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## New companies cash in on medical innovations

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CLEVELAND - Laszlo Nagy can breathe easier because of the work of inventors who turned a high-tech innovation into a healing aid targeted for wider use by a startup company.

Nagy, 41, crippled and breathing with a ventilator after a motorcycle crash, was able to resume his stockbroker career with the help of a diaphragm assist device developed by University Hospitals Case Medical Center and Case Western Reserve University.

The promising device was the brainchild of the startup Synapse Biomedical Inc. as Case ramped up efforts to capitalize on medical innovations. Case spawned just two startups in 2002 but four in each year since.

Across the country, there has been a similar surge in new companies created by hospitals and universities to market medical devices, techniques and drugs.

"It can be out and sold worldwide in a matter of a few years," said Christopher Coburn, executive director of the Cleveland Clinic's spinoff arm, CCF Innovations. The operation began in 2000 and has 18 spinoffs since 2003.

The tech-transfer trade group Association of University Technology Managers said the number of spinoffs at academic institutions rose from 494 in 2001 to 628 in 2005, a 27 percent increase. The 10-year increase was 181 percent, with many innovations in the biomedical field.

The traditional outlet for new campus inventions has been licensing, which involves turning over manufacturing and sales to an established company, usually one with a track record for developing a product brand.

The faster industry pace hasn't come without problems. There have been increasing calls for closer government oversight so patients know what they are getting and disclosure of ethical conflicts when doctors pitch their new medical device or drug ideas.

The best-known byproducts of academic research on the medical side include the cochlear inner ear implant - which can provide a sense of sound to the deaf - and the stop-smoking nicotine patch. Emerging ideas that may have a bright future include an easier way to diagnose irregular heartbeats and to speed up biopsy results.

Industrywide figures, often confidential, are elusive but the profits from spinoffs can be important, especially for hospitals facing reduced patient-care reimbursements and state universities constrained by declining subsidies and tuition issues.

The clinic gets about \$6 million a year in CCF Innovations royalties, according to Dr. Delos M. "Toby" Cosgrove, clinic CEO and inventor of 30 patented ideas. Northwestern University's licensing income surged from \$1.5 million in 2004 to \$30 million last year, with five startups in 2006, up from four in 2004.

Spinoff profits typically are split between the institution, inventor and the inventor's department, fueling further innovations.

How the startup ownership is divided often is governed by the institution's tech transfer rules and the inventor's negotiating skill, according to Indrani Mukharji, tech transfer executive director at Northwestern.

Factors on whether an invention leads to a spinoff or licensing are "all over the map" and typically include whether the inventor is determined to get the item to market and the level of investor interest, Mukharji said.

One barrier to selling innovations developed on campus can be faculty distrust of business and the marketplace, according to Mark E. Coticchia, vice president of research and technology management at Case.

Coticchia said one-third of his job is to convince professors that their work will get wider acceptance if sent to the marketplace. He cited as an example a professor who simply wanted to post his discovery on the Internet and let knowledge take its course, without regard to royalties or marketing.

The quicker pace of developing new drugs and medical devices and the spinoffs they engender hasn't been without problems. Cleveland Clinic cardiologist Dr. Steven E. Nissen has warned Congress that questions about drug and device safety have led to patient skepticism.

"Unfortunately, patients are increasingly suspicious of new therapies and sometimes are reluctant to accept potentially lifesaving medications or devices," he said in an appeal for stricter Food and Drug Administration oversight. Nissen said doctors don't always get prompt information about possible safety problems with new drugs.

Often ethics issues involve money and self-interest. Last year the clinic fired a noted cardiologist for failing to disclose royalties from a stroke-preventing device that he invented and pitched to fellow physicians.

The Council on Governmental Relations, representing research universities, said ethical conflicts are likely to arise with startups and should be handled with disclosure and ethics oversight.