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Drug, Diagnostic, and Device Combinations

Healthy Convergence

After a decade of failures, convergence—the merging of formerly distinct market segments for pharmaceuticals, diagnostics, and medical devices—has become a powerful new growth opportunity in health care.

By Ashish Singh, Chris Zook and Norbert Hueltenschmidt

- Industry changes are forcing pharmaceutical and med-tech companies to modify or scrap their long-standing strategies for growth. Universal cost-containment pressures are raising the bar that defines product success; and obvious growth opportunities like blockbuster drugs are shrinking.
- At the same time, unmet patient needs and the blurring of boundaries between drugs, devices, and diagnostic products have set the stage for well-positioned companies to grow by expanding the scope of their offerings into related development areas.
- Convergence within the health care industry is one way to deliver on an unmet need. It happens when the right combination of market readiness, advancing technology, and process innovation triggers the acceptance of a new offering in the marketplace.
- The most effective strategies for convergence in health care focus on market opportunities adjacent to a company's core business.

Health care companies seeking new growth have few places left to turn. Blockbuster drugs have become more expensive than ever to produce, with an average development price tag of \$1.7 billion, according to Bain & Company analysis. Pressure from providers and payers has cut returns on pharmaceuticals, devices and services, squeezing growth on all sides. Marketing costs continue to rise, along with competition from generics as lucrative drugs go off patent. In short, most of the traditional opportunities for large-company expansion have become far more elusive.

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Yet, some health care firms have managed to work around these constraints by pursuing a strategy of convergence—finding new combinations of formerly distinct market segments for pharmaceuticals, therapeutic devices, and diagnostics. New coronary artery drug-eluting stents (DES) are the most apparent example of convergence opportunities today.

The DES market has quickly turned into a most significant source of growth and profits. **Johnson & Johnson**, the early leader in a rapidly growing new DES segment, saw its stent market share climb from 27% in 2002 to 70% in 2003, the year its *Cypher* DES received marketing approval. But in July 2004, J&J acknowledged that new competitor **Boston Scientific Corp.** had eroded J&J's US DES stent market share to just 30%. Still, analysts estimate that J&J's stent sales will grow from 5% of its worldwide medical sales in 2002 to 13% in 2005.

Medtronic Inc., which is playing catch-up in DES development, has also tapped a new source of rapid growth with the *Infuse* bone graft, a device that merges a standard tool of orthopedic surgery—a graft-holding titanium cage—with a biological agent (bone morphogenetic protein-2, or BMP-2) that promotes bone fusion after back surgery. Analysts predict that Medtronic's device will capture 60% of the US spine fusion device market and half of the \$600 million worldwide market by 2006.

Convergence opportunities are not limited to drugs and medical devices. Just as the successes of the cancer drugs trastuzumab (*Herceptin*, from **Genentech Inc.**) and imatinib mesylate (*Gleevec*, from **Novartis AG**) have inspired the development of targeted therapies, the advent of personalized medicine is opening up a key growth opportunity for *in vitro* diagnostics (IVD) companies seeking to link their tests to a drug therapy label.

Vysis Inc., a wholly owned subsidiary of **Abbott Laboratories Inc.**, markets a test for HER-2, the gene that codes for the target of *Herceptin* whose overexpression causes an aggressive form of breast cancer. Since early 2002, the US Food and Drug Administration has allowed Vysis to include information about *Herceptin* on its label. As a result, the company says, it has captured nearly half of the highly competitive market for this genetic test, which also includes offerings from **Dako Corp.** (an older test, developed with but no longer favored by Genentech, as it does not identify as many potential responders), **Ventana Medical Systems Inc.**, and home brews. At the same time, Genentech's sales of *Herceptin* have grown: up 22% between 2001 and 2003, with similar growth predicted through 2005.

These are just some of health care's most visible early convergence success stories. Opportunities for growth through new product combinations or substitutions have started to appear in major diseases across the health care value chain. (See *Exhibits 1, 1a.*) But while the combination of previously distinct product categories breaks open the competitive landscape in a number of market segments, convergence also creates new risks for incumbents. New molecular imaging technologies, for instance, could eventually displace traditional biopsy-and-microscope diagnostics. Used mostly in drug development and a few clinical settings, notably oncology, *in vivo* imaging could nonetheless present incumbents with an emerging threat from an unexpected quarter as costs decline.

Sizing the Opportunity

Given its checkered past, convergence may seem an unlikely source of new growth. For example, disease management—the proactive support of chronic conditions through therapeutic drug monitoring, which entails the tandem use of devices and diagnostics with specific drugs – turned out to be a convergent idea that was ahead of its time. Consider, too, the hit sustained by drug companies that reached too far from their cores when they acquired pharmaceutical benefit managers. **Eli Lilly & Co.**, for one, stumbled badly after it purchased **PCS Health Systems Inc.** from **McKesson Corp.** in 1994 for \$4 billion, selling it later for a \$2.6 billion loss.

Many of these mistakes resulted from confusion about the true nature of convergence. Companies can be misled into thinking that new technologies or expanded capabilities will carry them to new customers in markets they haven't yet tapped. False convergence lands companies

Potential Convergence Opportunities and Timing

EXHIBIT 1A

Opportunity	Likely Timing of "Takeoff"
Implantable drug pumps	Next 2-5 years
Targeted drug delivery	Now
Closed loop diabetes management systems	Next 2-5 years
Biomarker-led IVD and therapeutics	Next 2-5 years
Non-invasive in vivo diagnostics	Next 2-5 years
Remote monitoring and therapy management	Next 2-5 years
Targeted cell/gene therapy delivery	Next 5-10 years
Image-guided surgery	Now – next 2 years
Non-invasive therapies/intervention(e.g. radiotherapy, cryotherapy, heat therapy)	Now – next 5 years

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in trouble: without a clear understanding of the market opportunity and the benefit to customers from combining two previously distinct market segments, companies are likely to wind up competing in someone else's core business.

True convergence, on the other hand, happens when the right combination of market readiness, advancing technology, and process innovation triggers the acceptance of a new offering in the marketplace. It requires relatively low barriers to adoption. And it is more likely to succeed if the converged product or service extends directly from a company's core business. When Bain analyzed the growth patterns of 181 companies across many industries from 1995 through 2004, and linked them back to individual company performance, we found that three-quarters of firms that have attempted to expand outside their core businesses have failed.

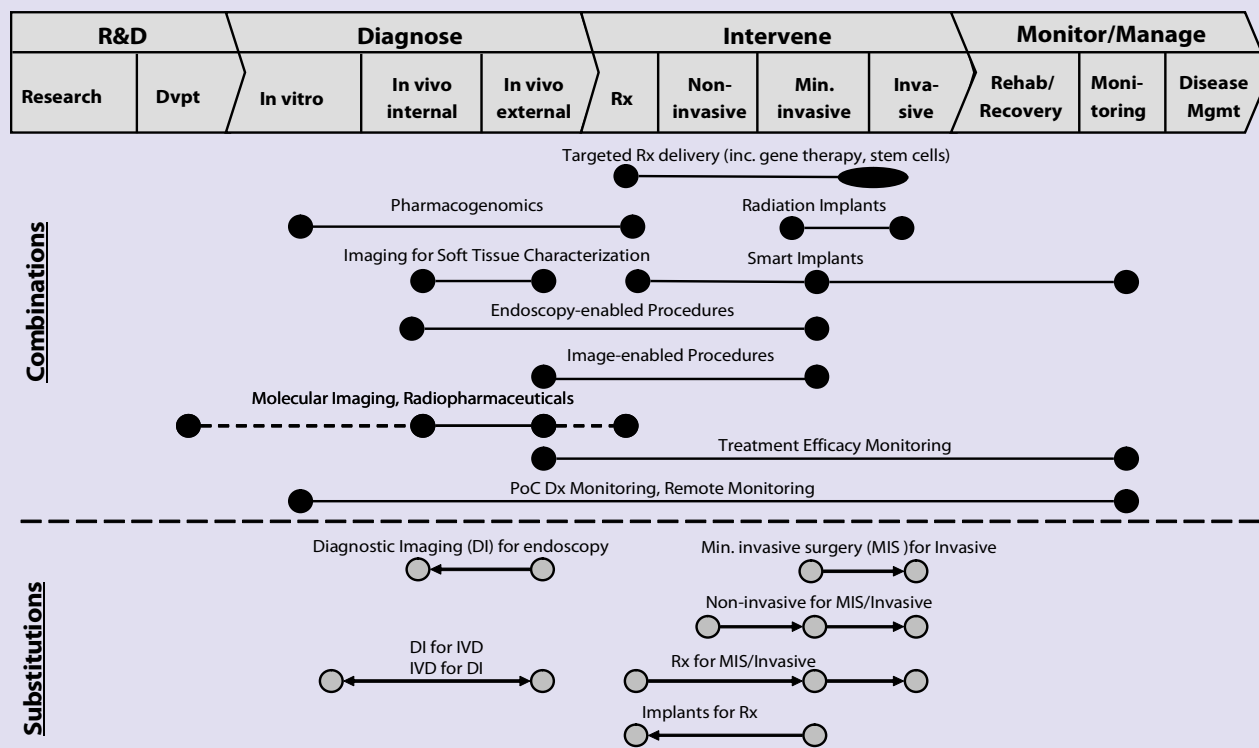
Making Convergence Moves Work

Health care companies seeking to grow through the convergence of products in their core business areas need a rigorous method to determine strategic fit: does the opportunity represent true convergence, or a glorified product extension that takes them down a misguided path into a competitor's core business? Companies also need a growth strategy that enables them to systematically expand into nearby markets adjacent to their own core businesses—and to assess opportunities that may lie further out. Although convergence opportunities may vary by technology, disease, or industry subset, the processes for evaluating them remains constant.

Six considerations help companies evaluate health care convergence opportunities and arm them

Examples of the Continuum of Healthcare Convergence Opportunities

EXHIBIT 1



SOURCE: Bain & Company

to develop a response to potential convergence threats from the outside. The first is whether the business/market segment has already demonstrated opportunities for convergence. Next, is to ask: what are the unmet needs – patient, physician, and payer – that are difficult to address via conventional technologies? (Both of these conditions exist broadly throughout the health care industries.)

A company considering tackling a convergence opportunity also requires a core technology capability that can generate innovative, convergence-driven solutions to existing unmet needs. The firm needs to scan for recent changes in technology, customers, and competitors that could favor specific convergence opportunities. It needs to determine whether adoption barriers (for physicians and payers, typically) would slow the introduction of new solutions. Finally, a company needs to assess its vulnerability to non-traditional competitors who leverage convergence opportunities: Who are the likely market entrants?

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Convergence leaders like J&J, Boston Scientific, and Medtronic share some similar characteristics in the way they have approached these issues. First, they have been rigorous about identifying unmet needs. Studying product use carefully allows firms to glean insights about customer needs and behaviors – an unglamorous but promising route to spotting untapped opportunities. Identifying unmet needs within the market segments that companies know the most intimately has proven an especially successful expansion strategy, allowing firms to follow familiar pathways to build new business. Health care companies also need to pinpoint unrealized clinical benefits.

These firms have a good track record in spotting new ways to exploit existing technologies. The scientific advances that make converged products feasible are usually well understood—it's their application in new combinations that can lead to breakthroughs. Convergence can't be forced; it results from a timely recognition of existing opportunities. These companies also pressure-test the economics of converged products and make sure adoption barriers are manageable. The economics must be acceptable – better yet, attractive—to the payers, providers, and suppliers who are integral to a new product's success. While payers may be happy to underwrite an effective, low-cost alternative to a costly procedure, it won't catch on if it requires so much new skill of physicians that they refuse to adopt it.

Companies can use these three principles to identify and capitalize on a broad array of convergence opportunities occurring in health care. For instance, pre-cancerous polyps are commonly both found and removed during colonoscopy, merging diagnosis and treatment in one step. Treatment efficacy monitoring is being applied at diagnosis, during intervention, and through into the monitoring and management of disease. And soon personalized medicines – targeted therapies tailored to an individual's genetic makeup as determined by diagnostic genetic testing – will help enhance drugs' effectiveness and minimize their undesirable side effects, blending diagnosis and treatment.

Identifying Unmet Needs

Rather than using telescopes to scan the horizon for broad emerging trends, pharmaceutical and med-tech companies searching for convergence opportunities are better served by using microscopes to thoroughly examine their customers for unmet needs and unrealized clinical benefits. In a separate Bain study, we found that nearly 80% of successful growth moves were built around insights about customer behaviors. Indeed, the best place to look for adjacent opportunities is inside a company's strongest customer base. Studying customers is a logical first step; the more attuned a company is to their preferences and needs, the more readily it can spot untapped opportunities.

Sometimes, the opportunities are obvious, as with DES. J&J and Boston Scientific each knew that bare metal stents were failing to keep open clogged heart vessels in more than a quarter of patients. Because of post-surgical scarring, the vessels were re-narrowing, requiring repeated angioplasties. None of the customers were happy with the results: patients needed repeated procedures; cardiologists were frustrated by their high failure rate; and payers picked up the tab for the repeated procedures.

J&J's **Cordis Corp.** addressed the unmet need of all these constituencies by leveraging stent-coating technology developed by **SurModics Inc.**, and by licensing **Wyeth's** sirolimus, a drug that battles post-surgical scarring. The resulting *Cypher* DES reduced the incidence of re-narrowing to 9% of patients in 2003, its first year of clinical use in the US. Boston Scientific was close behind with its *Taxus* DES, which delivers paclitaxel: it received US regulatory approval in March 2004.

The financial results for the two DES leaders have been dramatic. (See *Exhibit 2*.) *Cypher* is expected to generate \$2.3 billion in sales for J&J by 2005 – up from \$415 million in bare metal stent sales in 2002. The benefits of breaking in early to a new product category are also evident for Boston Scientific, whose *Taxus* stent has quickly come to dominate the race with much-larger J&J. For April, *Taxus's* second month on the market, Boston Scientific reported \$163 million in US *Taxus* sales. The company said that, based on reorders, it has gained more than 70% of the US market.

To be sure, DES's haven't been without their problems. Last year, the FDA issued two warnings about clotting complications with J&J's *Cypher*. The agency had received over 290 reports of blood clots within 30 days of stent insertion, with related deaths in more than 60 of the cases. And just this month, Boston Scientific recalled 200 *Taxus* stents because of a design problem that could impede balloon deflation during angioplasty, causing serious injury or death. But however the market eventually develops, both companies have matched customers' unmet needs, and they produced big new revenue streams and a much-improved technology for providers and patients.

Pulling Technological Triggers...

When Genentech's *Herceptin* was introduced in 1998, clinicians were aware that the drug worked only on a subset of patients overexpressing the HER-2 protein. This subgroup—

comprising up to 25% of patients—carry extra copies of HER-2. Abbott's Vysis division had developed an *in vitro* test for the gene called *PathVysion*, launched in 1999.

Sales of PathVysion have more than doubled since 2002, when the FDA approved the use of the test for selection of Herceptin-responsive patients.

Late in 2002, Genentech won a similar FDA approval to include the Vysis genetic test on *Herceptin's* label. In 2003, US sales of *Herceptin* rose by \$61 million, or 18%, to \$406 million. The

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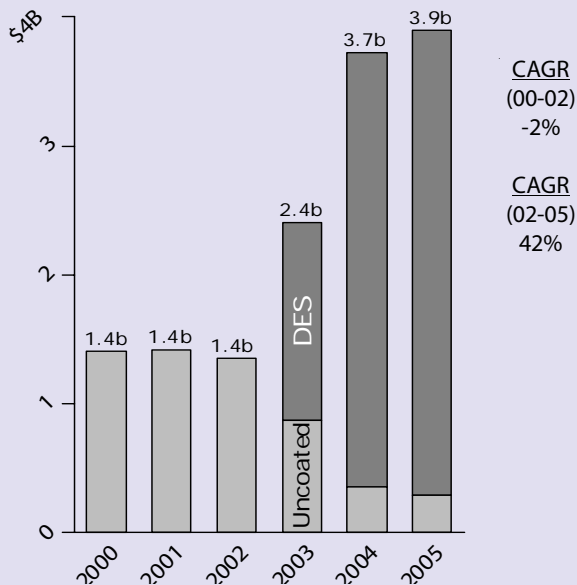
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Market Impact

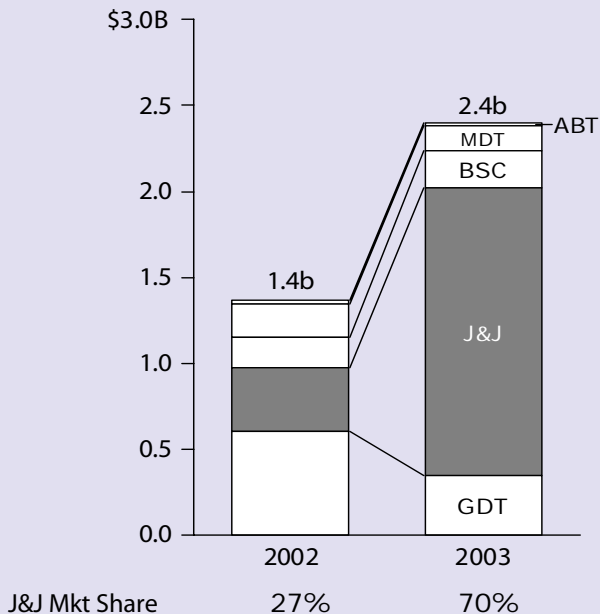
EXHIBIT 2

DRUG ELUTING STENTS

Total US Stent Revenue

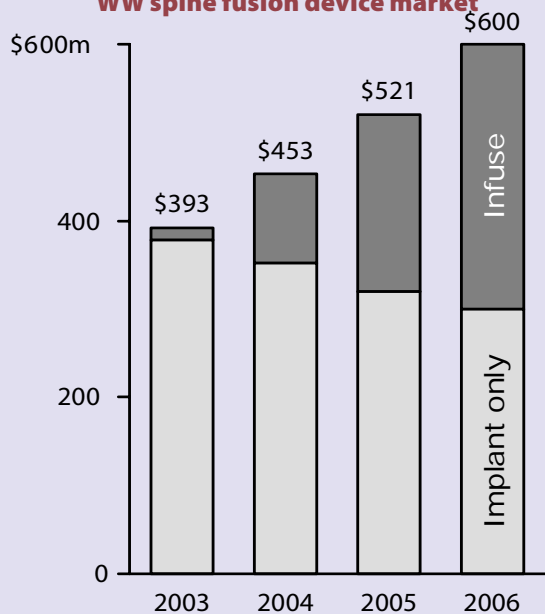


Impact on Market Share

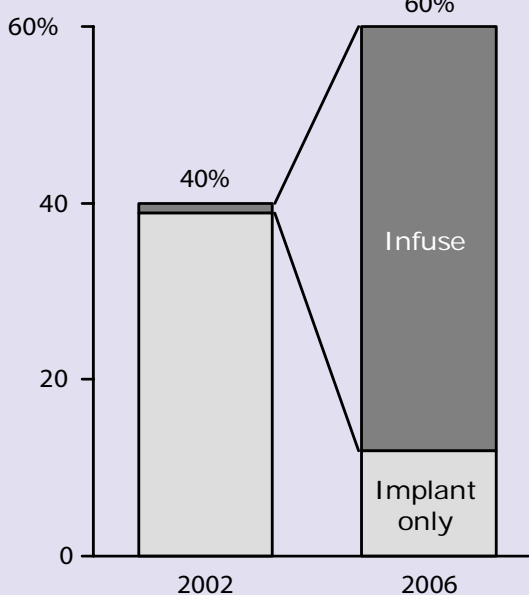


ORTHOBIOLIGICS

WW spine fusion device market



% Medtronic US spine fusion market share



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technology trigger for this convergence opportunity—the identification of the genetic subgroup in which *Herceptin* was effective against spreading breast cancer – allowed each company to leverage the technology of the other, to their mutual benefit.

...and Pressure-Testing Economics and Barriers to Adoption

Yet to date, *PathVysion* appears to be more the exception than the rule, and pharma has yet to buy into the notion of tandem development of diagnostics. This convergence may result in drugs that target patient subgroups, and so show relatively higher efficacy rates, but it also reduces the potential market size. On the other hand, the economic driver for such products will be payers. As biomarker sets that help stratify patients become clinically validated, the pharmacogenomics opportunity—of which patient stratification is a significant portion—will grow, reaching close to \$2 billion by 2008.

Before moving into new product combinations, companies must make sure that the economics are as attractive as possible for payers, providers, and suppliers. It's also important to anticipate or avoid major adoption barriers—like asking surgeons to learn entirely new procedures, for instance, or requiring payers to reimburse for an expensive procedure that doesn't pay for itself in the long term.

Drug-eluting stents make the case for following this rule. Indeed, therapeutic drug/device combinations seem more likely near-term convergence opportunities than tandem drug/diagnostics development. Payers are embracing them because patients who receive stents don't appear to require repeat angioplasties or heart bypass surgery. An important factor in the success of the new product is its comparable cost: \$16,800 for one-year of treatment costs, compared with \$16,500 for inserting the bare metal stent. Providers like DES because they don't lose revenue: payment to physicians for insertion is comparable to that for inserting bare metal stents. And physicians aren't required to learn an entirely new skill, but rather to adapt an existing one.

The economics are most compelling for DES suppliers. When J&J introduced *Cypher*, it was able to charge \$3,100—nearly quadruple the cost of its bare metal stent. Competition with Boston Scientific is now driving that price down; both companies' drug-eluting stents are selling for as little as \$2,400. Still, that's more than triple the \$800 price of J&J's bare metal stent.

By keeping adoption barriers low, Medtronic has had similar success with *Infuse* (its **Medtronic Sofamor Danek** division acquired rights to use BMP-2 in spine from **Wyeth-Genetics Institute Inc.** in 1995.) Until recently, patients who needed surgical fusion of vertebrae – small bones in the back—to alleviate lower back pain had to undergo harvesting of bone from their hip to be used as the grafting material to make the backbones grow together. Nearly half experienced persistent pain at the site where bone was harvested – pain that was typically far worse than that at the surgical site in their lower back. Medtronic (and others) saw a convergence opportunity. By putting this protein in a pre-existing, Medtronic-manufactured titanium cage that's inserted during spinal fusion surgery, the company eliminated the need for hip-bone harvesting – and the attendant pain. (See "When the Body Alone Can't Build Bone," *START-UP*, July 1999.)

Medtronic stayed close to its core product in developing *Infuse*: other companies developing BMP—notably **Stryker Corp.** with BMP-7—tried to develop similar convergent products for other bone-growth applications, with less success. The tapered cage that holds Medtronic's BMP is identical to the cage Medtronic used for spinal fusion surgery when the patient's own bone was the graft material. The screws that fuse the vertebrae are also unchanged. Only the "glue" – the material in the cage that causes two separate vertebrae to grow into one—is different.

The new product shared other key attributes with its predecessor. The customers for Medtronic's pre-existing titanium cage were orthopedic surgeons; this didn't change when Medtronic put the new bone-spurring protein in the cage. *Infuse* used its existing distribution channels and sales teams to reach these surgeons. The upshot: By changing just one key variable—using its cage to deliver a protein—Medtronic was able to expand into orthobiologics without taking undue risks.

Following this third rule of convergence paid off handsomely for both the company and its customers. The surgical success rate increased, to 95% of patients with a fusion two years out, as compared to 89% using autograft bone in the cage. Patients are spared the hip pain. Despite a more complicated fusion procedure, surgery using *Infuse* costs a tad less than with an autograft. And analysts predict that

Convergence Brings New Opportunities and Threats

EXHIBIT 4

	Opportunities	Threats
Big pharma	• Potential growth channel (extend drug reach/life)	• Channel/partner risk (drug could become secondary; could lose customer access)
Med tech	• Huge growth potential (become "mainstream")	• New liabilities (poorly understood as of now) • PharmaCos back in the game?
Providers	• Potential productivity enhancement	• Department obsolescence • Blurring specialty boundaries
Payers	• New, safer, cheaper treatment	• Proliferation of treatment (and cost)

SOURCE: Bain & Company

Medtronic will capture 60% of the US spine fusion device market by 2006 – up from 40% in 2002, with all the new growth coming from *Infuse*. If current sales trends hold, Medtronic should enjoy half of a \$600 million global market by 2006—up from a scant \$15 million in 2002, amounting to less than 5% of the global market. (See Exhibit 3.)

What's more, by testing this close-in adjacency in the spinal surgery area first, Medtronic may well have established a solid base from which to expand the uses of its convergent product. In May 2004, the company won FDA approval to sell *Infuse* as a treatment for fractures of the tibia – the thick lower leg bone.

To be sure, *Infuse*'s launch has not been without challenges – among them some adoption barriers. The safe mixing and dosing of the recombinant bone protein requires a highly skilled professional. And managing overgrowth of bone at the graft site has become a new, delicate problem for surgeons. Still, because the clinical benefit is so tangible, these provider adoption barriers have been manageable. And while most payers are not yet reimbursing for the procedure, they are expected to begin doing so because of the comparable economics: the net cost of the *Infuse* procedure, at \$19,800, is slightly less than that of a standard autograft procedure from the hip, at \$20,400.

With *Infuse*, Medtronic has clearly demonstrated the value of hewing to close-in adjacencies. Following this rule lessens risk while allowing successful moves into adjacent space—moves that work out because they don't attempt too much at once.

First Steps for Companies Developing a Convergence Strategy

1. Define your Customers Broadly—Then Talk to Them

Your customers aren't just the purchasers of your product immediately downstream. They include the patient who lives with it; the physician who inserts it; and the insurers and employers who shoulder the burden of paying for it. Companies need to probe within this diverse set of experiences to identify unmet needs. To elicit these insights, companies need systematic processes for gathering feedback from customers. Consider the example of Medtronic, which built its early success in convergent products by creating strong feedback loops through its employees out in the field as well as its worldwide network of cooperating doctors.

2. Rethink Your Innovation Model

Typically, R&D at healthcare companies occurs mainly within business units. But R&D for convergence opportunities generally takes longer and entails greater risks than business units are accustomed to. In addition, the benefits of convergence R&D are spread over multiple business units. A centralized R&D group can be more efficient in identifying such opportunities.

3. Organize to act quickly on the convergence opportunities you've identified

Large companies can be hobbled if they don't coordinate quickly across divisions once a convergence opportunity is identified. Corporate offices need to champion these opportunities, making cross-unit collaboration happen. Johnson & Johnson learned this the hard way when its Cordis Inc. division began developing a drug eluting stent. Cordis wasn't a drug developer and lacked expertise in conducting clinical trials. So Cordis had to bring in pharmaceutical knowledge and expertise from other divisions of J&J. Because J&J hadn't fostered this level of coordination, it took longer to develop its stent.

Companies need to learn how to feed new products that cut across business units. Otherwise, convergence opportunities may die on the vine.

Preparing for Convergence

For some companies, convergence represents more of a threat than an opportunity. That's the situation now confronting firms that are invested in the development of *in vitro* diagnostics (IVD) – the tests and procedures by which cancers and other diseases are identified outside the body, using samples of tissue, blood, or other bodily fluids.

The IVD market has grown from \$450 million to \$21 billion between 1970 and 2001, with a 13% CAGR during this time. Seven companies account for close to 70% of IVD market share: number two Abbott Diagnostics provides a high-profile example of an established company whose diagnostic oncology business is threatened by a new, convergent technology.

Through its Vysis subsidiary, Abbott markets genetic tests for breast, ovarian, and bladder cancer. It brought the first prostate specific antigen test to market in 1991. And it sells at least six other diagnostic cancer tests. Diagnostic cancer testing brought the company \$283 million in revenues in 2003, not including the \$70 million of Vysis' revenues. But Abbott now confronts a significant threat to its cancer testing business. *In vivo* diagnostics—the use of non-invasive scans and other means to make diagnoses without the need for surgery – is taking off, typified by the success of PET imaging.

After about a decade of slow growth, the use of PET scanners has exploded recently in US

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hospitals, prompted by the federal Medicare program's 2001 decision to boost coverage for PET scans used to diagnose cancer. PET scanning produces a picture of the biological activity of an organ, by measuring the decay of a radioactive substance injected in the patient before the scan. Differences in the activity between cancer cells and healthy cells allows PET scans to quickly and non-invasively detect cancers even in their earliest stages and, later, to monitor the effects of cancer therapy.

The big three makers of PET scanners, which sell for \$1-2.5 million, are **General Electric Co.'s GE Health care** division, **Siemens AG**, and **Philips Medical Systems Inc.**, with overall sales of \$13 billion, \$7 billion, and \$8 billion, respectively. But there's another set of players who are poised to benefit from the boom in PET scanning: the companies that make the radioactive reagents injected before the scan. The three leading players—**Eastern Isotopes Inc.**, **Syncor International Corp.** (acquired by **Cardinal Health Inc.** in 2002), and **PET Net Pharmaceuticals Inc.**—make FDG, a radiolabeled glucose molecule that's used in 95% of PET scans. (See "Imaging in its Heyday: Clinical Applications (Part II)," *START-UP*, April 2002.) Estimates indicate that the market for all radiolabeling agents will grow at 20%, more than doubling between 2001 and 2006, to \$2.2 billion. By then PET agents, which accounted for roughly 12% of the market in 2001, will comprise more than 40% of it.


IVD companies need to prepare to meet a major threat to their dominance of cancer diagnosis. Similarly, pharmaceutical companies that are invested in drugs for Parkinson's disease and epilepsy need to guard their flanks: companies that make electrical stimulation devices are developing their own implants to treat these diseases. The broad lesson for established companies: look for threats where you least expect them; convergence produces attacks from unanticipated quarters.

Convergence has the potential to reshape strategy in nearly every sector of the health care industry. It provides a rich opportunity for pharmaceutical executives to grow their businesses and exploit their drugs' full potential. For med-tech companies, convergence offers the possibility of becoming franchise players in health care, competing at the same level as Big Pharma, with the major growth potential that presents. For providers, there's the promise of both increased income and better patient results. And for payers, convergence enables safer, cheaper treatments.

The risks are also large. A drug company could lose access as its partner med-tech firm takes the lead with customers, and the two segments may well battle over who deserves what margin on sales, based on how they value their technology contributions. The drug maker could be relegated to providing technology, back end systems, regulatory know-how and other behind-the-scenes support, while med-tech firms must be attentive to potential new liabilities from the sale of device/drug combination products.

What's more, the competition increases as pharma companies move into markets traditionally served by med-tech firms—and vice versa. For providers, converged therapies and diagnostics blur the boundaries of specialties, and could make some departments obsolete. And for payers, convergence can present a familiar danger: the proliferation of treatments and therefore costs. (See *Exhibit 4*.)

Indeed, the risks of convergent transformation – and the scale of the enterprise – make it unlikely that any of the major pharmaceutical or med-tech companies are going to be concentrated solely in convergent products in the foreseeable future. But given how quickly converged products have developed as significant sources of revenue and profits, companies that want to grow should have a game plan for capitalizing on convergence.

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