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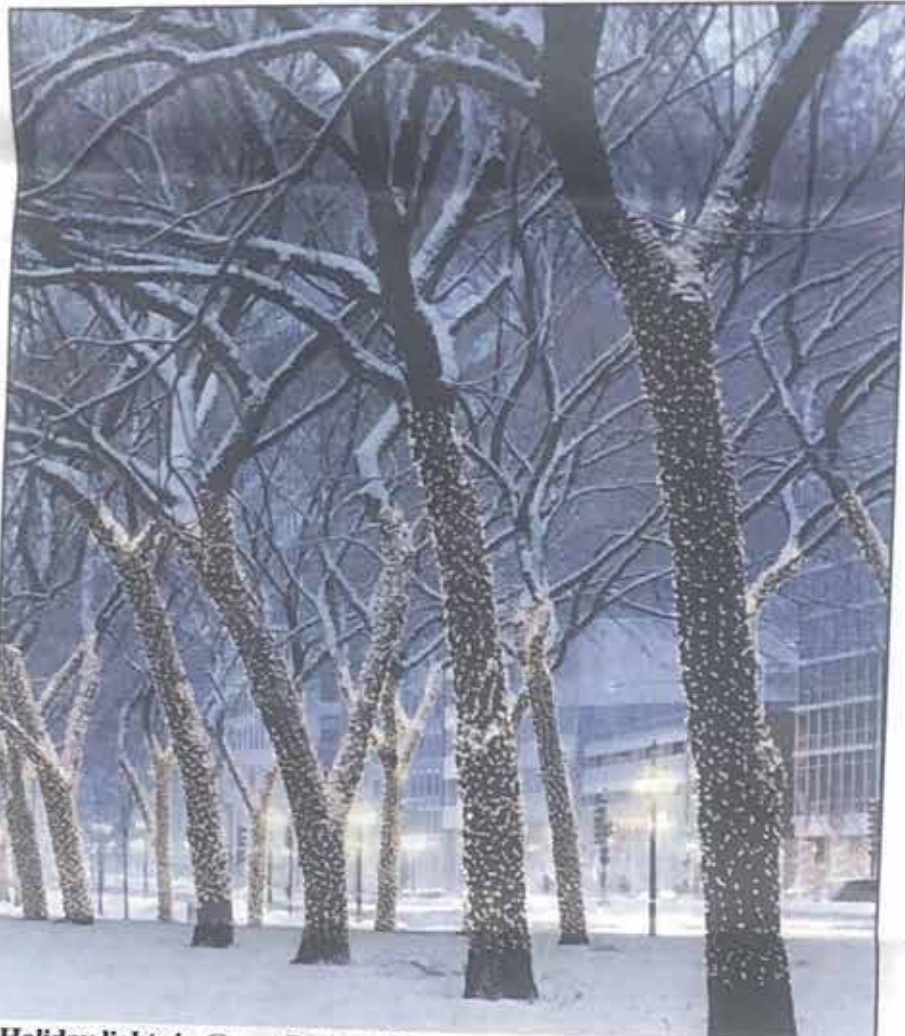
Medicare details claim appeal levels

The Centers for Medicare and Medicaid Services (CMS) has begun implementing its revised claims appeal process for Medicare Part A. Changes to the Part B process will take effect Jan. 1. The altered process for both Parts A and B includes five levels of appeal.

First-level appeal: redetermination. A patient or physician can appeal an initial claim determination within 120 days of the initial decision regardless of the size of the claim. The Medicare contractor who made the initial determination has 60 days to respond. If there is no response, patients or physicians can immediately escalate the appeal to the second level.

Second-level appeal: reconsideration. If patients or physicians are not satisfied with the first-level appeal, within 180 days a second-level appeal may be made regardless of the size of the claim. All relevant evidence must be submitted at the time.

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Holiday lights in Grant Park, Chicago.

(Photo © Ron Schramm)

More outpatient surgery data in '06

The state's public health agency is required to give consumers comparative cost figures for outpatient surgeries performed at Illinois' 126 state-licensed "ambulatory surgery treatment centers," also called outpatient surgery centers. State law says this data must be posted at the Illinois Department of Public Health's Web site by Jan. 1, 2006.

The purpose of the law, sponsored by Democratic state legislators Julie Hamos of Evanston and Susan Garrett of Highwood, is to give health care consumers more of the information they need to make fiscally sound choices about their surgeries.

Typically, outpatient surgery centers perform procedures like union removal, carpal tunnel surgery, colonoscopies, corneal transplants, liposuction, pain management, hernia repair and biopsies in a "one-stop" setting designed to reduce medical expenditures.

"It is important that this information be obtained to get a more accurate picture of this component of health care," says state public health director Dr. Eric E. Whitaker.

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Buitreraptor: Great-something grandmother of Big Bird?

Embedded in a rocky cliff, fossilized bones that might have been mistaken for a large ancient rooster are causing scientists to rewrite the history of dinosaur evolution.

The roundish body might have

been mistaken for a huge bird, that is, except for long hind limbs, massive shoulder muscles meant for grabbing live prey and then – the kicker – two long forelimbs (probably feathered) with a large, sharp sickle-shaped talon on the second

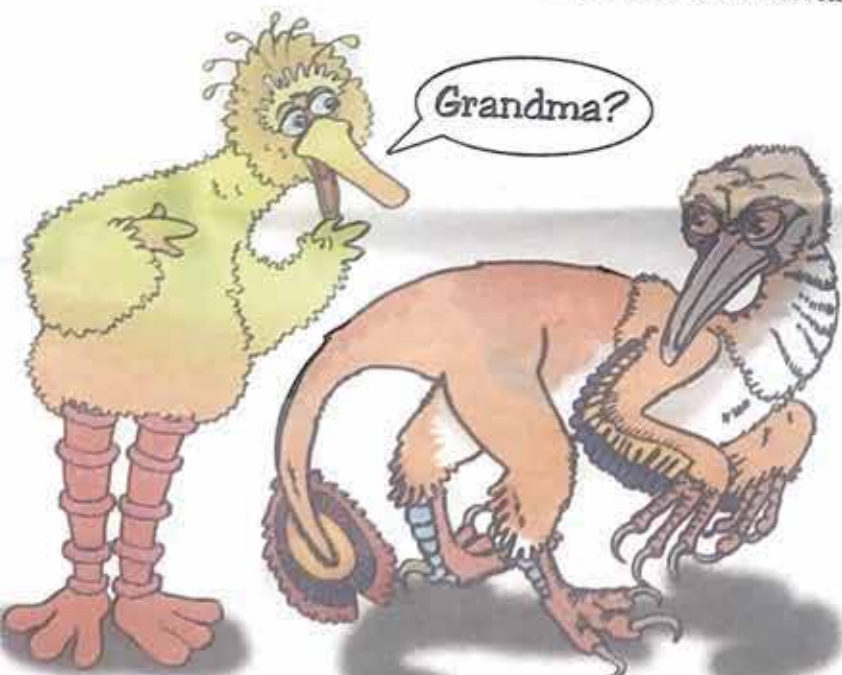
digit of each hand-like appendage.

The bones could be nothing but a dinosaur – in fact, a hitherto unknown kind of dromaeosaurid. (Dromaeosaurs were nicknamed "raptors" in the movie "Jurassic Park," but true raptors are a category of hunting birds that includes eagles.)

The newfound dromaeosaur has been officially designated as a *buitreraptor* (bwee-tree-rap-tor) after the place where it was discovered, *La Buitrera* ("vulture roost" in Spanish), an area in Argentina once populated by many meat-eaters, including crocodiles and what is thought to be the largest dinosaur, *giganotosaurus*.

Like *Tyrannosaurus rex*, another kind of dromaeosaur, the newfound creature has a wishbone and a pelvis angled toward the backside. But the *buitreraptor*'s bulging eyes and rounded body make it look more like a relative of Sesame Street's Big Bird than of *T. rex*.

The *buitreraptor*'s long, slender skull and small teeth may have enabled it to hunt inside burrows for



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Social Security up 4.1 percent

Monthly Social Security payments to 52 million older or disabled Americans will increase 4.1 percent in 2006 – an amount likely to be gobbled up by higher Medicare and other costs.

The annual Social Security increase is set by federal law and based on the rise in the Consumer Price Index between the third quarter of 2004 and 2005.

Though glad for any increase, older Americans and their advocates are not clicking their heels. For example, says Barbara Kennelly, head of the National Committee to Preserve Social Security and Medicare, "This cost-of-living adjustment is the only income raise many seniors will see, and yet it is already disappearing before their eyes."

Last month, Medicare announced a 13 percent hike in outpatient premiums (Part B), an increase from \$78.20 this year to \$88.50 in 2006.

In addition, many older people are particularly concerned about the like-

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Adult stem cells: The power to divide and conquer disease

"My only alternative was to continue getting worse until I eventually died." Dennis Turner, a retired nuclear engineer from San Clemente, Calif., is talking about why he agreed to be a subject in testing a potential new treatment for Parkinson's disease.

The treatment involved removing a pea-sized sample of tissue from one area of Mr. Turner's brain, growing a cluster of adult stem cells extracted from the tissue and injecting the cells back into his brain six months later.

(Research on adult stem cells is not related to the controversial research on embryonic stem cells or on cloning. Adult stem cells have been used successfully for a number of years to treat patients whose immune systems have been destroyed by chemotherapy and radiation.)

Before stem cell treatment, Dennis Turner had developed extreme shaking in his right arm and leg and severe stiffness in all movements, including walking.

"I had almost no use of my right arm," he says. "I was living all by myself and watching myself fall apart."

But thanks to the experimental therapy, Mr. Turner, 63, now spends part of his time actually caring for another Parkinson's patient — a friend.

"My friend and I got Parkinson's disease at about the same time," says Mr. Turner. "But my friend ended up in a nursing home because he didn't get the treatment."

symptoms had been reduced by more than 80 percent."

That was six years ago. A few months ago, Mr. Turner returned from pursuing his hobby — big game photography. Since the therapy he has been able to go to Africa several times, taking photos of lions and rhinos. He drives a car, still lives by himself and spends an hour and a half a day at the gym.

'Miracle' cells

Adult stem cells serve as part of the biological repair system for the body's trillions of specialized cells, such as blood, muscle, nerve, skin and liver cells. The unique characteristics of adult stem cells make them very promising for someday treating Alzheimer's disease, arthritis, cancer, heart disease, diabetes, Parkinson's disease, retinal degeneration, spinal cord injury and other major disorders.

When a stem cell divides, each resulting cell can remain a stem cell or adopt a "differentiated" specialized role, such as a blood cell. The differentiation process depends on signals from a cell's genes, which carry blueprints for cell structures, and on signals from other cells in the immediate environment.

A differentiated cell carries on specific functions. A red blood cell carries oxygen through the blood stream; a nerve cell transmits electrochemical signals. Differentiated cells can only divide and replicate a certain number of times; before they die.

Adult stem cells can divide many more times. They remain inactive until traveling to sites where tissue has been injured. In the process, they differentiate into new specialized cells for repair.

Adult stem cells are known to exist in the brain, cornea, retina, heart, fat, skin, dental pulp, skeletal muscle and intestines.

The healing potential of stem cells has been demonstrated in the treatment of various human diseases, including heart disease, diabetes and advanced kidney cancer. However, the new therapies are being offered only to a very limited number of patients who are accepted into clinical research trials.

Heart problems

"We have been very pleasantly surprised by the potency of adult stem cells," says Emerson Perin, M.D., Ph.D., medical director of the Stem Cell Center at the Texas Heart Institute in Houston.

Dr. Perin and his research team conducted a clinical trial on 14 heart failure patients with colleagues at Pro-Cardiaco Hospital in Rio de Janeiro. They used the patients' own adult stem cells taken from the blood to treat "very, very sick people who couldn't be helped by any conven-

tional treatment," says Dr. Perin.

Threading a special catheter tube into the patient's heart tissue, Dr. Perin brought into play special mapping technology developed to track missiles.

"We have the inside of the patient's heart modeled in 3-D on a computer — like a computer game," says Dr. Perin. "The screen tells us where we are in the heart and how well the muscle is conducting electrical activity. Then, through the catheter, we plant stem cells like little crops of seeds in the dead or damaged areas."

This initial stem cell experiment took place four years ago.

"Mortality from advanced heart failure is usually quite high," says Dr. Perin. "But 12 (of the original 14) are alive, and all of them are doing much, much better than before the treatment."

One of the patients died of an unrelated stroke 11 months into the two-year study.

"We were able to autopsy the heart and see that there had been regeneration going on in terms of new muscle tissue and new blood vessels," says Dr. Perin.

The initial study showed that the procedure is safe, simple (people go home the next day) and powerful in treating heart failure, he says.

The Houston researchers are now involved in several trials on larger numbers of patients in the United States and Spain, including an advanced, randomized, double-blind clinical study.

"It's not a question of whether adult stem cells work — we know that they work," says Dr. Perin. "There's the question of how aggressive we should be. Me, I have to look patients in the eye every day. I don't like to tell someone that all hope is gone, so I believe in being thoughtfully, carefully aggressive."

There are many other questions under study, as well.

"We know that stem cells secrete a cocktail of proteins, and we want

to know the extent to which these substances stimulate repair and regeneration among surrounding heart cells," says Dr. Perin.

The researchers also want to determine the best kinds or combinations of stem cells to use for therapy and how long the replacement cells will continue to function.

"We need a better treatment for chronic heart failure," says Dr. Perin. "Transplants are not as effective and available as we'd like; artificial hearts are very, very expensive."

When Dr. Perin asked 55-year-old Ruth Pavelko, one of his patients, if

Mrs. Pavelko, of LaPorte, Texas, had suffered four heart attacks and gone through open-heart surgery. Thirteen stents had been inserted to open up clogged arteries, but the stents themselves kept clogging.

Ten weeks after having treatment with her own stem cells, though, she began feeling better. "Now I can walk up and down a flight of stairs," she says. "I can cook dinner and do the dishes."

Mrs. Pavelko says that images of her heart show it has turned a healthy purple color rather than the gray hue it displayed a few months ago. "That's from new blood ves-

with a clinical trial.)

Treatment abroad

"Currently there are at least 12 clinical trials around the world using adult stem cells to treat cardiovascular problems," says Don Margolis, founder of TheraVita, a private, multinational company that has developed a proprietary technology, VesCell™ that grows stem cells from the patient's own blood.

Early results of a clinical trial that TheraVita doctors performed in May 2004 in a Bangkok, Thailand, hospital were highly successful. In fact, they were so positive that officials gave the go-ahead for TheraVita to begin treating private patients who could not be helped by other therapies — which the company did in January this year.

"Trials at various sites over the past four years show that 75 to 85 percent of heart failure patients develop significant improvement in the first year of adult stem cell treatment," says Mr. Margolis. Fifteen to 25 percent show no improvement, but no harm has been done.

Forty patients have been treated for heart failure and blocked coronary arteries by Thai doctors in Bangkok hospitals using TheraVita's VesCell™ stem cell product. Ten of the 40 were treated recently and have not been tested yet for improved cardiovascular function. Twenty-four of the remaining 30 have shown marked improvement and six have had little or no improvement.

Treatment by TheraVita involves a two-week trip to Bangkok. The first day is spent in medical evaluation; blood is drawn on the second. During five days, when the blood is sent to Israel for stem cell culture by clinicians there, patients are housed in a Bangkok hotel. The cultured stem cells are injected during the second week, and patients fly home after a final evaluation.

The cost of the treatment for congestive heart failure is about \$22,000 for cell culturing; \$8,000,

hospital and doctors' fees; \$1,500, hotel; \$1,000, air fare for one person, and \$10-30 a day for food in Bangkok restaurants.

"We believe that stem cell therapy has proven itself well enough that it is time to use it in alleviating suffering," says Mr. Margolis.

Twenty-nine-year-old Jeannine Lewis has lived with heart failure since she was 17 — possibly the result of a viral infection. She had reached the point where she could no longer take care of herself and her two-year-old son. Her heart's pumping ability (ejection fraction) was 25 (normal is 55); death is imminent when that number reaches about 10.

"We had few other options," says Mrs. Lewis. She and her husband, who live in Huntington Mills, Pa., researched adult stem cell treatment on the Internet. There they linked up with the doctors at TheraVita.

"I noticed improvement within a month," says Mrs. Lewis. "We took a vacation in Washington, D.C., and I suddenly realized that I could walk the distance from the Washington Monument to the White House."

Mrs. Lewis' ejection fraction has risen to 41. Her heart palpitations and shortness of breath have disappeared. Fatigue is no longer a debilitating problem.

"Now that I feel better, I'd like to return to Bangkok and see the country," says Mrs. Lewis. "The friends we made there would like to meet our son."

Autoimmune diseases

One of the more perplexing questions in medical research is how to keep the body's immune system from attacking its own tissues — as happens in autoimmune disorders such as rheumatoid arthritis. With the disease, the body's immune cells attack cellular proteins as if they were toxins.

Adult stem cells are being used experimentally in clinical research to treat patients with multiple sclerosis, lupus, Crohn's disease and rheumatoid arthritis by Richard K. Burt, M.D., chief of immunotherapy at Northwestern University's Feinberg School of Medicine in Chicago.

As part of an FDA-approved study, Dr. Burt and his researchers draw stem cells from patients' blood. While the stem cells are being grown and purified in a laboratory, he uses chemotherapy to destroy the patient's malfunctioning immune cells. The growth-enhanced stem cells are then reinserted into the patient's body through a blood transfusion. They migrate to the bone marrow and begin growing new, healthy immune cells.

"A patient in Europe has been in remission from rheumatoid arthritis for five years after this treatment,"

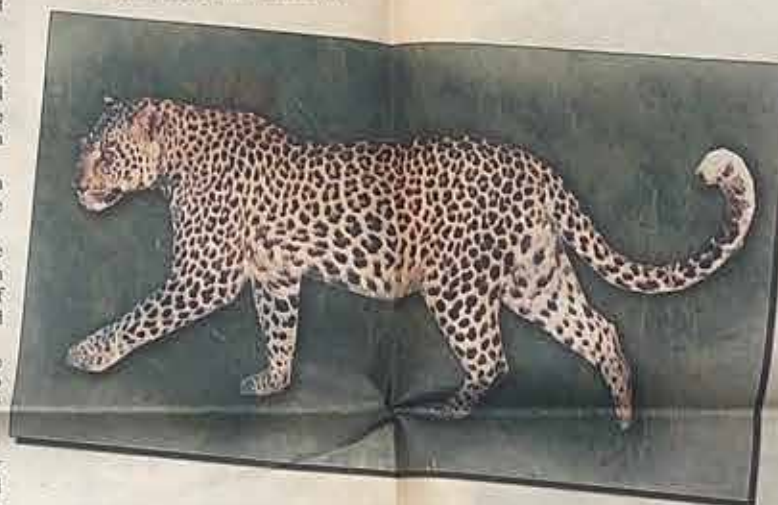
says Dr. Burt. "Our first patient at Northwestern has been in remission for two years and is still going strong."

Another patient at Northwestern was treated with adult stem cell obtained from a donor-matched sibling. The 52-year-old patient had severe rheumatoid arthritis in 38 joints.

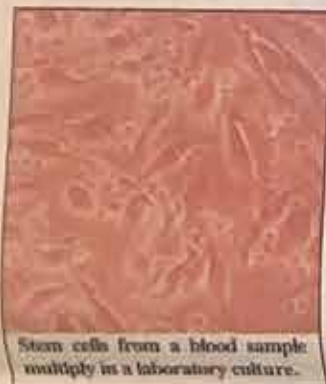
Her arthritic nodules were completely gone nine months after treatment. She has been in remission for three years.

Dr. Burt is one of many scientists who hope, therefore, that the federal government will spend more money on adult stem cell research.

"As a doctor, I don't like to tell patients with incurable diseases to accept their fate," says Dr. Burt. "I believe in biting the bullet and finding something to help them have better quality of life."



Stem cell treatment allows Dennis Turner to pursue his hobby, big game photography, despite Parkinson's disease.



Stem cells from a blood sample multiply in a laboratory culture.

Mr. Turner found out about the opportunity to be a subject in adult stem cell research when a doctor in his hometown referred him to Michael F. Levesque, M.D., a Los Angeles neurosurgeon.

"I was happy to be a test case," says Mr. Turner. "There's nothing unethical about using your own cells from your own body."

Soon after having the stem cells injected, Mr. Turner's symptoms began to improve.

"My trembling grew less and less," he says. "Eventually a neurologist tested me and found that my

she would like to participate in stem cell trials, she was overjoyed.

"I didn't feel that I had too much time to live," she says. "I had inherited a predisposition to heart disease and a blood-clotting disorder. Diabetes had ruined my blood vessels. I couldn't even walk up a flight of stairs."

sels and new tissue," she says.

(Adult stem cell therapy for heart disease is currently considered experimental in the United States and is not routinely available. Occasionally, health insurance coverage can be obtained — on a patient-by-patient basis — for treatment in connection



Doctors in Bangkok are already treating congestive heart failure patients with adult stem cells. (Photo courtesy TheraVita)



Dr. Emerson Perin uses a computer model of the patient's heart to inject stem cells into damaged areas. (Photo courtesy Texas Heart Institute)



Mary Tyler Moore has appeared before the U.S. Senate to advocate for stem cell research.

Aftermath

It has been six years since Dennis Turner's experimental treatment with adult stem cells, and his Parkinson's disease symptoms are starting to reappear.

"I've had six more years of normal life than I would have had otherwise," he says. "Once I had to scramble up a tree to avoid being run over by a rhino. I swam in the South Atlantic with great white sharks. I have gotten some stunning photos of cheetahs and leopards in the wild."

"I'm very happy with the results and would dearly love to have a second treatment." That day may come when Dr. Levesque gets FDA permission to begin another clinical trial. His studies are supported by NeuroGeneration, a biotechnology company, www.neurogeneration.com.

(Information about trials seeking volunteers can be obtained at www.clinicaltrials.gov. TheraVita can be accessed through the toll-free number 1-866-690-2008.)

— M.A.S. ■