

BEN WIRTZ SIEGEL



## THE COMMERCIALIZATION OF DISCOVERY: Taking the conflict out of technology transfer

by ELLEN SPIVAK WITH MELISSA EVANS

Beneficial new treatments and research from Case Western Reserve University School of Medicine make a world of difference to health care providers, business interests, and a watchful public. Through integration of technology transfer, research administration, and conflict-of-interest management, the University works to maintain an untainted balance between

commercializing its discoveries and maintaining its academic integrity.

The School of Medicine plays an essential and multifaceted role in the reformation of Northeast Ohio into a medical and biotechnological powerhouse. The School attracts and retains world-class faculty, researchers, and students, who collaborate with physicians at the forefront of clinical

care. Patients from around the world visit School of Medicine faculty members for treatment and participation in potentially life-saving clinical trials.

Facilitated by a powerful technology transfer process, the School's most groundbreaking discoveries are reaching a growing audience and are resulting in transformative health care benefits.

> Illustrations are examples of noninvasive electrocardiographic imaging (ECGI), including epicardial potentials, arranged in an Andy Warhol-like grid painting.

## >> FUELING INNOVATION

The growth of research enterprise has its roots in the 1980 Bayh-Dole Act, which enabled universities to retain ownership of intellectual property developed under federally funded research programs. This created the incentive for Case Western Reserve and its affiliates to protect innovations through patents and licensing, and ultimately created the motive to partner with commercial enterprises.

“Advancing science takes precedence over profit for School of Medicine researchers,” says Joe Jankowski, Ph.D., associate vice president for technology management in the University’s Technology Transfer Office. “Reduced federal funding of research opened doors to private investment as researchers were motivated to see their innovative work continue.”

Medical advances developed at the School of Medicine have fueled 24 start-up companies and spawned 120 biomedical deals, such as licenses and patents — injecting nearly \$200 million in new equity into the region’s economy. This is a large proportion of the growing investment seen across the University and the region, and it only represents a small portion of the School’s potential.

“To date only a very small percentage of the work of medical researchers is ever commercialized, and technology transfer is usually not a profitable venture,” Dr. Jankowski says. “However, our technology transfer efforts have been profitable for the last seven years — a rare record of financial and entrepreneurial success.” And the School’s knowledge base continues to grow, as shown by the volume and magnitude of health-related research presentations at Case Western Reserve’s annual spring Research ShowCASE that have a prospective commercial aspect.

## >> INSTITUTIONALIZING TRANSPARENCY

“Technology transfer conveys a tremendous amount of knowledge to use for the greater good,” says Michael Edwards, associate vice president for research administration at Case Western Reserve.

University officials recognize that exposure of research, scholarship, and other innovative endeavors to outside interests is beneficial to society and enhances the institution’s prestige and reputation.

As such, the University provides necessary support to ensure its continued success in technology transfer and seeks to accomplish its commercialization goals while fully preserving the honorable mission of the institution and its individual members.

Meeting the need to balance academic integrity with the need to bring benefit to society, Case Western Reserve implements a unique process that integrates conflict-of-interest management with support for innovation and collaboration among the University and its affiliates.

“Managing conflict is a hot topic now, fueled by a general interest in greater transparency,” Mr. Edwards says. “It could be said that technology transfer itself creates conflicts of interest — but managing those conflicts appropriately, which is what we all strive to do, accrues

value to all stakeholders. Not disclosing conflicts, even inadvertently, or being perceived as not disclosing conflicts, can be costly not only in terms of reputation, which is of paramount importance to our medical researchers, but also through fines levied by regulatory agencies, expenses deployed to remedy mistakes, and lost opportunity.”

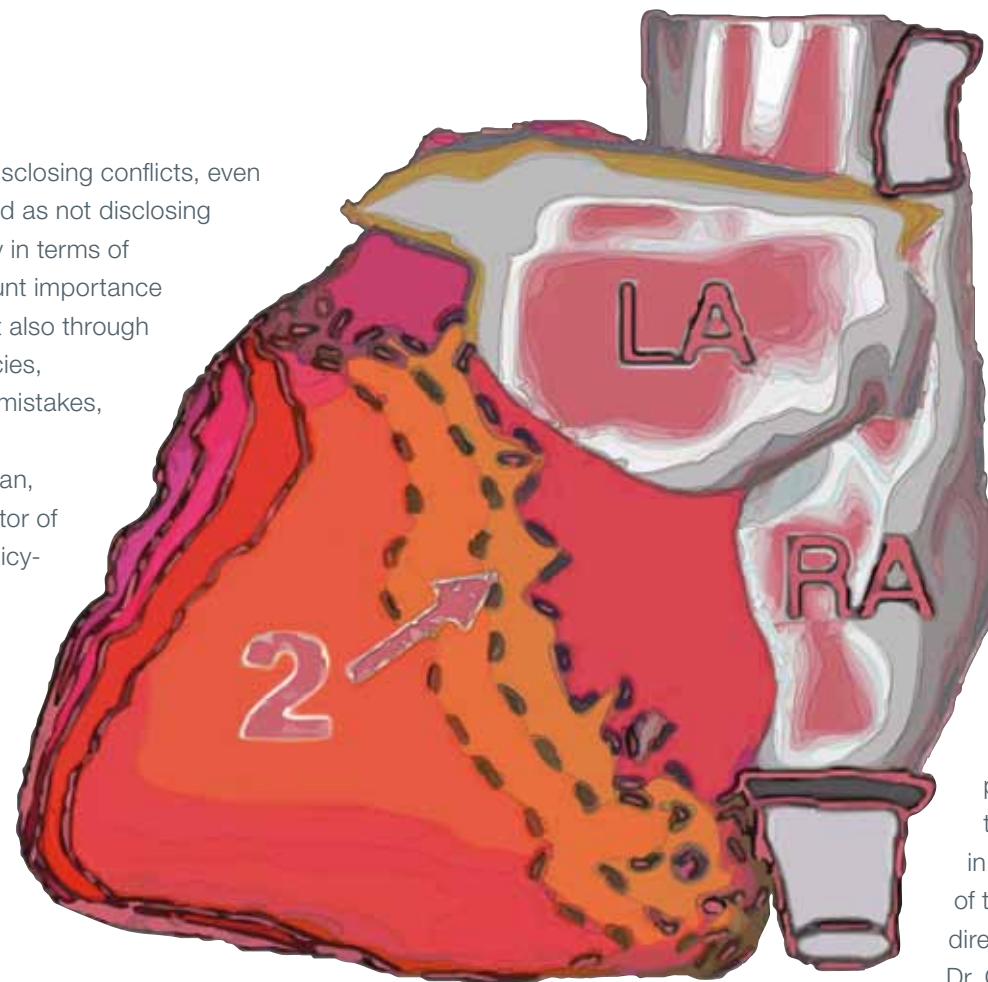
Guided by Maxwell J. Mehlman, J.D., professor of law and director of the Law-Medicine Center, a policy-drafting group, in collaboration with constituencies across the University, recently revised Case Western Reserve’s conflict-of-interest policy. The 2009 policy — approved by the faculty senate and the board of trustees — facilitates greater transparency and addresses institutional conflicts of interest.

Mr. Edwards is chair of the Outside Interests Committee, formerly the Conflicts of Interests Committee, whose members are appointed by and report to President Barbara R. Snyder. Committee members include research officials from across the University, as well as an institutional review board representative from each of Case Western Reserve’s affiliate medical centers: University Hospitals, MetroHealth Medical Center, Cleveland Clinic, and Louis Stokes Cleveland VA Medical Center. Members of the committee review financial interest reports from faculty and investigators and address their related concerns; participate in national dialogue on conflict-of-interest issues; and educate the University community regarding outside-interest issues. Collaboratively, they develop, help to implement, and monitor management plans that address individual or institutional conflicts of interest, providing expert advice and ideas for conflict management.

## >> EMBRACING CONFLICT

Jeffrey Duerk, Ph.D., is chair of the Department of Biomedical Engineering, director of the Case Center for Imaging Research, and a member of the Outside Interests Committee. He and his business partner, Jonathan Lewin, M.D., founded Interventional Imaging Inc. (I3MRI), a development-stage medical device company created in the Department of Radiology at University Hospitals.

He says embracing one’s conflicts of interest and finding solutions to manage dual responsibilities is key to successful, ethical conflict-of-interest management. “My conflict relating to I3MRI is that I am a founder and on the board, while my lab continues to be involved in independent and corporate-sponsored research,” Dr. Duerk explains. “Management of the conflict involves a plan to assure full disclosure of



how I divide my time and maintain my scientific integrity.”

Dr. Duerk believes that part of his role as a professor is to help the next generation of inventors understand conflicts of interest. “In teaching, we have an opportunity to involve students in business-related issues, and they are intrigued to learn about consulting, or patent preparation, or to speak with CEOs,” he says, “but it is important that they understand dual roles and potential conflicts.”

Mahmoud A. Ghannoum, Ph.D., E.M.B.A., is another entrepreneur who emerged in the business world in part because of Case Western Reserve’s technology transfer process. A professor in the Department of Dermatology, director of the Center for Medical Mycology, and co-director of the Skin Diseases Research Center, Dr. Ghannoum is also a founder of Great Lakes Pharmaceuticals and is its chief scientific officer.

His company focuses on research and development of products for prevention of microbial infections. “I was doing clinical translational research and discovered a way to inhibit catheter-related infections. I had no thought to commercial interests, but Joe Jankowski saw the potential, and we started to work together, which resulted in the formation of the company,” Dr. Ghannoum says. “Of course, now there is a conflict of interest among my various roles, but disclosure and a comprehensive plan to manage the conflict resolves it. I feel strongly that scientific data keeps me objective. The data is the data, and I don’t worry about anything else.”

Dr. Ghannoum challenges his colleagues to keep their reporting updated and to “disclose, disclose, disclose.”

Dr. Duerk says it is the responsibility of today’s researchers to remain open to opportunities to bring transformational products into commercial development, where they can ultimately provide the most benefit to the most people.

“If faculty have conflicts it’s a way to validate that others find what they are doing useful,” he says. “We have a responsibility to the community to make our research and technology available.”

## >> TAKING IT PUBLIC

The Office of Outside Interests, which is directed by Maureen Landies, Ph.D., works with faculty and staff to develop appropriate management plans early in a project and to be compliant in reporting.

“We currently have about 80 management plans in place, highly individualized to the specific situation, and guided by a balanced approach to managing, reducing, or eliminating conflict,” she says.

Dr. Landies says the office educates the University community regarding outside interests and conflicts of interest, and provides assistance for faculty, staff, and researchers. “We also assist investigators in understanding guidelines of the Association of American Medical Colleges, the Association of American Universities, and the requirements of regulatory agencies, such as the National Institutes of Health or the Food and Drug Administration, as it pertains to their research,” she says, adding that the office helps researchers get their projects started off on the right foot by addressing conflicts of interest from the start. The office can also serve as an entry point to the technology transfer process.

Organizations outside Case Western Reserve, such as the Northeast Ohio Technology Coalition (NorTech) and BioEnterprise, play a critical role in bringing the University’s discoveries to the public. NorTech leads an economic agenda to link and leverage the region’s technology, entrepreneurship, and innovation assets. BioEnterprise is a business formation, recruitment, and acceleration initiative designed to grow health care companies and commercialize bioscience technologies. BioEnterprise’s founders and partners include Case Western Reserve and its affiliated medical centers, and it works in close collaboration with the Office of Technology Transfer.

Baiju Shah, J.D., is president, CEO, and a founder of BioEnterprise. He cites an annual investment of nearly \$500 million in research and \$160 million of equity investments in the community among the major medical institutions, all of which are connected through the School of Medicine. Those dollars alone have an economic impact on multiple levels: affecting the individuals who conduct the research, the clinicians who bring it to the patients, and the individuals who come to School of Medicine-affiliated hospitals for treatment. And the reach extends even further.

“On a larger scale, there is the additional consideration of the economic impact of the investment dollars that fund the development of companies and their products that are selling around the world,” he says.

## >> DRIVING GROWTH

Today, health care in Northeast Ohio is the dominant industry and the principal economic force for the region by all measures. It employs nearly one-quarter million people and is helping the region define a new global identity. Cleveland is now known as one of the centers of health care innovation around the world, driven by the research base at Case Western Reserve.

The School of Medicine’s legacy of excellence in research is well-documented. The institution’s professional reputation in translational research allows it to transfer discoveries into commercial enterprise. Its interface with outside interests is resulting in a growing confidence by developing companies and investors who recognize that, driven by a successful technology transfer process, School of Medicine researchers will continue to gain the confidence of watchful accrediting bodies, legislators, and the public.