of Biomet Inc. by a private equity consortium led by Kohlberg, Kravis & Roberts comes as little surprise. Still, the price paid by the PE firms - $11 billion for a company with top line sales of only $2 billion – was enough to raise some eyebrows. To understand the mechanics of such a deal, see the sidebar “Private Equity Math.”

In the end, however, there is a limit to how much the device industry can grow. The system constraint ultimately comes down to the ability and willingness of society to pay for the medical innovations that the sector generates. With US expenditures on health care now approaching 16% of GDP and health care costs around the world increasing at 2-3 times underlying economic growth, the brakes – however tentatively at first – will be applied. In the meantime, the medical device industry will continue to attract massive investment, so it is up to industry executives to husband their abundant resources wisely to ensure payback.

The authors are all partners with The Boston Consulting Group. Pete Lawyer and Jim Andrew are Senior Vice Presidents and Directors and Marin Gjaja, PhD, is a Vice President and Director in BCG’s Chicago office. Christoph Schweizer is a Vice President and Director in the firm’s Munich office.

THE GATHERING WAVE

How to approach Low-Cost Country (LCC) manufacturing is a persistent question among medical device executives. As other industry sectors (e.g., auto, consumer electronics, etc.) have amply demonstrated, waiting too long to set the strategy forecloses all options but a retreat to higher ground. The attached exhibit, based on information disclosed on the FDA website, illustrates that device companies could easily fall prey to the same trap.

At the Class I end of the spectrum, LCCs are already a firmly-established part of the fabric. Having garnered 26% of all registrations in 2000, LCCs accounted for a staggering 43% of all new Class I devices in 2005. The results for Class II devices are equally impressive, as LCCs boosted their share of registrations from 10% to 17% between 2000 and 2005. Gains in the Class III segment have been more modest, rising from 4% to 5% in the same time period.

And who are the biggest players? Interestingly, Pakistan emerges as the LCC with the highest market penetration of Class I registrations, growing from 5% in 2000 to a staggering 19% in 2005. Over the same time period, China boosted its share of Class I devices from 5% to nearly 12%. As the LCC leader in Class II devices, China also doubled its share of these higher end devices from 2% to 4% between 2000 and 2005. Taiwan had a 3% share in 2000, down from 5% in 2005. With roughly 2% each, Korea, Hong Kong and India rounded out the top LCC providers of Class II devices, followed by Israel and Mexico, which each supplied 1%.

![Exhibit 7](image-url)

The Gathering Wave

Low-Cost Country Share of Class I, Class II and Class III Devices

(1) Low Cost Country: includes Africa, Asia (excl. Japan), Eastern Europe, Latin America, and the Middle East

SOURCE: FDA website, The Boston Consulting Group Analysis
Medical devices ride the cash curve. Device companies have been able to innovate and generate cash returns, but will the good times last? By pete lawyer, james p. andrew, marin gjaja, phd, and christoph schweizer. â– The medical device industry has generated returns over the past decade that exceed pharmaceuticals and many other sectors. â– These returns have been driven by payback on innovation, which the au-thors define as generating cash returns from new ideas.Â facing health care, and industry executives must keep their business models in step as medical device cash curves respond to the current environment. PAYBACK REVISITED. A Study on Medical Device for Cold and Hot Hydrotherapy. July 2017. Seung-yhul Yang.Â Medical devices ride the cash curve. January 2007. P. Lawyer. Medical Devices. CDRH International Programs. Device Advice: Comprehensive Regulatory Assistance. Digital Health. Medical Device Safety. News & Events (Medical Devices). Products and Medical Procedures. Resources for You (Medical Devices). Science and Research (Medical Devices). Home. Medical Devices. Topic Paragraphs. The FDA warns that biotin may interfere with certain lab tests.Â Medical Device Safety. Safety Communications, Recalls, Letters to Health Care Providers, Reporting Adverse Events (MDR and MedSun). Products and Medical Procedures.