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Why medical devices are made in America

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It would be hard to conceive an industry better suited to American manufacturing strengths than medical devices. Advantages read like a primer on what it takes to keep U.S. manufacturers onshore:

- High value-added products
- Sophisticated and technologically advanced manufacturing processes
- High degree of customization
- Well-developed and highly competent supply chain
- Exacting standards
- Precision
- High dependence on research and development
- Strict regulatory oversight

Making products for the cheapest price possible isn't on the list. "In medical devices, product decisions are more about quality, safety and efficacy and less about cost," says Gordon Pan, a Chicago-based partner with **Baird Capital Partners** who specializes in healthcare.

That calculus extends to valuations and mergers and acquisitions. "Certainly, you want very efficient manufacturing operations, but it's not as critical as found in other industries, where price is the primary consideration," says Pan.

All this helps explain why medical device manufacturing, which runs the gamut from silicone tear duct plugs to artificial toe joints, has not only remained firmly on U.S. shores, but dominates the global industry. Estimates vary (as do those items included in the industry), but the U.S. accounts for more than 40% of the world's production. With the possible exception of aircraft, there isn't a higher valued-added export than medical devices. Exports in 2008 totaled \$31.4 billion.

Perhaps most importantly, medical devices provide some of the most lucrative employment of any industrial sector, generating, on average, \$58,000 a year for its more than 400,000 workers. "We don't ever think of going offshore," says Kevin Meyer, the president of medical silicone products maker **Specialty Silicone Fabricators**, which employs 300 workers in Paso Robles, Calif., and Elk Rapids, Mich., complexes. "The real value of our company is in the people."

America's medical device (often called medical technology) industry totaled about \$136 billion in 2008, the last year available, according to the Advanced Medical Technology

Association. That's a slight rise from 2007 but stellar compared to most U.S. manufacturing, which fell sharply in the second half of 2008.

The medical equipment industry is "as vibrant" as any in the U.S., says Robert Scott, an international economist with the Washington-based think tank Economic Policy Group.

Despite that, medical device manufacturers and those who surround the sector are anything but sanguine. They fear a combination of U.S. government policy, capital market difficulties and rising overseas competition could imperil or at least diminish current American dominance in the years to come. "People don't see as much blue sky," says Kenneth Liebman, a Minneapolis-based partner at **Faegre & Benson LLP** who chairs the firm's medical technology industry group.

An anxiety is affecting everything from venture capital to initial public offerings to buyouts. "There's a lot of flux in the device industry," says Pan.

Conversation these days often centers on a provision in the healthcare reform legislation that raises taxes on profits of medical device makers, although exactly what the impact will be isn't certain.

Also uncertain is the reimbursement rates under the new healthcare package. Most new devices to hit the market aren't revolutionary breakthroughs, but incremental improvements on existing products. The concern is the government may decide new devices will get no more reimbursement than older models, putting a severe strain on development costs.

On top of all this, there are complaints the Food and Drug Administration is increasingly dragging its feet on approvals. "I hear from a lot of small companies that they're having difficulties with the FDA," says Rep. Erik Paulsen, R-Minn., whose suburban Minneapolis district includes one of the country's highest concentrations of medical device technology.

Some of that may be the usual grumbling. In fairness, the FDA is a big reason why medical device makers locate in the U.S. The FDA not only approves products, but commands strict production oversight as well.

Paulsen, for one, says he's concerned that U.S. companies could lose their edge to rivals in Europe whose governments, he says, are quicker to approve new devices. However, longer term, China -- no surprise there -- stands as the most potent threat to American dominance. "Manufacturing capabilities in China in healthcare are not there. They're still in the evolutionary stage," says Pan, who also oversees **Baird Asia Ltd.**, a Hong Kong-based company that supports Baird portfolio companies in China. But he adds: "Every time I go to China, I find the pace of change is phenomenal. There's no question that China will obtain that goal of high value-added manufacturing."

When it comes to medical devices, China doesn't simply lack the requisite manufacturing skills, but what Pan terms a necessary "ecosystem" of suppliers, similar

to ones China has successfully developed in consumer-related industries. "That's a lot harder challenge," he says.

This is where America shines. Manufacturers tend to cluster in certain locations, depending on specialization. They include not only the makers of the devices themselves, but the plastic, metal and electronics that go into them. In the Milwaukee area, for example, **GE Healthcare** leads, with X-ray and other imaging and scanning equipment manufacturing. According to Timothy Sheehy, president of the Metropolitan Milwaukee Association of Commerce, that supply base is 11,000 companies, most of which are in the greater Milwaukee area.

"Geography allows us to turn things very quickly and make improvements," says Jeff Hanthorn, COO of two-year-old Indianapolis-based neural and spinal medical device company **Nico Corp.** Hanthorn describes the choice of **Medivative Technologies LLC** as contract manufacturer. "They're 15, 20 minutes from our office. Others we looked at were two hours away. You need proximity."

Hanthorn and other key Nico executives came from Suros Surgical Systems Inc. **Hologic Inc.** bought the Indianapolis maker of breast biopsy systems in 2006 for \$240 million.

By sheer numbers, California leads in medical device companies and dominates specializations such as eye-care. But on a per capita basis, medical devices are most critical for Minnesotans. Minnesota has emerged a world leader in medical devices related to cardiovascular, urology and the spine, according to Liebman.

Minneapolis-based **Medtronic Inc.**, along with New Brunswick, N.J.-based **Johnson & Johnson**, which has operating companies scattered all over the U.S., leads medical devices both in total size and recent acquisitiveness. But equally strong are startups. Doctors invent devices and link up with those in larger companies with business and financial acumen looking to strike out on their own.

Then there's Warsaw, Ind., 11,000 strong, which lays claim to hosting the biggest aggregation in the world of orthopedic device makers. Thank a traveling salesman named Revra DePuy, who in 1895 founded a factory in Warsaw to produce fiber splints. **DePuy** Manufacturing is credited as the world's first commercial orthopedic manufacturer. DePuy's first sales representative eventually broke off to start **Zimmer** Manufacturing in the 1920s. Both thrived. Both remain in Warsaw. Zimmer is the world's largest purely orthopedics-related medical device company. J&J acquired DePuy in 1998.

Warsaw is also home to private equity-owned **Biomet Inc.**, publicly traded **Symmetry Medical Inc.** and more than a dozen smaller companies. Startups populate Kosciusko and Whitley counties.

However, getting necessary capital to new companies in Indiana and elsewhere is becoming more daunting. Even before recent concerns about new taxes, startups and

their venture capital backers were singing the blues. "Our task is as hard or harder than it's ever been," says William Link, a founding partner who specializes in medical devices at the California venture firm **Versant Ventures**. "It takes more capital than ever."

Exits are more problematic because the appetite for medical device-related IPOs has substantially decreased over the past decade. At the same time, the capital requirements of medical device-related startups have increased substantially, making it difficult for VCs to maintain the portfolio size they carried in the past. According to Link, the average capital requirement of his firm's portfolio companies is close to \$70 million, with Versant's average investment \$12 million.

Despite the tougher environment, Link says exits are possible, with impressive results. In July, eye-care giant **Alcon Inc.** announced it would buy **LenSx Lasers Inc.**, a Southern California company that developed a laser system used in cataract operations. Alcon agreed to pay \$361.5 million in cash plus a further \$382.5 million, depending on performance. Versant invested in LenSx in 2008.

Early this year, J&J bought another Versant portfolio company, Acclarent Inc., for \$785 million. Acclarent, based in Menlo Park, Calif., makes devices used in sinus surgery.

"In medical devices, when things go well, there are exits," Link says. He also believes that when it comes to medical device manufacturing, the U.S. will continue to hold significant advantages in years to come. "That will continue to be fine," he says.

Others agree. "See where value flows. If you only do what others can do, it will flow to where the costs are lowest," says Meyer, who also serves as a consultant in the industry. In medical devices, "the value is in customization, and customization is where manufacturing in the U.S. can really excel. There's really no reason to go overseas."