The technology management industry continues to produce results:

- Patents up 11.3%
- Licensing agreements up 4.5%
- University discovery-based businesses up 12%
- Net product sales up 27.2%

Highlights* of AUTM's *U.S. Licensing Activity Survey
FY2014

AUTM®

Association of University Technology Managers®
Advancing Discoveries for a Better World®

A helmet-to-helmet collision …

… gave Frontier High School football player Cody Lehe a headache so severe that he asked his mom to take him to see a doctor. But the CT scan showed no damage, and his doctors gave him a "clear to play" report. The next day, Cody took a simple shoulder hit during the Falcons' practice on their Brookston, Indiana, field. By itself, this occurrence would have been routine. But coupled with the undetected concussion from the day before, Cody experienced second impact syndrome (SIS). Now, nearly a decade after the 2006 events, he can barely remember things that occurred earlier in the day, and he cannot walk on his own.

Over the past few years, media coverage of the devastating after-effects of traumatic brain injury (TBI) has grown from a trickle to a flood. Along with rising recognition of the long-term suffering created by severe TBIs, researchers have turned their attention to the more subtle damage caused by mild-to-moderate TBIs, which many health professionals believe go undiagnosed and untreated at a rate of as much as 50 percent. And because those who suffer even a mild TBI incident are at risk for moderate-to-severe disability a year after their injury, this lack of diagnosis and treatment is placing untold numbers of people at risk of ongoing symptomatology that has no apparent explanation.

Even more alarming, undiagnosed concussion victims often resume dangerous activity. Anyone who experiences a second blow to the head while recovering from an initial concussion—like Cody—is at risk of SIS, which has led to approximately 30 to 40 deaths over the past decade and left uncounted others to endure a lifetime of mental and physical impairment.

Against this backdrop, researchers at the University of California, Los Angeles (UCLA) have achieved a breakthrough in TBI diagnostic technology: a transcranial Doppler imaging device that accurately analyzes metabolic damage caused by concussion. And through their partnership with Neural Analytics—a company formed by UCLA faculty and alumni with the help of the UCLA Office of Intellectual Property & Industry Sponsored Research—the problem of "Is it a concussion or not?" is about to become one of those "Remember when" memories that medical practitioners will be glad to forget.

BACKGROUND

The challenge of quantifying tech transfer

The story of Cody Lehe and the recent breakthroughs by Neural Analytics to diagnose traumatic brain injury and curtail the calamitous effects of second impact syndrome is one example of how tech transfer practices by universities and other nonprofit entities facilitate work at microscopic and macroscopic levels to improve the human condition. Simultaneously, academic tech transfer powers the innovation economy, creating jobs, improving productivity and offering solutions to environmental challenges. Although tech transfer is a complex and time-intensive process, its ultimate value is simply that it makes the world a better place.

For more than 24 years, the Association of University Technology Managers (AUTM) has implemented its annual *Licensing Activity Survey* to play a key role in advancing and highlighting the public value of technology transfer, including the ongoing benefits of the 1980 Bayh-Dole Act, which was dubbed "innovation's golden goose" by *The Economist*.[1] AUTM's education, advocacy and industry engagement activities provide substantial support to its members and other technology transfer professionals around the world, and the organization actively supports legislation that preserves the spirit of Bayh-Dole and the continued protection of key intellectual property rights.

Every year since 1991, AUTM has conducted the *Licensing Activity Survey* to collect, synthesize and disseminate academic technology transfer data, both as a resource to the industry and in demonstration of its value to our economy and standard of life.

AUTM's survey data continue to show impressive gains in several essential categories, including a continuing increase in university technology startups launched and an overall impact on the economy.

The numbers reported in these *Highlights* are drawn from the FY2014 survey and reflect the activity of those U.S. institutions reporting (191 responses out of 302 recipients) and therefore do not represent the entirety of tech transfer results in 2014. They do, however, provide strong indicators of the major role tech transfer plays in transforming our society and our economy.

These AUTM *U.S. Licensing Activity Survey* FY2014 *Highlights*—an overview of the complete fiscal year 2014 report—offer a glimpse into the tech transfer field's current state. (The comprehensive AUTM *U.S. Licensing Activity Survey* FY2014 report will be published later this year.) Alongside the statistics—and perhaps even overshadowing them—these *Highlights* also offer stories that illustrate the larger impact of technology transfer as measured by products that improve our individual and collective quality of life and increase the competitiveness and productivity of our global society.

This year's *Highlights* show that—even while federal research funding continues to decline—academic licensing and startup activity are nonetheless growing substantially and continue to play an important role in the economy. However, because federal research funding continues to be the primary fuel for innovation ecosystems throughout the United States, the declining levels are a paramount threat to the advancement of research, technology transfer and global economic viability.

When our annual AUTM survey results come out, we need to ask, 'What is behind these numbers?' The answer, put simply, is *a lot of good news*.

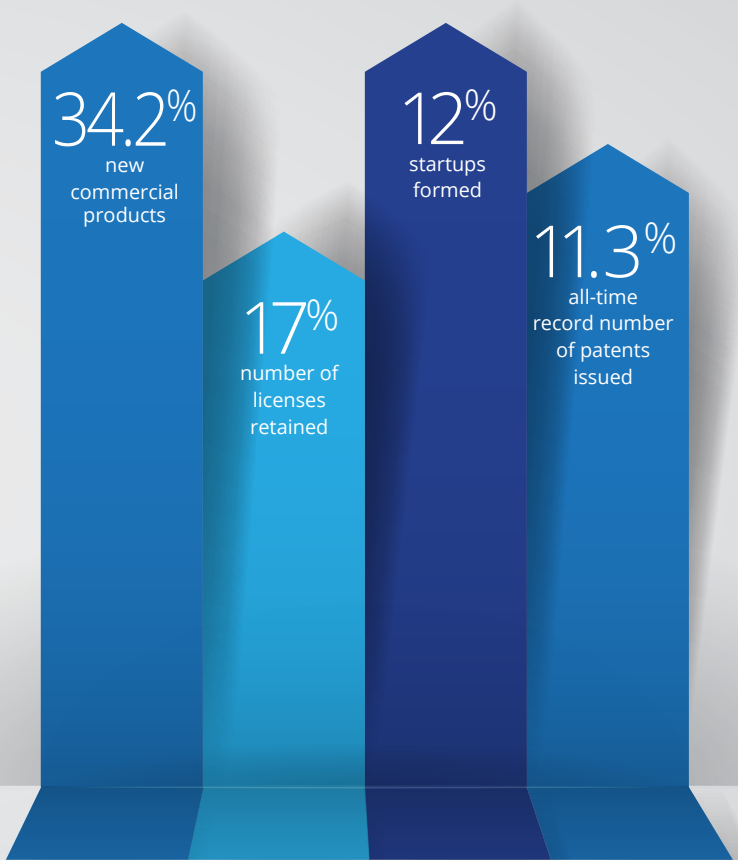
—*AUTM President* Fred Reinhart

[1] *The Economist*, Technology Quarterly: Innovation's golden goose. December 12, 2002: www.economist.com/node/1476653

Remarkable gains

The 2014 survey reveals impressive year-to-year gains in the number of startups formed (12 percent increase); the number of licenses with equity retained by AUTM member institutions (up 17 percent); and the economic impact of tech transfer activities, as evidenced by metrics such as net product sales (up 27.2 percent), the number of new commercial products (up 34.2 percent) and the all-time record number of new U.S. patents issued (an 11.3 percent increase over the record set in 2013).

Academic-based research generates a significant return on investment for local, national and global economies. In addition to jobs created by startup companies, product sales for companies and the evolution of new industries, academic-based research creates jobs directly through the hiring of principal investigators, research teams, lab technicians and others whose work supports the research. Indirectly, research creates jobs through innovations leading to new technologies, new companies and new industries.



It's worth noting that these remarkable gains in 2014 coincided with a 5 percent decline in federal research dollars reported in the survey, part of a continuing downward trend, and it appears the decline hasn't hit bottom. Coupled with essentially the same level of industry support of academic research as in 2013, this trend puts at risk the historic benefits that AUTM and the technology transfer industry overall have worked to achieve.

A study by the American Association for the Advancement of Science found that, at the current rate of disinvestment, overall federal research and development funding could be reduced by $57.5 billion or 8.4 percent by 2017. Research grants funded by the National Institutes of Health (NIH) have declined every year since 2004.

In the face of this growing challenge, research institutions are pursuing additional means to combat the decreased investment in research by finding alternative operational revenue sources. One method being pursued by technology transfer professionals lies in retaining equity in the companies that license the institutions' technology. In 2014, the number of licenses executed that included equity acquired by the research institution was up 17 percent, from 469 in 2013 to 549.

$62.8 billion

total research expenditures ▼3.6%

$37.9 billion

federally funded research expenditures ▼5%

$4.61 billion

industry-sponsored research expenditures ▲1%

John Ritter, vice president of Metrics & Surveys for AUTM and director of the Office of Technology Licensing at Princeton University, notes that despite the lagging funding from the government, the tech transfer sector has continued to rack up impressive gains in several key measures.

"We're encouraged about the continued growth in the number of new startups, total product sales of licensed technologies, and the number of U.S. patents issued in the past year," Ritter says. "Despite the economic uncertainty of the past few years, our membership has maintained an extraordinary level of commitment that has paid off in new commercial products and an increasing number of new businesses."

The AUTM Better World Project, launched in 2006 with the publication of the first Better World Report, showcases many of the discoveries that have led to these new products and businesses. With this initiative, AUTM's members tell their stories about the many ways that research discoveries and new technologies are building a better world. Over the years, more than 500 of these stories have been published.

More recently, AUTM has expanded the Better World Project to illustrate the benefits of tech transfer through videos that directly reflect the results of the commercialization of discoveries. The Put A Face On It videos showcase examples of real people impacted by technology advancements that help them lead healthier, safer and more fulfilling lives.

One facet of AUTM's work includes collaborating with AUTM members, who are on the front lines, to learn of successful products arising from campus labs and progressing into the marketplace. Survey data show there are close to 10,000 patented products currently being sold that originated in academic research laboratories.

Case study: REMICADE®

These products include blockbusters such as anti-inflammatory drug REMICADE®, an artificial monoclonal antibody developed by a pair of New York University (NYU) researchers to treat a wide range of autoimmune diseases, including Crohn's disease, rheumatoid and psoriatic arthritis, ulcerative colitis and ankylosing spondylitis. The NYU discovery was commercialized by Janssen Biotech.

For people like Sara Ringer, age 33, REMICADE has been a life-changer. Sara's life had been defined by Crohn's since she was 10 months old, but it was not until 2011 that doctors accurately diagnosed her condition. Crohn's disease belongs to the group of conditions of the gastrointestinal tract known as inflammatory bowel disease (IBD). After years of incorrect diagnoses, chronic pain, internal bleeding, bathroom accidents, severe weight loss, multiple and prolonged hospitalizations, medications (including steroids), emergency surgeries (including the removal of her large intestine), transfusions, intravenous feeding—not to mention the extreme challenges of trying to be normal through high school and college—Sara now undergoes regular REMICADE infusions (the prescribed protocol), along with methotrexate injections and a regimen of vitamins, supplements and strict nutrition, to bring her once-incapacitating symptoms under control. Now she has a blossoming career in the beauty industry and is an outspoken IBD activist, complete with blog, videos, counseling and motivational speaking engagements to help others cope with this debilitating ailment.

The Crohn's & Colitis Foundation of America (CCFA) reports that as many as 700,000 in the United States may be affected by Crohn's disease, which can occur at any age, affecting both males and females, but it is more prevalent among adolescents and young adults between ages 15 and 35.[2]

REMICADE, already used to treat more than 1.3 million people worldwide, works to reduce symptoms of Crohn's in both adult and teen patients who haven't responded well to other treatments, as well as to induce and maintain remission.

[2]Crohn's & Colitis Foundation of America: What is Crohn's disease? *CCFA.org.* www.ccfa.org/what-are-crohns-and-colitis/what-is-crohns-disease

Growth in critical partnerships

Technology transfer offices play an indispensable role in facilitating one of the most critical components of a robust innovation ecosystem: strong collaborations between academia and industry. When a license agreement is signed, it marks the beginning of a long-term relationship between a research institution and its industry partner.

Data derived from the FY2014 survey reflect healthy increases in partnership metrics. Highlights of the 2014 data show:

5,435
licenses executed
▲4.5%

1,461
options executed
▲7.7%

549
executed licenses containing equity
▲17%

Case study: **Aes-103**

Donald Abraham, professor of medicinal chemistry and director of the Institute for Structural Biology and Drug Discovery at Virginia Commonwealth University (VCU) from 1988 to 2007, has brought a singular focus to one specific problem throughout his work, even as a chorus of well-meaning colleagues told him he was throwing away his career.

"I threw everything, my whole heart and science into sickle cell disease (SCD)," Abraham says. "Ever since my postdoctoral days in 1963, my great desire was to use structural biology to discover a drug."

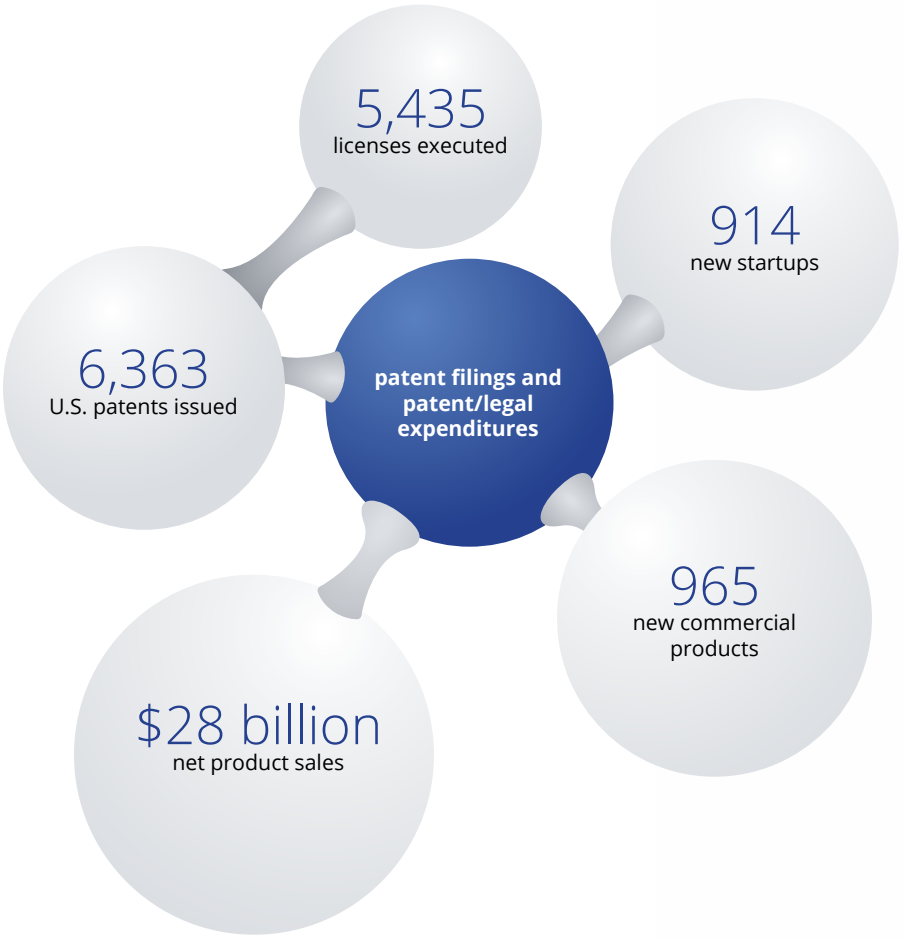
Because SCD afflicts fewer than 100,000 in the United States (and millions more worldwide, largely in less-developed nations), Abraham's pursuit of this "orphan" disease faced a severe hurdle—limited funding opportunities. But he felt structural biology could pinpoint the specific molecule that could prevent the sickle cells from forming. By 2002, his team had found the molecule, and by 2009 they were ready to partner with Massachusetts-based startup AesRx, with support from the National Heart, Lung, and Blood Institute and the Therapeutics for Rare and Neglected Diseases (TRND) program. TRND is part of the National Institutes of Health's National Center for Advancing Translational Sciences and assisted in developing a multiphase, multiinstitute, public-private research collaboration to drive the discovery, called Aes-103, to market. AesRx was acquired in 2014 by Baxter International.

With the Phase II and III trials still ahead, Abraham and his team are optimistic that his long-held dream of bringing relief to sickle cell patients will become reality.

MISSION

From the lab bench to the marketplace

Academic research characteristically emphasizes the timely dissemination of research findings and the education of the next generation of research scientists and engineers. Alongside that mission, a frequent outcome of academic research is intellectual property that demonstrates commercial promise. To encourage investment in technology that might otherwise lay dormant, research institutions file patents on these disclosures and enter into license agreements with businesses anxious to bring those ideas to market.



For the industries dependent on innovative intellectual property—and which comprise a significant portion of the U.S. economy—patents and licenses are the point of connection with universities actively pursuing marketplace development. Patents and licenses provide a reliable foundation that justifies a company's substantial investment in resources and time—five to 10 years or more—to develop the technology into commercially viable products.

Activities related to academic intellectual property management increased in FY2014, with data showing a rise in the expenses to academia for intellectual property protection.

Collaborations between academia and industry represent a rapidly expanding segment of our national economic health. The 2014 survey data describe continued strength in these key lab-to-market metrics.

Predicting sinkholes before they occur
Case study: **FutureScan**

How do you predict a catastrophic sinkhole event? How do you "look" underground to assess risks without costly and destructive excavation?

For Dr. Erez Allouche, of Louisiana Tech University, the solution was ground-penetrating radar that uses ultrawide band (UWB) radio waves to provide a virtual picture of actual underground conditions and detect pipe defects and, more importantly, the soil voids that signal high risk for sinkholes.

With support from the National Institute of Science and Technology (NIST), the State of Louisiana and the National Science Foundation, Dr. Allouche and his team developed the FutureScan radar device. Now, thanks to a partnership with Orlando-based CUES, Inc., FutureScan is a commercially available tool housed in a casing the size of a smartphone box that can analyze any nonmetallic type of pipe and detect soil voids and other anomalies.

Winning the race against AMR infections
Case study: **CSAs**

The emergence of antimicrobial drugs early in the last century birthed a miracle age in healthcare, with many deadly infections and diseases almost entirely eliminated. But overuse and misuse of these drugs has led to a resurgence of many of these infections, which over time adapted strong antimicrobial resistance. Antimicrobial-resistant (AMR) infections have emerged as one of the greatest threats to global health. Scores of researchers, including Paul Savage of Brigham Young University (BYU), have made the search for new treatments for AMR infections their life's work.

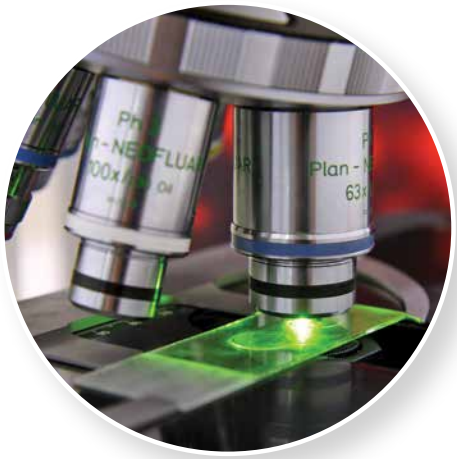
"The National Institutes of Health offered biotech training when I was a Ph.D. student in organic chemistry," says Savage, a professor of chemistry and biochemistry. "I was exposed to bacterial processes that I began to understand at a chemical level."

So he began to focus on antimicrobial peptides (AMPs), naturally occurring amino acids that are often the body's first defense against infection. Finally, Savage realized that a synthetic AMP could be both less expensive and more effective.

That insight, along with years of hard work and support from the BYU Technology Transfer Office, led Savage and his team to develop a new class of antimicrobial agent, cationic selective antimicrobials (CSAs). And they were right—CSAs were both cheaper and more effective against the infections. But even better: CSAs could also prevent biofilm colonies of infectious agents from forming on surfaces like catheters and tubing, which have been identified as a high-risk nexus for introducing infections into patients.

Licensed to CSA BioTech, and fully approved for veterinary use, this breakthrough technology is headed for human health applications in Latin America, Europe and, eventually, the United States.

Collaborating to defeat a deadly bacterium
Case study: **Neutralizing a killer**



Pseudomonas aeruginosa (Pa) is a common bacterium that attacks individuals with weakened immune systems that claims the lives of 20 percent to 30 percent of infected patients. Scientists from the Medical College of Wisconsin (MCW) and the University of California, San Francisco (UCSF) joined forces to develop a monoclonal antibody (MAb) that could neutralize Pa. Prior treatments had focused on secondary toxins or symptoms. This breakthrough targets the total virulence system.

With coordinated support from the technology transfer professionals at both universities, MAb166 has earned a total of 35 foreign and domestic patents and is the focus of a licensing partnership with KaloBios, which has conducted several successful human trials with an eye to bringing the therapy to market in the near future.

KaloBios is an enthusiastic participant in academic/business collaboration. KaloBios VP of Research and Chief Science Officer Dr. Geoffrey Yarranton notes, "Three of our projects have come from academia. We want to work where there's the greatest scientific knowledge about a project, so we'll be successful. It's a two-way street because the academics are excited to have what they developed be tested in the clinic. There's a lot of knowledge and many good [technologies] out there to be licensed."

The refined survey tool developed by the AUTM Metrics & Surveys Committee in 2013 to measure the annual professional activity of the organization's membership provided a set of metrics that offered a more complete picture of tech transfer activity and impact. To assure accurate year-to-year comparisons, the committee elected to use the same model for the 2014 study.

This year's survey revealed the following key activity measures:

914
startups were formed
▲12%

702
of them had their primary place of business in the licensing institution's home state
▲14.8%

4,688
startups were in operation at the end of FY2014
▲11.4%

$28 billion
of net product sales were generated last year
▲27.2%

965
new commercial products were created by companies licensing university technology
▲34.2%

Startup companies can be an effective mechanism for transferring nascent technology from the university research environment to the marketplace. In FY2014, the 914 new companies born of technology transfer activities represent an 12 percent increase over the prior year, with an average of 2.5 new companies created per day. More than 77 percent of these companies operate in the home state where the original research took place, creating thousands of new jobs. Research from the U.S. Department of Labor's Bureau of Labor Statistics indicates that young companies like these create more jobs and are more responsive to economic changes, than older, more established companies.[3]

The increase in new companies is promising, but what about their long-term prospects? Again, the data indicate that startups derived from tech transfer activity show admirable staying power. In 2014, the total of 4,688 startups still in business represents a healthy 11.4 percent increase. According to The Science Coalition, "Companies spun out of research universities have a far greater success rate than other companies, creating good jobs and spurring economic activity."

"The phenomenal 34 percent one-year jump in the number of new commercial products introduced is proof that university discoveries have real-world applications and companies are getting better at commercializing them," says AUTM's Reinhart. "Overall U.S. economic impact is very strong, with remarkable increases in net product sales and a 12 percent increase in the number of university startups."[4]

Indeed, the significant metric of total product sales of $28 billion—an increase of more than 27 percent—is one of the key indicators of the impact tech transfer activities have had on the U.S. economy over the past year. Couple that with the 914 new companies formed out of tech transfer efforts, and the overall benefits to economic health become even more evident.

Taken together, these data convincingly demonstrate the significant contributions of academic technology transfer to the U.S. economy and quality of life through jobs, competitive strength, deployment of leading-edge technology and meeting human needs in healthcare and other critical areas.

—*AUTM President* Fred Reinhart

[3]Bureau of Labor Statistics, United States Department of Labor: Startups and older firms: which is more responsive to economic change? *Monthly Labor Review*. April 2014: www.bls.gov/opub/mlr/2014/beyond-bls/startups-and-older-firms.htm

[4]The Science Coalition: Sparking economic growth: how federally funded university research creates innovation, new companies and jobs. April 5, 2010: www.sciencecoalition.org/downloads/1392649827sparkingeconomicgrowthfullreportfinal4-5-10.pdf

A TECH TRANSFER TRIUMPH

The search for a portable, non-invasive diagnostic for TBI

The Centers for Disease Control and Prevention estimate that 1.7 million traumatic brain injuries (TBIs) occur in the United States annually, with more than 1.36 million requiring emergency room treatment, 275,000 resulting in hospitalization, and 3 percent, or 52,000, leading to death. About 30 percent of all injury-related deaths in the United States involve some aspect of TBI, and the combined direct medical costs and indirect costs of TBI (for example, lost productivity) totaled an estimated $60 billion in the United States in 2000.[5]

About 75 percent of TBIs that occur each year are classified as mild traumatic brain injury (MTBI). Despite the "mild" designation, these events can cause physical, mental and emotional impairment, appearing as long as a year after the event. Many MTBI victims never realize they have suffered a serious injury, so the resulting symptoms may remain unexplained in the absence of an initial diagnosis.

Even more alarming: Because existing diagnostics fail to properly detect a TBI, patients are often given a "clear to play" report that, as in the case of Cody Lehe, can result in tragedy. Existing field diagnostic methods are limited. EMTs and doctors can observe basic physical effects—such as light-responsiveness and complaints of headaches, nausea or dizziness—typical of concussion. Asking the patient a series of questions designed to reveal cognitive dysfunction can reveal confusion and disorientation. But these techniques lack the precision to diagnose MTBIs. And because traditional neurologic/radiologic tests (for example, CT, MRI and EEG) are designed to detect structural damage, they fail to detect the metabolic damage characteristic of TBI, even in patients who have suffered a severe injury. Estimates of incorrect diagnoses that clear a patient who has in fact suffered a TBI range as high as 50 percent.

Researchers at the UCLA Department of Neurology have developed an accurate, affordable and non-invasive device to monitor changes in bloodflow to the brain following a head injury that provides greater accuracy in detecting TBIs. This breakthrough will make it possible for first responders and clinicians to accurately diagnose mild TBI (concussions) to severe TBI. This pathophysiology-based approach to concussion diagnosis will help personnel on the scene make an informed decision regarding return-to-activity versus the need for further medical treatment.

Neural Analytics has received a National Institutes of Health (NIH) Small Business Innovation Research grant of $150,000 for the development of a portable, acute concussion-diagnostic device for use on athletic sidelines and in other non-clinical settings. Under this grant, Robert Hamilton, Ph.D., co-founder and chief scientific officer of Neural Analytics, will lead a clinical study to validate the startup's portable concussion diagnostic device. A significant aspect of its approach is the development of an objective concussion evaluation method based on the pathophysiology—rather than the symptoms—of mild TBI.

The core principle is the use of a proprietary analysis platform that can detect subtle, physiologic changes in cerebral bloodflow. Aside from improving accuracy in diagnosis of MTBIs, this analysis can also help medical personnel monitor the intracranial pressure of severe TBI patients to accurately assess whether invasive surgery is necessary, reducing unneeded surgeries while also boosting the outcomes for those who do need that course of treatment.

Neural Analytics projects that successful commercialization of the product could result in annual savings to the U.S. healthcare system in the range of $250 million. Neural Analytics recently received a $6 million angel investment to further develop their technology—alongside grants from NIH and the National Science Foundation totaling around $300,000 so far, and another $75,000 from the Center for the Advancement of Science in Space. The Neural Analytics team is on track to turn their funding support into a huge return on investment.

[5]Finkelstein E, Corso P, Miller T: *The Incidence and Economic Burden of Injuries in the United States.* New York: Oxford University Press, 2006.

About the U.S. survey

AUTM invited 302 U.S. institutions (including universities and colleges, hospitals and research institutions, national laboratories and third-party technology investment firms) to participate in the FY2014 U.S. survey. AUTM received 191 completed surveys, for a response rate of 63.25 percent. Respondents for 2014 included 163 universities, 27 hospitals and research institutions, and one third-party technology investment firm. The numbers reported in these *Highlights* are drawn from 2014 as a measure of those U.S. institutions reporting and therefore do not represent the composite activities comprising technology transfer. They do, however, reflect the significant role that tech transfer plays in the economy.

About AUTM

The Association of University Technology Managers is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnering and advocacy. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions and teaching hospitals around the world, as well as numerous businesses and government organizations.

A Better World by Bringing Research to Life

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