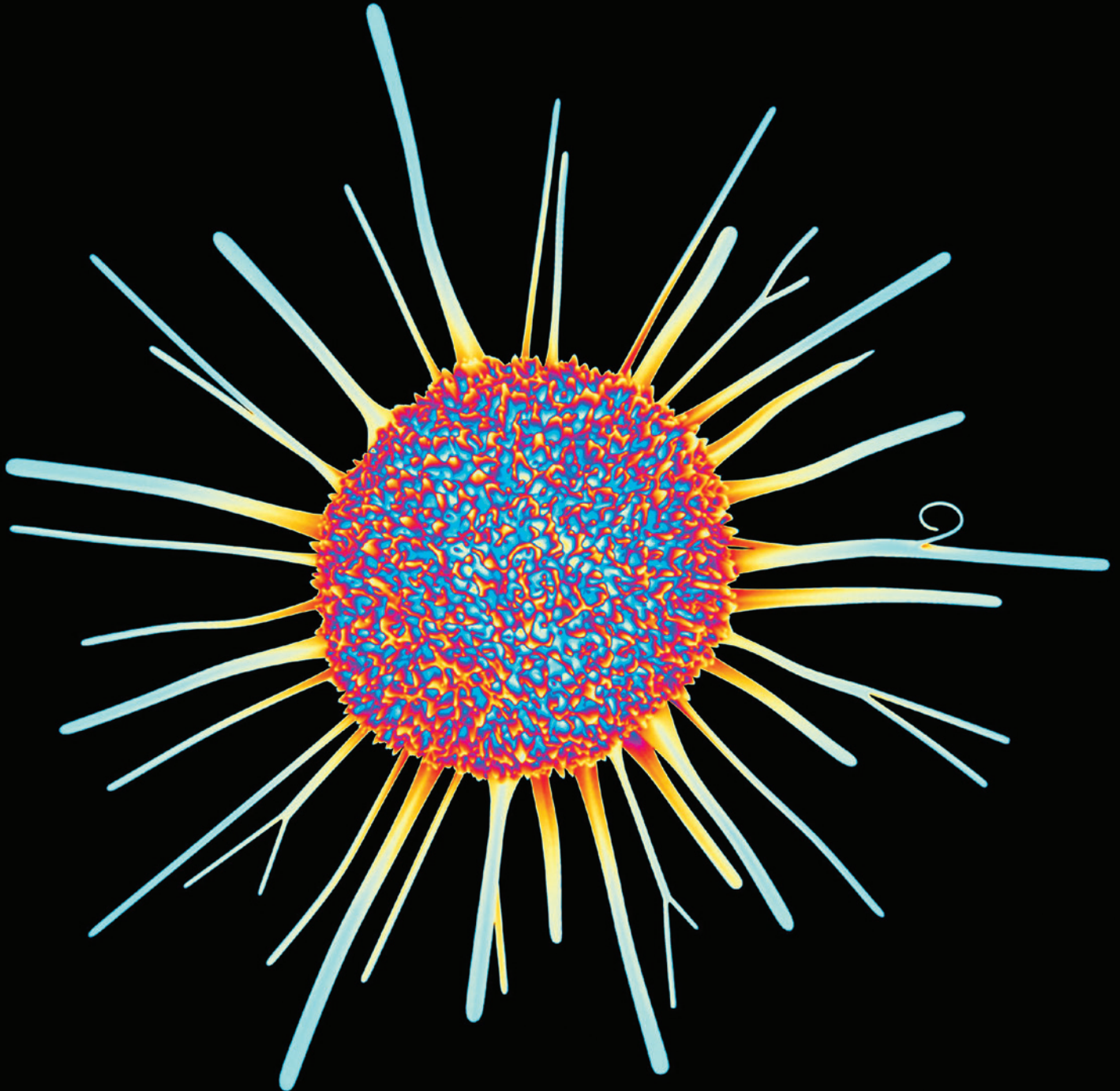


2011 California Medical Technology Industry



Overview of the Medical Technology Sector in California

California has far more medical technology workers and companies than any other state — California is home to more than 1,300 medical technology firms, more than any other state in the nation. There are more than 107,000 medical technology jobs in California, which pay an average wage of nearly \$60,000. It is the largest segment (40 percent) of the total 268,000 California life sciences (medical technology, biopharmaceuticals, academic research, etc.) jobs.

California leads the nation in medical technology venture capital funding — Beyond large employers, the majority of medical technology companies in the state are smaller, venture capital-backed firms with fewer than 50 employees. In 2010, medical technology venture capital investment in the state was \$1.15 billion, or 50 percent of the total \$2.3 billion in total medical technology venture capital nationwide.

The medical technology sector in California supports local economies and jobs throughout the state — Medical technology “clusters” exist throughout the state. While the largest such clusters exist in the San Francisco Bay/Silicon Valley and Orange County areas, the Los Angeles, San Diego, Ventura/Santa Barbara, Riverside/San Bernardino, and Sacramento regions support thousands of jobs as well.

Many medical device and diagnostics companies work closely with California universities and research institutes, licensing technologies developed in academic settings in order to develop, commercialize and bring them to market.

Medical technology is an export industry that helps California’s, and the United States’, balance of trade.

California’s medical technology industry, producing advanced products like coronary stents, implantable defibrillators, insulin pumps and molecular diagnostic tests, benefits millions of patients in the United States and around the world.

Patient profile

Bill Walton striding back from the brink



Bill Walton, the NBA great who played for John Wooden at UCLA, has never forgotten the play that wrecked his back — and changed the arc of his basketball career and life.

On a frigid January night in 1974, the Bruins traveled to Washington State out on the Palouse in southeastern Washington. A rowdy sellout crowd lusted for victory against a proud and mighty UCLA team that had won an NCAA-record 84 consecutive games over the previous three seasons.

During the hotly contested game, Bill — a spirited and rangy 6’11” center — soared high above the rim when an opposing Washington State player “low-bridged” him, flipping Bill upside down and sending him hard to the tartan floor.

“It was a despicable act of intentional violence and dirty play,” Bill would reflect 35 years later. “I broke two bones in my spine that night, and things were never the same for me again.”

Bill received treatment but was not at his best when UCLA traveled to Notre Dame 12 days later. The Fighting Irish snapped the Bruin’s 88-game winning streak, and an injured Bill Walton was about to embark on a long, slow, downward spiral that would cause him trouble and grief for the next three-and-a-half decades.

Since his life was exercise and sport, Bill worked diligently off the court. Core-strength training, yoga, acupuncture, stretching, physical therapy, weight training, massage, swimming, biking — as well as taking prescribed medicine and nutritional supplements — kept him playing basketball, but never without a struggle. “It was always there,” he said. “That pain. That discomfort. That limitation. That restriction.”

That pain and discomfort is the main reason why Bill — called one of the greatest players in collegiate basketball history — set an NBA record he never wanted: the most games missed during a playing career. His knees, feet, ankles, wrists, and aching back rebelled at the demands he placed on them and continued until his playing days were over.

Bill eventually transitioned into a broadcasting career, where the constant travel and lifestyle — 200 nights a year on the road — compounded the problems with his deteriorating back condition.

“I lived in this increasingly unbearable world of pain and disability,” he said. “I ate my meals on the floor, face down. I couldn’t get sleep. I couldn’t get dressed.” After 30-plus different orthopedic surgeries, however, including having both ankles surgically fused, nothing could stop the debilitating nerve pain emanating from his back. At one point, feeling like there was no hope, he stood atop a high bridge and contemplated jumping. At least his troubles and the pain would finally be over. The turnaround began when Bill was introduced to Dr. Steven Garfin, chairman of the Department of Orthopedics at the University of California, San Diego who practices the new surgical technique of operating on the spine by entering through the side, using a Neurovision probe. The instruments are developed by NuVasive, based in San Diego. “I just wanted my life — any life — back,” remembers the 57-year-old former basketball star, “and I was hoping and praying that Dr. Garfin could be the guy to do it for me.”

Bill underwent eight-and-a-half hours of surgery and was amazed by the near immediate relief from the unrelenting, excruciating, and debilitating nerve pain that ran through his back, into his groin, and down his legs.

“I had to stay in the hospital a week, though. Mine was not an easy case,” Bill said. “For my spine, walking was the best therapy. But for my permanent knee, ankle, and foot problems, walking was the worst thing for me. I took longer than normal to recover, but what is normal in a surgery like this? Nothing has been easy or straight.”

“Slowly things got better, and I began to do things again I hadn’t been able to do in years, like put on my own shoes and socks and bend over and pet the dogs. But it was right around the seven-month mark when I turned the corner and found freedom again, pedaling my bike with no limitations. Riding on the open road, the wind and the sun in my face — that was the greatest outcome in the world for me,” Bill said with a smile.

Basketball legend Bill Walton has a message for anyone contemplating spine surgery: “I had lost everything. I had a life that was not worth living. But thanks to the precisely skilled mind, hands, and soul of Dr. Garfin, now I’m eternally grateful to be back in the game of life. And my life will never be the same again. There is nothing left to do but smile, smile, smile.”

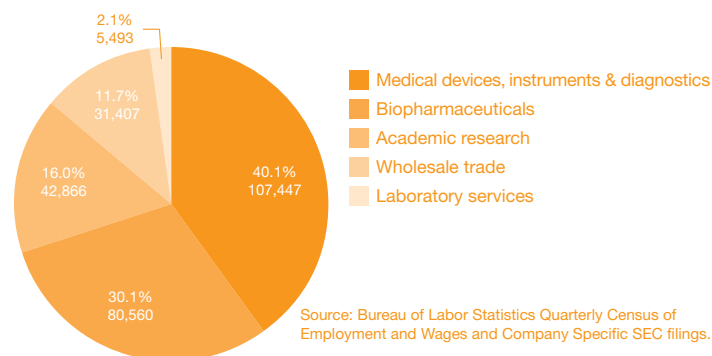
Employment

In 2009, nearly 268,000 Californians were employed directly by the biomedical industry, most of them within the state’s key biomedical “clusters” (Figure 1). These communities have grown up around academic research centers, most notably the University of California (UC) campuses in San Francisco, San Diego, Los Angeles and Orange County. San Diego’s Salk Institute, The Scripps Research Institute and Sanford-Burnham Medical Research Institution also have been magnets, drawing brilliant minds to build world-class laboratories and spinning out new companies to commercialize their inventions.

Historically, the largest concentration of industry-related jobs has been in the San Francisco Bay Area, and this remained true in 2009. Companies and academia there employed nearly 52,000 people. Los Angeles County companies and institutes employed nearly 44,000 people, while Orange County reported nearly 28,000 biomedical industry jobs. San Diego County rounded out the top four clusters with more than 24,000 industry positions.

Broken down by sector, the overall biomedical employment in the state included more than 107,000 people in the medical devices, instruments and diagnostics sectors — for about 40 percent of the overall total jobs. Biopharmaceutical companies employed the next largest segment with just under 81,000 jobs or approximately 30 percent of the total. The state’s academic research centers employed nearly 43,000 people in life sciences positions for approximately 16 percent of the total. Wholesale trade accounted for more than 31,000 personnel or about 12 percent of the state’s biomedical employees. The remaining 5,500 employees, or just over 2 percent, worked in the laboratory services sector.

Figure 1: California biomedical employment by sector



Not only has the California biomedical industry sustained most of its jobs, it continues to compensate employees well. In 2009, life sciences employees earned a total of \$19.4 billion. The average annual wage for the industry across the state in 2009 was \$72,000, down slightly from \$75,000 in 2007 and 2008.

Compensation varies among the industry’s sectors. At an average of \$100,000 in 2009 — a decrease of approximately \$9,000 or 8.3 percent from 2008 and 2007 — biopharmaceutical companies still paid the industry’s highest average annual wages. Wholesale trade came in second with average annual wages of about \$80,000, unchanged from 2008 but down nearly 6 percent from 2007 levels. Laboratory services, academic research, and medical device organizations’ salaries remained steady in the mid- to high-\$50,000 range.

Adding together the indirect and collateral impact of the biomedical industry on the state, total labor income for 2009 was estimated to be \$69 billion. Moreover, the value added — the additional value created through employee compensation, proprietors’ income, income to capital owners from property and indirect business.

Figure 2: Change in California biomedical employment by sector (March 2008 to March 2009 and March 2009 to March 2010)

Sector	March 2008 to March 2009	March 2009 to March 2010
Academic research	173	-546
Biopharmaceuticals	252	802
Laboratory services	4	840
Medical devices, instruments & diagnostics	-2,216	-1,790
Wholesale trade	-739	-303

Investment

It takes many millions, and sometimes billions, of dollars to build and operate a biomedical company. Beyond the capital-intensive need for specialized equipment and highly trained staff, the expense of meeting the FDA's regulatory requirements is unique to biomedical products.

At the same time, biomedical companies are high-risk ventures. Only a small percentage of products ever recoup their investments. Investors, especially in a struggling economy, have stringent guidelines for backing potential products and their developers. Potential licensees or acquirers — the industry's large pharmaceutical companies and major medical device manufacturers — are equally discerning.

Figure 3: Percent of total U.S. venture capital to California firms and, by percentage, to biotechnology and medical device companies

	2009	2010*
U.S. venture capital investments (\$M)	\$17,680	\$16,689
Percentage of VC in California	50%	50%
Percentage of CA VC in biotechnology	16%	14%
Percentage of CA VC in medical devices	13%	12%

Venture capital

Venture capital continues to drive many of the country's innovative new companies. All told, venture capital investments in the United States totaled \$17.7 billion in 2009 (Figure 3). That total was decreased from \$28.1 billion in 2008. In the first three quarters of 2010, VC investments had reached \$16.7 billion, leading to expectations that 2010 would be on par with the 2009 levels. In all three years, half of the national total was put to work by California companies — a rate that has remained stable for the past decade.

Life sciences companies took the largest share of California's VC investments in 2009 and through the first nine months of 2010 (Figure 4). The state's biotechnology, medical devices and diagnostics sectors secured approximately \$2.6 billion in VC investments in 2009 and an additional \$2.2 billion in the first three quarters of 2010.

Figure 4: Top five industries in California by VC investment

Industry	2009	2010*
Life sciences	\$2,597,945,600	\$2,175,036,800
Industrial/energy	\$1,213,303,800	\$1,610,018,400
Software	\$1,665,063,100	\$1,490,932,000
Semi-conductors	\$645,477,100	\$719,859,100
IT services	\$492,269,900	\$561,767,900

Source: PricewaterhouseCoopers/National Venture Capital Association MoneyTree Report based on data from Thomson Reuters.
* Includes data through 3rd quarter of 2010.

Patient profiles

John Grigsby: Breakthrough heart valve benefits patient in clinical trial

In January 2010, Grigsby was hospitalized again with severe aortic stenosis, a dangerous narrowing of the aortic valve in the heart. The condition is debilitating and frequently deadly. In the hospital, Grigsby got an unexpected yet timely visit from Dr. Craig Miller, professor of cardiothoracic surgery at Stanford.

“He came to El Camino Hospital on his own time,” said Grigsby, who fit a stringent set of inclusion criteria for a clinical trial for which Miller was an investigator. “He explained that my aortic valve was about the size of a pencil eraser,” Grigsby said, “when it should have been one inch in diameter.” Because of Grigsby’s age and health, another open heart procedure was out of the question. “He [Miller] told me I had two to six months’ life expectancy,” Grigsby said. “Then he told me about the clinical trial.”

The trial was set up to demonstrate the efficacy of an experimental treatment for older, high-risk patients like Grigsby. The device, designed and manufactured by Edwards Lifesciences Corp., of Irvine, is made of cow tissue and sits inside a metal frame. The device is crimped onto a balloon catheter, which Miller would thread through the femoral artery to Grigsby’s heart. After positioning the artificial valve inside the old valve, Miller would use the balloon to open it up.

“It was a no-brainer,” said Grigsby about enrolling in the trial. As a retired engineer, Grigsby also appreciated the contribution his participation could make toward proving — and perhaps improving — an experimental medical device.

The device, called the Edwards SAPIEN Transcatheter Heart Valve, has been marketed in Europe since 2007, and Edwards is working toward FDA approval in the United States.

The company anticipates that the valve could be introduced to the U.S. market in 2011.

Grigsby said he underwent the hour-long procedure on January 12, 2010, a Tuesday, and was walking around that evening. He said he experienced no pain and went home the following Saturday.

“Everything has worked fine,” said Grigsby, who walks a mile to a mile and a half three days a week and works out at the gym on alternate days. “I had check-ups at one month and six months, and they told me to come back in a year” for the next exam.

Grigsby said, “I don’t have the strength that I’d like to have, but I credit that to the hospital stays” in 2010, sedentary spells that cost muscle mass and stamina. “But just sitting and talking, I’d never know I’d had a problem,” he added.

“There is no question that without it, I’d be a dead man.” Instead, he’s working to help his grandson win a bet: The youngster is betting that Grigsby will live to be 102.

CHI-California Healthcare Institute

CHI-California Healthcare Institute is a non-profit public policy research organization for California’s biomedical R&D industry. CHI represents more than 275 leading medical device, biotechnology, diagnostics and pharmaceutical companies and public and private academic biomedical research organizations. CHI’s mission is to advance responsible public policies that foster medical innovation and promote scientific discovery. CHI’s website is www.chi.org. Follow us on Twitter @calhealthcare and Facebook.

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