$1 billion campaign officially launched for Stanford Hospital and School of Medicine

By Ruthann Richter

Stanford University President John Hennessy yesterday announced the launch of a campaign to transform health care at a local, national and global level. The $1 billion Campaign for Stanford Medicine will make investments in medical research and teaching, build a new Stanford hospital, and accelerate the translation of new medical knowledge into leading-edge coordinated patient care.

The medical center is already halfway to its goal, with $500 million in pledges and expectations from individuals and corporate donors.

The Campaign for Stanford Medicine will help fund the construction of a new hospital on the current Palo Alto site, combining the most innovative technologies with amenities to create a healing environment. The new hospital, which will replace aging facilities and bring the medical center up to state seismic standards, will be designed around four patient-care pavilions.

Among the early supporters, three fundamental partners made gifts of $50 million each to ensure the successful launch of The Campaign for Stanford Medicine and the construction of the Stanford Hospital. These gifts are from Tashia and John Morgridge, Anne T. and Robert M. Bass, and the Redlich Family. For their support, the Morgridges and Redlich family will each name a patient pavilion.

In addition, seven companies have committed $175 million for the project through the Stanford Hospital Corporate Partners initiative. These include founding members Apple, eBay, Hewlett-Packard, Intel, Intuit, Oracle and NVIDIA, which joined the group in April.

“Providing the most advanced health care possible to people — locally, nationally and globally — will be one of the great challenges of this

See CAMPAIGN, page 4

JOURNAl UBER ABIEST

So2m9n Islanders’ blond hair has unique roots

By Rosanne Spector

The common occurrence of blond hair among the dark-skinned indigenous people of the Solomon Islands is due to a homegrown genetic variant distinct from the gene that leads to blond hair in Europeans, according to a new study from the School of Medicine.

“This is one of the most beautiful examples to date of the mapping of a simple genetic trait in humans,” said David Reich, PhD, a professor of genetics at Harvard University, who was not involved in the study.

The study identifying the gene responsible for blond hair in the Solomon Islands, a nation in the South Pacific, represents a rare case of simple genetics determining human appearance, and shows the importance of including understudied populations in gene mapping studies, said co-senior author Carlos Bustamante, PhD, professor of genetics at Stanford. The findings were published May 4 in Science.

“Since most studies in human genetics only include participants of European descent, we may be getting a very biased view of which genes and mutations influence the traits we investigate. Here, we sought to test whether one of the most

Researchers have identified a gene that causes blond hair in 5-10 percent of the indigenous population of the Solomon Islands in the South Pacific. It is different from the gene that causes blond hair in Europeans. Striking human traits, blond hair, had the same — or different — genetic underpinning in different human populations,” Bustamante said.

Globally, blond hair is rare, occurring with substantial frequency only in northern Europe and in Oceania, which includes the Solomon Islands and its neighbors. “Its frequency is between 5

and 10 percent across the Solomon Islands, which is about the same as where I’m from,” said co-first author Eimear Kenny, PhD, who was born in Ireland.

Many assumed the blond hair of Melanesia was the result of gene flow — a trait passed on by European explorers, traders and others who visited in the preceding centu-

Proposal calls for reducing lectures in med school classes

By Tracie White

Dramatic changes are needed in medical student education, including a substantial reduction in the number of traditional lectures, according to a perspective piece published May 3 in the New England Journal of Medicine by two Stanford professors.

Medical education has changed little in the past 100 years despite dramatic changes in the world of medicine, the explosion in biomedical information and the ever-growing complexity of the health-care system. The traditional lecture format persists even as class attendance is plummeting and as many complain that the current system is failing to produce compassionate, well-trained physicians.

“Students are being taught roughly the same way they were taught when the Wright brothers were tinkering at Kitty Hawk,” write co-authors Charles Prober, MD, senior associate dean for medical education at the

See EDUCATION, page 7
High anxiety shown to lead to more severe cancer in mice

By Beth Mole

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New research shows that anxiety can lead to more severe cancer in mice, and this finding could have implications for human health. The study, which was published online April 25 in Science, found that mice subjected to chronic stress had higher levels of tumor growth and increased risk of metastasis compared to control mice. The study also showed that this was due to increased production of a protein called BDNF (brain-derived neurotrophic factor), which is known to promote tumor growth.

The researchers showed that mice exposed to chronic stress had higher levels of BDNF in their brains than control mice. This led to more rapid tumor growth and increased risk of metastasis. The study also showed that this effect was reversed when the mice were treated with a drug that blocks BDNF production.

This research has important implications for human health, as it suggests that chronic stress may contribute to the development of more severe cancer in humans. The findings also suggest that there may be potential therapeutic targets for reducing the impact of stress on cancer development.

**References:**


**Image:** A mouse with a tumor on its back. The mouse is looking at a small ball of food. The caption reads: "Mice receiving LM22A-4 regained their athletic prowess considerably more quickly than those given the dummy solution: both the accuracy of their foot placement and the swing speed of the limb on the side treated with LM22A-4 improved more rapidly. Moreover, analysis revealed twice as many new nerve cells in these mice's stress-affected brain areas, at six and 10 weeks after the event, than in those of their LM22A-4-denied counterparts. While the cause is not yet known, critical, said Buckwalter. "A major factor in their ability to retain their in- dentity didn't fully return, but something did contribute to their regain on feet around the stimulus," she said. Mice receiving LM22A-4 regained their athletic prowess considerably more quickly than those given the dummy solution: both the accuracy of their foot placement and the swing speed of the limb on the side treated with LM22A-4 improved more rapidly. Moreover, analysis revealed twice as many new nerve cells in these mice's stress-affected brain areas, at six and 10 weeks after the event, than in those of their LM22A-4-denied counterparts. While the cause is not yet known, critical, said Buckwalter. "A major factor in their ability to retain their in- dentity didn't fully return, but something did contribute to their regain on feet around the stimulus," she said. Mice receiving LM22A-4 regained their athletic prowess considerably more quickly than those given the dummy solution: both the accuracy of their foot placement and the swing speed of the limb on the side treated with LM22A-4 improved more rapidly. Moreover, analysis revealed twice as many new nerve cells in these mice's stress-affected brain areas, at six and 10 weeks after the event, than in those of their LM22A-4-denied counterparts. While the cause is not yet known, critical, said Buckwalter. "A major factor in their ability to retain their in- dentity didn't fully return, but something did contribute to their regain on feet around the stimulus," she said.
A new public cord blood collection program at Lucile Packard Children’s Hospital is now enabling new parents to donate their baby’s cord blood to an international stem cell transplant registry and help save lives.

By Erin Digitale

Amalia Kessler made the first donation to the Packard Children’s cord blood bank after her son Ari’s birth. She and her husband Adam Talcott suggested the bank’s founding when they could not find a public bank to give blood from their daughter Stella.

Kessler said, “We were bombarded with mailings and calls from private cord blood companies, which already has an established cord blood program. We wanted to do something that would be more valuable.”

“We were looking to expand the donor pool,” said Rajni Agarwal, MD, the clinical director of pediatric stem cell transplantation at Packard Children’s and medical director of the new collection program. “It will help us do more stem cell transplants and save more lives.” The new program makes Packard Children’s the first Northern California hospital to both collect cord blood donations and use them in stem cell transplants.

Blood left in the umbilical cord and placenta after delivery is a rich source of stem cells, which can differentiate into a variety of blood cells. Right now, nearly all cord blood is discarded as medical waste, while patients who need transplants sometimes die for lack of a donor. But with the right system in place, cord blood can be collected at birth and stored, frozen, and given to unrelated patients who need the stem cells. This public system is distinct from private cord blood banks, which charge families fees to collect cord blood and store it for the possibility of their own baby’s use.

“The chance of needing banked cord blood for your own child is very remote,” said Maurice Druzin, MD, division chief of plastic and reconstructive surgery at Packard Children’s. “Since blood cancers are so rare, very few families who privately bank cord blood use the cells. Druzin explained, “But these cells are potentially lifesaving for someone else.”

Cord blood has several important advantages over bone marrow — the most commonly used source of stem cells for transplant. It can be collected non-invasively at birth, and matched to more potential recipients than bone marrow. Additionally, while bone marrow registries have relatively few donors from ethnic minority groups, Packard Children’s obstetric patients reflect the great diversity of the Bay Area’s population, which means the hospital’s donations could greatly diversify the cells available for transplant, helping more minorities find a match.

The Packard Children’s program began because an expert mathematician, Stanford law professor Amalia Kessler, JD, PhD, was surprised that she could not find any Bay Area hospitals collecting cord blood donations. During her first pregnancy in 2009, Kessler and her husband, Adam Talcott, decided they would rather donate their baby’s cord blood than bank it privately.

“We were bombarded with mailings and calls from private cord blood companies,” Kessler said. “We wanted to do something that would be more valuable.”

Kessler asked a colleague, Hank Greely, JD, who is a professor of law with an expertise in genetics, to propose the idea of a cord blood donation program. Greely worked with bone marrow transplant expert Karl Blume, MD, an emeritus professor at the School of Medicine, to get the idea off the ground. Although the program wasn’t ready in time for Stella Talcott’s 2009 birth, that changed by the time Stella’s little brother, Ari, arrived in the fall of 2011. His cord blood became the first donated at Packard Children’s.

Packard Children’s new public cord blood program is a joint effort with MD Anderson Cancer Center in Houston, which already has an established cord blood bank. Start-up funds have been provided by Packard Children’s and a grant from the Joanne Pang Foundation, a San Francisco charity founded in memory of a child who died waiting for a stem cell donor. The charity is also funding a new public cord blood collection system across the state, in which expectant mothers can obtain a cord blood collection kit while pregnant to give blood from their daughter Stella.

However, Packard Children’s is currently the only hospital in Northern California with an in-house collection system that can enroll any eligible donor mother when she comes to the hospital active labor.

How does it work? A technologist at Packard Children’s obtains consent from expectant parents in labor and collects the cord blood. It is then stored and shipped to Houston. The MD Anderson staff screen the samples for infectious diseases and carry out genetic characterization. The samples collected at Packard Children’s are then entered into the international cord blood registry, becoming available to caregivers with patients in need anywhere in the world.

”We really want to encourage all our expectant mothers to consider making this altruistic donation,” said Kessler. “Another important goal is to expand the donor pool.”

Meanwhile, Agarwal is seeing firsthand the benefits of using cord blood for Packard Children’s leukemia and lymphoma patients who need stem cell transplants.

“ar the in past year, we’ve done 10 cord blood transplants,” she said. “And this is just the beginning.”

She has transplanted children with leukemia, thalassemia, an inherited form of anemia, sickle cell disease, and inherited neurodegenerative diseases.

“Using cord blood for stem cell transplant is the biggest advance in this field in the past 20 years,” she said. “Establishing our new public cord blood collection program is a very big deal.”

Stroke

continued from page 2

ability declines with age.

The notion of pharmacologically increasing the brain’s stores of BDNF, while tempting, is impractical, said Longo. “No molecule as small as LM22A-4 could possibly perform all the functions this complex protein does,” he said.

In addition, LM22A-4 has a longer half-life in the body and has superior ability to get into the brain than BDNF does. These differences may make LM22A-4 better-suited for drug development than a compound that stimulated both receptors.

The University of North Carolina at Chapel Hill and UCSC, where Longo worked before coming to Stanford, hold the patent for LM22A-4 for use in treating stroke. While at UNC, Longo also supported the work.

“Using cord blood for stem cell transplants is the biggest advance in this field in the past 20 years,” she said. “Establishing our new public cord blood collection program is a very big deal.”

Clinical trial testing drug for depression seeks participants

By Michelle L. Brand

School of Medicine researchers have launched a study to investigate the effectiveness of an insulin-sensitizing drug, pioglitazone, for treating depression.

The researchers are recruiting adults aged 20-65 who have depressive symptoms. Participants may be overweight but must not have unstable cardiovascular disease or a history of neurological disorder or have been diagnosed with diabetes.

The work is being led by Natalie Rasgon, MD, PhD, a professor of psychiatry and behavioral sciences and an expert in behavioral neuroendocrinology. Her work in recent years has focused on the interplay of insulin resistance, metabolic dysfunction and mood disorders.

It is estimated that one-third of the healthy, non-obese adult population is insulin-resistant, a condition in which the body overproduces insulin — a hormone that regulates the level of sugar in the blood — but doesn’t use it properly. While research has shown that insulin resistance is significantly correlated with depression, the relationship between the two is not well-understood.

Still, previous findings suggest that the treatment of depressive disorders results in reversal of insulin resistance, so Rasgon and her team decided to study the effects of using an insulin-sensitizing drug in patients with depression. They chose pioglitazone because it is widely used and is associated with fewer side effects than similar medications.

Rasgon and her colleagues will enroll a total of 80 participants in the double-blind, placebo-controlled study. Funding for the study is funded by the National Institutes of Health.

People who participate in this study will receive assessment of their cognitive and metabolic functioning. Total study recruitment is six visits over three months.

Those interested in participating or learning more should call 724-4539.
Two $50 million gifts, respectively from Christopher Redlich (left) and his family and John and Tashia Morgridge (right), emerged out of their desire to promote change in the health-care system locally and globally.

Campaign

continued from page 1

century,” Hennessy said. “The Campaign for Stanford Medi-
cine draws upon our particular strengths — the proximity of the university to its hospi-
tals and clinics — to focus on this issue and better serve the public. It will allow us to seek solutions to some of medicine’s most daunting problems, and it will begin in our own community with the new Stanford Hospital. With the early support of visionary and generous part-
ners, and others who will join us in this venture, we will realize a new, transformative model of health care.”

The new hospital, on which construction began in late 2011, will incorporate advanced technologies, in-
cluding state-of-the-art imaging equipment and new “hybrid” interventional platforms equipped for a variety of procedures, including surgeries and catheterizations. These flexible spaces will eliminate the need for separate patient prep and recovery areas for each type of proce-
dure, and are expected to reduce infection risks and im-
prove outcomes.

The hospital, a level-1 trauma center, also will in-
crease its space for treating major traumatic injuries and
offer greatly expanded emergency services for the com-
munity, with 59 treatment bays for patients. All patient
rooms in the new hospital will be private and will be surrounded by gardens and views of the foothills. De-
signed by renowned architect Rafael Viñoly, the project encompasses 823,000 square feet of new construction
and is scheduled for completion by 2017.

“Byerwalter: This campaign supports a transfor-
mative effect of that team. The campaign will also make critical investments in teaching and research programs that
will shape the next chapter of medicine, including
neurosciences, stem cell medicine, musculoskeletal
medicine and surgical science. These are all areas in
which Stanford Medicine will play a leadership role in
the future, globally.”

Byerwalter: For the past 50 years, local residents have had one of the world’s best medical teams — experts across all fields, working together — here in their

Q&A

Byerwalter on campaign’s transformative effect

Marianne Byerwalter, the chair of the board of directors of Stanford Hospital & Clinics, believes that the launch of the campaign to build a new hospital and to advance medical research is not only an historic moment for Stanford but for medicine at large. As a co-

chair of the campaign, she is well aware of how it could help change the way that health
care is delivered. Bastian Richter, the director of media relations for the medical school’s
Office of Communication & Public Affairs, spoke with her about the scope of the effort to
transform Stanford Medicine and how it could help enhance health care. Byerwalter also
serves on the board of directors of Lucile Packard Children’s Hospital, and she has served
on the university’s board of trustees until last month.

Q Why is this campaign so important?

Byerwalter: This campaign supports a transfor-
mation of health care, here at Stanford and around the
globe. It will enable the completion of the new
Stanford Hospital, which is critical to this commu-
nity. The campaign will allow us to invest in the work of
some of medicine’s best researchers and teachers, achieving medical milestones just ahead and training
future educators. And, because this campaign builds
on all the assets of both Stanford Medicine and Stan-
ford University, it will contribute solutions to the
daunting challenges of health-care delivery in this
country, addressing issues of quality, accessibility
and affordability.

Q What is the special significance of this project
for the community?

Byerwalter: For the past 50 years, local residents have
had one of the world’s best medical teams — experts
across all fields, working together — here in their

community, ready to deliver their patient care. Now,
we will have a hospital facility that matches the qual-
ity of that team. The campaign will also make critical
investments in teaching and research programs that
will shape the next chapter of medicine, including
neurovascular care, cancer (and women’s cancer),
neurosciences, stem cell medicine, musculoskeletal
medicine and surgical science. These are all areas in
which Stanford Medicine will play a leadership role
in the future, globally.

Q How does this campaign compare with previ-
ous campaigns at Stanford?

Byerwalter: Stanford Medicine has never asked its

community to support a fundraising campaign of this
magnitude. In the late 1980s, generous donors sup-
pported the Stanford Hospital Modernization Project,
which built the newer patient care units in the exis-
ting hospital. But we have never targeted anything this
ambitious. The recently completed Stanford Chal-
lenge, the most successful fundraising...
May 12 ‘Healing Matters’ shows future of medicine and medical center

Community members are invited to a get-a-first-hand view of some of the newest facilities at Stanford University Medical Center as well as hearing about the future of medicine from experts in fields such as cancer, stem cells and dementia.

The medical center is sponsoring “Healing Matters” on May 12 to showcase its contributions to both medical research and patient care. It will run from 8 a.m. to 1 p.m. at the School of Medicine’s Li Ka Shing Center for Learning and Knowledge. A light breakfast and a boxed lunch will be provided.

The day will begin with welcoming remarks from Ron Johnson, CEO of JC Penney and a member of the Stanford Hospital & Clinics board of trustees. Afterward, participants will attend breakout sessions on such topics as:

- Transforming billions of points of data into new insights and diagnostics for disease.
- How to prevent, diagnose and treat dementia.
- How the genomic age is affecting the understanding of breast cancer.
- Movement disorders and what can be done about them.
- Earlier detection of cancer.
- The prospects of using stem cells to repair heart damage.

In addition, participants can choose to take walking tours of the Joan and John Freeman Center for Translational Research that is now under construction, or the newly opened Lucile Packard Children’s Hospital. The children’s hospital eventually will double in size, adding 150 private patient rooms and new family-friendly surgical, diagnostic and treatment areas.

The campaign funds also will be applied to training the next generation of pediatric leaders and discovering new cures for childhood diseases.

May 8, 2012

Inside Stanford Medicine

“One of the most differentiating factors of the Stanford School of Medicine — built into the history of this institution, very much part of its DNA — is a willingness to take on the really hard problems, a willingness to say, ‘You think that can’t be done? We’re going to do it. And let us show you how.’ That’s been our history through now, and that will be our work for the future. The Campaign for Stanford Medicine is about bringing forth new ideas and leveraging them in unique ways that will transform our community and galvanize the world.”

— Philip Pizzo, MD, dean of the School of Medicine.

“When you think about the great leaps forward in human history — social, economic, technological — they usually occurred because a significant breakthrough collided with a pressing need. That’s where we are in medicine right now: We are at the intersection of incredible scientific potential and pressing human need. Dramatic biomedical breakthroughs lie just ahead. At the same time we have a critical need to make sure high-quality, affordable health care is available to all. Stanford Medicine, in partnership with this community, will help lead this transformation. And all of us — individuals, corporations, members of this community — are part of the equation.”

— Ron Johnson, CEO of JC Penney and a co-chair of the Campaign for Stanford Medicine.

“Phil Pizzo, MD, dean of the School of Medicine, and Amir Dan Rubin, CEO of Stanford Hospital & Clinics, of what the patient experience will be at the new Stanford Hospital scheduled to open in 2018. The presentation will include a virtual fly-through of the new hospital.

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May 8, 2012
As an executive in the life-sciences industry, Gayle Kuokka had often repeated the mantra about clinical trials being the standard treatment regimen of surgery and chemotherapy. But when her genetic counselor revealed the BRCA2 mutation, her treatment options were limited to a clinical study of a new BRCA-targeting compound.

As Kuokka weighed her options, she sought input from her network of bio- tech colleagues. With their encouragement and a strong sense of confidence in her doctors, she agreed to join the trial. “It seemed like a promising drug,” she said, “and I knew that if it didn’t work I could fall back on the standard of care.”

Kuokka was one of four cancer patients to share their clinical trial experiences at an April 24 presentation sponsored by the Stanford Cancer Clinical Trials Office. The event was part of the inaugural Clinical Trials Awareness Week held April 23-27 in the Stanford Clinical Cancer Center.

The week featured a daily series of presentations by patients and physicians, educational poster sessions and a staffed information desk, all to provide clinical trials information to millions of people telephones. It’s also one of the most linear experiences of my career.”

It was such a striking signal pointing to within a week we had our initial result. “For instance, the genetics of skin pigmentation are largely determined by a single gene — a result you could hang your hat on. That rarely happens in science, but it is one of the best experiences of my career.”

In terms of genetic studies, the analysis was straightforward, said Kenny. But gathering blood samples and analyzing them in September 2010, the week she started at Stanford. “Within a week we had our initial result. It was a return trip for Myles who had been to the island before, said卅an Bronstein, a researcher with Max Planck Institute molecular anthropologist Mark Stoneking, PhD, (also a co-author of the study) to investigate whether the language variations corresponded with genetic variations. While there, Myles was fascinated by the ubiquity of blond hair, which was especially common among children. “They have this very dark skin and blond bright blond hair. It was mind-blowing,” said Myles. “As a geneticist on the beach watching the kids playing, you count up the frequency of kids with blond hair, and say, ‘Wow, it’s to 10 percent.'”

A grant from the Wenner-Gren Foundation for Anthropological Research gave Myles, who at that time was doing a stint as a postdoctoral researcher at Cornell University, his chance to study the genetics of the Solomon Islanders’ hair color. Myles worked with Bustamante, who was also at Cornell, to design the study. Then back in the islands, Myles and Timpson went village to village explaining what they wanted to do and asking for permission to gather data. Myles speaking in Solomon Islands pidgin, the most widely understood language.

When the local chief gave the OK, the researchers recruited participants and assessed hair and skin color using a light reflectance meter, took blood pressure readings and measured heights and weights. They asked the villagers to spit into small tubes to provide saliva to be used for DNA extraction. In the span of a month they collected more than 1,000 samples.

While the islands fit many people’s notion of a tropical paradise, they lack amenities Westerners take for granted. For instance, simply finding a level spot for the scale to weigh study participants was a challenge.

Then in 2010 Bustamante joined Stanford’s faculty and, with funding from the Department of Genetics, the team looked for genes underlying this striking phenotype. Soon after, Kenny joined the lab and started the analysis, selecting 43 blond- and 42 dark-haired Solomon Islanders from the opposite 10 percent extremes of the hair pigmentation range. She also remarked on the care and attention she received from her doctor, Melinda Telli, MD, and the staff at the Stanford Clinical Translational Research Unit, which is the medical school’s prime facility for conducting patient-oriented research to translate basic scientific knowledge into a better understanding and treatment of diseases. As part of its mission, CRU provides trial participants with a comfortable and supportive environment, in addition to the highest-quality care.

During the course of her treatment Kuokka joined a few other related studies, including one assessing a new imaging technique. “I tried to do anything and all that I could because I recognize that it can be hard to get people to do clinical trials,” she said. In a way, an important lesson from the panel noted that trials are designed to study much more than new drugs. Some seek to reduce side effects of current therapies, test treatment combinations or improve quality of life for patients after treatment.

Lori Baldwin, a cancer survivor who also shared her story as part of the week’s events, told of how she had successfully navigated the ups and downs of her breast cancer treatment, but three years later she was still having a hard time dealing with depression. When she called for participants, she joined a trial to assess the potential benefits of acupuncture treatment for mood disruptions associated with cancer treatment.

Baldwin reported that the acupunc- ture sessions gave her a sense of calmness and serenity that persisted for days, and greatly enhanced the depth and duration of her sleep. She also referred to the empowering aspect of clinical trial participation. “I am very proud to have been in a clinical trial,” said Baldwin, a volunteer for Y-Me, a national organization providing information and support for people consumer decisions. “I want to be just another person with cancer; I wanted to do something to help improve other patients’ quality of life.”

The week featured a daily series of presentations by patients and physicians, educational poster sessions and a staffed information desk, all to provide clinical trials information to millions of people.
Goodman on better FDA detection of drug risks

May 1 by a committee from the Institute of Medicine recommends steps that the agency can take to better identify risks of drugs after FDA approval. The medical school communications office asked committee co-chair Steven Goodman, MD, PhD, to write about why this topic has come to the fore and the need for clinical and translational research and a professor of medicine and of health research and policy.

The FDA sometimes approves a drug and then later, with new evidence, changes its position. Why is it hard for the agency to get it right the first time?

**GOODMAN:** These sorts of changes are inevitable. The evidence that the FDA has at the time of approval is based on many tens of patients who can be followed for a relatively short time. The evidence that comes after the drug is approved can involve millions of patients, with all their diversity, who are taking a drug in natural living conditions. The follow-up can be for as long as the drug is on the market. So the FDA’s evidence for this second decision is far greater than for the initial approval. Our conclusion is that we view the initial approval as just one early step in a process that requires continuous, long-term monitoring, which we call the “life-cycle approach.”

2 What’s wrong with the FDA’s current tracking of drug safety post-approval?

**GOODMAN:** The FDA has many approaches to monitoring the effects of drugs once they are approved, but none are as comprehensive or as systematic as the attention the drug gets before approval. One is based on voluntary reports from doctors about drug adverse events seen in their patients. The FDA also does drug surveillance using specialized databases, but they do not capture critical information about each patient that would enable the FDA to determine whether the observed drug effects should be associated with a particular drug.

This is an imperfect system, and it’s changing. A 2007 law gave the FDA the power to require a manufacturer — after a drug’s initial approval — to conduct post-approval safety. These post-approval studies focus specifically on drug and a well-documented patient population, rather than casting a large net. One asks how to best use the FDA’s new powers to improve patient safety. That’s what our report seeks to provide.

3 The report calls for the FDA to create a new type of plan for monitoring each drug. Why is it better to be duced to the market. How would that improve safety?

**GOODMAN:** The report recommends that the FDA adopt a systematic way to anticipate what type of investigation each drug will need post-approval and then closely follow up on the results of that investigation. We hope that in being as systematic in requiring such studies after the drug is approved as it is before approval, the FDA can reduce the kind of crises that have occurred over the last decade. With the proper studies in place before a drug is approved, the necessary safety evidence can be obtained much earlier. To use a common metaphor, right now many studies are like fire drills conducted after the fire. We think it’s better to initiate them when there’s just smoke.

4 The report highlights a variety of warning signs that are present at the time of a drug’s approval. A trigger, for instance, could be the drug’s approval was based on clinical trials that provide conflicting evidence regarding risks, such as an anti-hypertensive drug that lowers blood pressure but also increases the risk of heart failure. Such a drug might be flagged for drugs that are “first in class” and that were approved based on predictors of clinical outcomes (surrogate endpoints) rather than the outcomes themselves.

Various technological and methodological advances could improve the FDA’s drug surveillance systems. There is a scientific consensus that Stanford that we couldn’t cover in the report, and is just coming out. Nigam Sha, an assistant professor of medicine, has explored the potential harm using natural language processing of electronic medical records, and graduate student Nicholas Tisonetti, with genetics and bioengineering professor Russ Altman, has demonstrated how to find signals of drug interactions. We need methods that are faster, better and cheaper, and their work appears to be all three.

4 Congress is now reauthorizing the user fee that help fund the FDA. Does the legislation affect its approach to post-approval drug surveillance?

**GOODMAN:** Not really, although it is changing as we speak. It focuses mainly on ways to expedite drug approval using new methods or different data sources. But our recommendations are highly relevant to this, because I think that the model for the approach to drug’s monitoring process, the more flexible one can be on the approval stage.

5 The report says that conducting a study of a drug after its approval can raise ethical concerns. Why is this so?

**GOODMAN:** The ethics of post-approval safety research have emerged as an issue because of high-profile cases in which the FDA had to decide how to respond to troubling evidence about widely used drugs. The agency faced a dilemma: Requiring further studies on the drug could be ethically problematic. It’s unusual to expect patients to enroll in such a trial. We recommended that the FDA adopt a systematic way to monitor a drug that might raise the heart attack risk without established, offsetting benefit. Others felt that the evidence was too weak to make a decision. The drug from the market. The ethical complications should be obvious if you think about it. The FDA sometimes requests that people enroll in a trial not because of a treatment’s potential benefit, but to see what harm it does. This raises red flags, as did the situation of Avandia a decade earlier. There was a hint in the early data that Avandia adversely affected lipid profiles. If the FDA had required a critical clinical trial focused on the safety question at the time Avandia was approved, the evidence about its harm would have been there before it became a major ethical/scientific problem.

Still, there are going to be cases that will arise. Five years later, we may want some time after approval to investigate safety signals related to drug safety, and that’s the purpose of the user fee. But we think that people want a relative to enroll in such a trial. One way to avoid this conundrum is to get a better system in place now. A decade earlier, there was a hint in the early data that Avandia adversely affected lipid profiles. If the FDA had required a critical clinical trial focused on the safety question at the time Avandia was approved, the evidence about its harm would have been there before it became a major ethical/scientific problem.

New funding for research on parasitic eye disease

Brooke Anderson-White, PhD, a postdoctoral scholar in pathology, has received a grant from the Knights Templar Eye Foundation Inc. for research to develop vitally needed new treatments for severe eye infections caused by the toxoplasma gondii parasite.

The parasite infects as many as a billion people worldwide, many of whom have no symptoms. However, it can cause severe problems in those with weakened immune systems or in infants. It is particularly leading to the condition toxoplasmic retinochoroiditis. Infected children can develop severe vision impairment and blindness as a result of retinal scarring caused by the disease. Toxoplasmatic retinochoroiditis is a major source of visual impairment in the United States.

The drugs currently used to treat infections are not very effective. They are only 50 percent effective, and those used for infected infants often result in hypothermia, which can lead to death. That’s why the research was necessary. Treatment is also limited to those who have the disease. Reactivation of the infection is also common with current treatments, the said.

Anderson-White and her co- leaders in the laboratory of Matthew Boggs, PhD, associate professor of pathology and internal medicine, are studying the molecular components of the process used by the parasite to invade and destroy the eye. They use a chemical probe to explore the factors that regulate parasite invasion, which could lead to developing po- tential new drug targets.

Knights Templar is an interna- tional charity that is headquartered in the Freemasons. The group will provide Anderson-White with $33,198 in research support.
Vascular surgeon Weesam Alkhatib dies at 34

By Emily Hite

Weesam Kassim Alkhatib, MD, a clinical instructor in surgery at the School of Medicine and a vascular surgeon at both Stanford Hospital & Clinics and the Veterans Affairs Palo Alto Health Care System, died at his parents’ home in Woodland, Calif., on April 14 of a rare form of cancer. He was 34.

Alkhatib was appointed a clinical instructor of surgery in 2010, after completing a two-year vascular and endovascular surgery fellowship at Stanford. The team he chose to graduate from medical school at the University of Kansas, where he also completed his residency.

“Dr. Alkhatib was an outstanding surgeon, scholar, role model and friend,” said Ronald Dalman, MD, the Dr. Walter C. Chilcote Professor and chief of vascular surgery. “In his short but meaningful career, he showed passion, skill and commitment to his patients were an inspiration to all who knew him.”

Alkhatib had undergone several treatments during his fellowship and throughout his faculty appointment, but continued to practice surgery and to teach.

“He really had made a big impact,” Dalman said, noting that Alkhatib’s primary responsibility was in resident education, and that he had been inspired to be a program director. Dalman said he was popular with the residents who were attracted to his outgoing nature and sense of humor. He enjoyed sports, playing varsity tennis as an underdog at Kansas State University.

For the last two years, Alkhatib directed the division’s didactic educational program, and at the time of his death he was completing a new handbook on board certification for vascular surgeons. In his honor, his manuscript is being finalized by his trainees and will be submitted to the publisher for publication.

“He was just at the start of a bright and promising career and had so much life ahead of him,” Dalman said. “It’s tragic.”

In lieu of flowers, the family asks that people contribute to a memorial project dedicated to both Weesam and his younger brother, Shwan Alkhatib, who predeceased him. Melanie donations are being collected at goemaw.com/fatty.html. Checks can be mailed to Dickinson County Bank, Box 217, Enterprise, KS, 67441. Checks can be made payable to: Shwan “Fatty” Alkhatib Memorial Fund.

Alkhatib is survived by his parents, Kassim and Sorkel, of Woodland, and his sisters Avene of London, Canada, and Cheen of Dallas.

Arvin, Barres, Kim elected AAAS members

Three School of Medicine faculty members were among the 220 elected this year to the American Academy of Arts and Sciences. The new class will be inducted at a ceremony Oct. 6 in Cambridge, Mass.

The academy, one of the country’s most prestigious honorary societies, is a leading center for independent policy research. Members contribute to academy studies of science and technology policy, global security, social policy and American institutions, the humanities and education.

A total of nine Stanford faculty were elected this year. The three from the School of Medicine are:

Ann Arvin, MD, the Lucile Salter Browne Professor of Pediatrics at Stanford; and professor of microbiology and immunology. She is also the university’s vice provost and dean of research. Her research focuses on herpes viruses, viral vaccines, viral immunology and the molecular virology of the varicella-zoster virus.

Ben Barres, MD, PhD, professor and chair of neurobiology. He also holds appointments in developmental biology and in neurology and neurological sciences. His research focuses on glial cells, which constitute 90 percent of the cells in the brain but whose function remains poorly understood. His approach involves separating all the component cells in the developing nervous system and studying their interaction through innovative techniques.

Stuart Kim, PhD, professor of biochemistry and of genetics. His research focuses on the organ development in the millimeter-long roundworm Caenorhabditis elegans, an insect-like and cellular level. Its small size, fully sequenced genome and short life span have allowed him to ask larger questions about neurodevelopment and cellular processes such as aging and development.

Karen Byerwalter: The early weeks of the campaign will be dedicated to making sure that our goals, priorities and purposes are communicated clearly to our stakeholders; that those who will be acting as our ambassadors are well-equipped to do the job. The transformations this initiative will enable are exciting, but require much hard work from all of us to see how health care will be in the future. That requires philanthropic commitments, large and individual, but it also requires the thinking, moral support, volunteerism, advocacy.

Why are you personally involved with the campaign?

Byerwalter: I have a deep respect and passion for the life changing work taking place at Stanford. For over 25 years I have contributed to the growth of the university. This campaign is the culmination of years of planning and preparation for the next transformation at Stanford Medicine, and it is unquestionably my top personal volunteer service commitment. I have felt inspired by the remarkable combination of volunteers, visionaries, community leaders and philanthropic partners combining to improve teaching, healing and discovery. Today we are launching a more remarkable transformation, and with our collective efforts we can make a difference for generations to come.

What do you hope to accomplish in the next few weeks to launch the campaign?

Byerwalter: The early weeks of the campaign will be dedicated to making sure that our goals, priorities and purposes are communicated clearly to our stakeholders; that those who will be acting as our ambassadors are well-equipped to do the job. The transformations this initiative will enable are exciting, but require much hard work from all of us to see how health care will be in the future. That requires philanthropic commitments, large and individual, but it also requires the thinking, moral support, volunteerism, advocacy.

What will the remaining part of the campaign look like?

Byerwalter: After the excitement of the launch, and the wonderful early efforts that have yielded fundraising expectancies of $500 million down to the hard work of raising the remaining $500 million [CHECK]. We’ll continue to look for potential donors at all levels, and we will be seeking to engage all members of our community. It is hard work, but it is also very exciting. What we’ll achieve at the other end truly does have potential to change lives.