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# **#76**

**Human Technology Research Synopsis**

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**Compiled By Ralph Turchiano**

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**Top Five:**

- 1. Bitter melon extract attacks breast cancer cells**
- 2. Vitamin B3 shows early promise in treatment of stroke**
- 3. New evidence that green tea may help fight glaucoma and other eye diseases**
- 4. Lactobacillus improves Helicobacter pylori infected gastritis**
- 5. Flower power can still calm the masses**

**In this issue:**

- 1. Mother's exposure to bisphenol A may increase children's chances of asthma**
- 2. Flu vaccination rate at BJC HealthCare rises dramatically due to mandatory policy**
- 3. First discovery of the female sex hormone progesterone in a plant**
- 4. Inhibiting serotonin in gut could cure osteoporosis**
- 5. Flower power can still calm the masses**
- 6. Lactobacillus improves Helicobacter pylori infected gastritis**
- 7. Researchers develop dietary formula that maintains youthful function into old age**
- 8. Inhibiting serotonin in gut could cure osteoporosis**
- 9. One in Two Children Has Chronic Health Issues**
- 10. High levels of vitamin D in older people can reduce heart disease and diabetes**
- 11. New evidence that green tea may help fight glaucoma and other eye diseases**
- 12. Progesterone for traumatic brain injury tested in phase III clinical trial**
- 13. New study shows sepsis and pneumonia caused by hospital-acquired infections kill 48,000 patients**
- 14. Bitter melon extract attacks breast cancer cells**
- 15. Vitamin B3 shows early promise in treatment of stroke**

## 16. Why BPA leached from 'safe' plastics may damage health of female offspring

**Public release date: 3-Feb-2010**

### **Mother's exposure to bisphenol A may increase children's chances of asthma**

Mouse experiments implicate common ingredient in plastic water bottles and food packaging  
GALVESTON, Texas — For years, scientists have warned of the possible negative health effects of bisphenol A, a chemical used to make everything from plastic water bottles and food packaging to sunglasses and CDs. Studies have linked BPA exposure to reproductive disorders, obesity, abnormal brain development as well as breast and prostate cancers, and in January the Food and Drug Administration announced that it was concerned about "the potential effects of BPA on the brain, behavior and prostate gland of fetuses, infants and young children."

Now, mouse experiments by University of Texas Medical Branch at Galveston researchers have produced evidence that a mother's exposure to BPA may also increase the odds that her children will develop asthma. Using a well-established mouse model for asthma, the investigators found that the offspring of female mice exposed to BPA showed significant signs of the disorder, unlike those of mice shielded from BPA.

"We gave BPA in drinking water starting a week before pregnancy, at levels calculated to produce a body concentration that was the same as that in a human mother, and continued on through the pregnancy and lactation periods," said UTMB associate professor Terumi Midoro-Horiuti, lead author of a paper on the study appearing in the February issue of *Environmental Health Perspectives*.

Four days after birth, the researchers sensitized the baby mice with an allergy-provoking ovalbumin injection, followed by a series of daily respiratory doses of ovalbumin, the main protein in egg white. The investigators then measured levels of antibodies against ovalbumin and quantities of inflammatory white blood cells known as eosinophils in the lungs of the mouse pups. They also used two different methods to measure lung function.

"What we were looking for is the asthma response to a challenge, something like what might happen if you had asthma and got pollen in your nose or lungs, you might have an asthma attack," said UTMB professor Randall Goldblum, also an author of the paper. "All four of our indicators of asthma response showed up in the BPA group, much more so than in the pups of the nonexposed mice."

The UTMB researchers said that although more work is needed to determine the precise mechanism of that response, it almost certainly has its roots in the property of BPA thought to contribute to other health problems: its status as an "environmental estrogen." Environmental estrogens are natural or artificial chemicals from outside the body that when consumed mimic the hormone estrogen, activating its powerful biochemical signaling networks in often dangerous ways. In a 2007 *Environmental Health Perspectives* paper, for example, Midoro-Horiuti, Goldblum and UTMB professor and current study co-author Cheryl Watson described how adding small amounts of environmental estrogens into cultures of human and mouse mast cells — common immune cells packed with allergic response-inducing chemicals such as histamine — produced a sudden release of allergy-promoting substances.

"Our results show that we have to consider the possible impact of environmental estrogens on normal immune development and on the development and morbidity of immunologic diseases such as asthma," Midoro-Horiuti said. "We also need to look at doing more epidemiological studies directly in humans, which is possible because BPA is so prevalent in the environment — all of us are already loaded with it to a varying extent. For example, it should be possible to determine if children who have more BPA exposure are more likely to develop asthma."

**Public release date: 3-Feb-2010**

## **Flu vaccination rate at BJC HealthCare rises dramatically due to mandatory policy**

Making flu shots mandatory in 2008 dramatically increased the vaccination rate among St. Louis-based BJC HealthCare's nearly 26,000 employees to more than 98 percent, according to a report now online in the journal *Clinical Infectious Diseases*.

**The study's lead author, infectious disease specialist Hilary Babcock, M.D., says the success of the mandatory program demonstrates it is possible to implement a vaccination campaign on a large scale in a health-care setting.**

"As a patient safety initiative, we knew the flu shot was safe and effective, and the best way to protect patients was to be sure that employees were vaccinated," she says.

For 10 years, BJC – affiliated with Washington University School of Medicine – offered the influenza vaccine free of charge to its employees, conducted extensive education campaigns about the benefits of the shot and provided incentives to employees. While vaccination rates were consistently above the national average, they remained below BJC's target of 80 percent. The nonprofit health care organization includes 13 hospitals in St. Louis, southern Illinois and mid-Missouri.

In 2006, 54 percent of BJC employees received the influenza vaccine, only slightly above average for health-care workers nationwide. In 2007, BJC employees who declined to get a flu shot were asked to sign a statement saying they understood the risk to themselves, their patients and their families. That year, the vaccination rose to 71 percent, still below BJC's target rate.

Then in 2008, with a focus on patient safety, BJC made the influenza vaccine mandatory for all its employees, regardless of whether they worked directly with patients. Again, the health system provided educational programs about the benefits of the vaccine and made the shot available at no charge to employees at multiple times and locations.

Employees could request religious or medical exemptions, which were reviewed by human resources and occupational health nurses, respectively. Interestingly, many fewer employees sought medical or religious exemptions than had signed declination statements in the previous year.

Overall, 25,561 (98.4 percent) of BJC employees received an influenza vaccine in 2008. In addition, 90 employees (.3 percent) received religious exemptions, and 321 (1.2 percent) received medical exemptions. Medical exemptions included severe allergy to eggs, prior allergic reactions to the flu vaccine and a history of Guillain-Barré syndrome.

"Some of the requests for medical exemptions reflected misinformation about the vaccine and influenza," says Babcock, an associate professor of medicine, who conducted the study with senior author Keith Woeltje, M.D., Ph.D., associate professor of medicine. For example, some requests cited asthma, cancer or a suppressed immune system, even though these conditions increase the risk of flu-related complications and are reasons to get vaccinated.

**In all, eight employees were terminated because they were not vaccinated or granted an exemption. Most of these employees did not submit an exemption request.**

Babcock attributes success of the program to the support of hospital leadership and consistent communication from BJC staff that emphasized patient safety. "Overall, the program went very smoothly," she says. "We were able to talk with the people who had concerns about the vaccine and allay their fears. A

large number of employees were really glad that we had made it mandatory and that co-workers were being vaccinated.”

At the two teaching hospitals that are part of BJC HealthCare, Barnes-Jewish Hospital and St. Louis Children’s Hospital, all 907 medical residents and fellows complied with the mandatory policy; five received medical or religious exemptions.

Although physicians employed by BJC were required to get the flu shot, most physicians affiliated with BJC HealthCare are in private practice or are employed by Washington University School of Medicine and are not covered by the mandatory policy.

In the United States, influenza is associated with 36,000 deaths and more than 200,000 hospitalizations each year, and it is the leading cause of vaccine-preventable death. Other vaccines, including those for the measles, mumps, rubella and chicken pox, already are required by many health-care organizations, including BJC.

Babcock says she now plans to collect data for the 2009 flu season, when employees have been required to get both the seasonal flu vaccine and the H1N1 vaccine.

**Ralph’s Note - I hope those eight employees sue, the heck out of these nuts... We know it has been shown the Flu vaccine has been coming into question especially in seniors and asthmatic children. The fact the a Company can implement a mandatory medication policy is probably one of the most disturbing things ever. What if the company implemented mandatory birth control pills, due its concerns over paying for pregnancy leave.**

**Public release date: 4-Feb-2010**

## **First discovery of the female sex hormone progesterone in a plant**

In a finding that overturns conventional wisdom, scientists are reporting the first discovery of the female sex hormone progesterone in a plant. Until now, scientists thought that only animals could make progesterone. A steroid hormone secreted by the ovaries, progesterone prepares the uterus for pregnancy and maintains pregnancy. A synthetic version, progestin, is used in birth control pills and other medications. The discovery is reported in the American Chemical Society's Journal of Natural Products, a monthly publication.

"The significance of the unequivocal identification of progesterone cannot be overstated," the article by Guido F. Pauli and colleagues, states. "While the biological role of progesterone has been extensively studied in mammals, the reason for its presence in plants is less apparent." They speculate that the hormone, like other steroid hormones, might be an ancient bioregulator that evolved billions of years ago, before the appearance of modern plants and animals. The new discovery may change scientific understanding of the evolution and function of progesterone in living things.

Scientists previously identified progesterone-like substances in plants and speculated that the hormone itself could exist in plants. But researchers had not found the actual hormone in plants until now. Pauli and colleagues used two powerful laboratory techniques, nuclear magnetic resonance and mass spectroscopy, to detect progesterone in leaves of the Common Walnut, or English Walnut, tree. They also identified five new progesterone-related steroids in a plant belonging to the buttercup family.

**Public release date: 7-Feb-2010**

## **Inhibiting serotonin in gut could cure osteoporosis**

**Finding, in animal model, offers proof of principle that inhibiting serotonin in the gut could become a novel treatment for 10s of millions of osteoporosis sufferers**

NEW YORK – An investigational drug that inhibits serotonin synthesis in the gut, administered orally once daily, effectively cured osteoporosis in mice and rats reports an international team led by researchers from Columbia University Medical Center, in the Feb. 7 issue of Nature Medicine. Serotonin in the gut has been shown in recent research to stall bone formation. The finding could lead to new therapies that build new bone; most current drugs for osteoporosis can only prevent the breakdown of old bone.

"New therapies that inhibit the production of serotonin in the gut have the potential to become a novel class of drugs to be added to the therapeutic arsenal against osteoporosis," said Gerard Karsenty, M.D., Ph.D., chair of the Department of Genetics and Development at Columbia University College of Physicians and Surgeons, lead author of the paper. "With tens of millions of people worldwide affected by this devastating and debilitating bone loss, there is an urgent need for new treatments that not only stop bone loss, but also build new bone. Using these findings, we are working hard to develop this type of treatment for human patients."

The Nature Medicine paper follows on a major discovery:

[http://www.cumc.columbia.edu/news/press\\_releases/Karsenty-cell-serotonin-lrp5.html](http://www.cumc.columbia.edu/news/press_releases/Karsenty-cell-serotonin-lrp5.html), also made by Dr. Gerard Karsenty's group (published in the Nov. 26, 2008 issue of Cell), **that serotonin released by the gut inhibits bone formation**, and that regulating the production of serotonin within the gut affects the formation of bone. Prior to this discovery, serotonin was primarily known as a neurotransmitter acting in the brain. Yet, 95 percent of the body's serotonin is found in the gut, where its major function is to inhibit bone formation (the remaining five percent is in the brain, where it regulates mood, among other critical functions). By turning off the intestine's release of serotonin, the team was able, in this new study, to cure osteoporosis in mice that had undergone menopause.

Based on their findings reported in the Cell paper, **Dr. Karsenty and his team postulated that an inhibitor of serotonin synthesis should be an effective treatment for osteoporosis.** Shortly thereafter, they read about an investigational drug, known as LP533401, which is able to inhibit serotonin in the gut. "When we learned of this compound, we thought that it was important to test it as proof of principle that there could be novel ways to treat osteoporosis with therapies that can be taken orally and regulate the formation of serotonin," said Dr. Karsenty.

Dr. Karsenty and his team developed a research protocol to test their theory, where they administered the compound orally, once daily, at a small dose, for up to six weeks to rodents experiencing post-menopausal osteoporosis. Results demonstrated that osteoporosis was prevented from developing, or when already present, could be fully cured. Of critical importance, levels of serotonin were normal in the brain, which indicated that the compound did not enter the general circulation and was unable to cross the blood-brain barrier, thereby avoiding many potential side effects.

Implications for the Treatment of Osteoporosis:

Most osteoporosis drugs, including those currently under clinical investigation, do not generate new bone but rather, prevent the breakdown of old bone. Only one drug currently on the market can generate new bone – but it must be taken by injection once a day, and because it may increase the risk of bone cancer, at least in rats, its use is restricted for short-term use in women with severe osteoporosis.

"There is an urgent need to identify new, safe therapies that can increase bone formation on a long term basis and to such an extent that they compensate for the increase in bone resorption caused by menopause," said Dr. Karsenty. "Furthermore, it is important to note that since this study was conducted in rodents, it will need further confirmation in human subjects."

Osteoporosis: A Disease of Bone Mass Decline...

Osteoporosis is a growing public health concern, with the aging population and the incidence of post-menopausal osteoporosis on the rise. It is a disease of low bone mass, most often caused by an increase in bone resorption not compensated by a similar increase in bone formation.

Far from being inert, bone constantly undergoes renovation, with some cells responsible for removing old material and other cells responsible for creating new bone. In humans, after age 20, the balance between bone formation and breakdown tips toward breakdown, and bone mass starts to decline. In women, the rate of decline increases after menopause, when estrogen levels drop and cells that tear down old bone become overactive. Osteoporosis is a disease in which bones become fragile and porous, increasing the risk of breaks. It is diagnosed when bone mass drops below a certain level.

**Public release date: 8-Feb-2010**

## **Flower power can still calm the masses**

Feeling stressed? Try chamomile! This 'traditional' remedy has been around for years, but how much truth is there behind this old wives' tale?

In an evaluation for Faculty of 1000, Michael Van Ameringen and Beth Patterson draw attention to the first randomized controlled trial of chamomile for the treatment of generalized anxiety disorder (GAD).

The study, recently published in the Journal of Clinical Psychopharmacology, reports that "chamomile extract therapy was found to be efficacious for mild-moderate GAD".

Patients with mild-moderate GAD were included in the study and received either chamomile or placebo. Those that received the chamomile treatment were found to have a significant change in the severity of their GAD.

Van Amerigen and Patterson comment on the results of the study, saying that they "suggest that chamomile may have modest [anti-panic] activity in patients with mild-moderate GAD and may potentially be used in those who are averse to traditional pharmacotherapy".

These findings are important "because many individuals who suffer from GAD do not view their anxiety as a medical condition, [and, therefore,] self-diagnosis and self-medicating with alternative, over-the-counter remedies is common".

Van Amerigen and Patterson said "a big strength of this paper is that the authors took a herbal remedy and subjected it to scientific rigor unlike many 'natural' remedies which have associated claims of efficacy with no supportive data."

**Public release date: 9-Feb-2010**

## **Lactobacillus improves Helicobacter pylori infected gastritis**

Helicobacter pylori (H. pylori) are considered to be the most important etiological agents of chronic gastritis. The eradication of H. pylori depends on the combination of antibiotics and acid suppression drugs. Unfortunately, the side effects of antibiotics reduce the curative effect and treatment compliance. Probiotics provides an alternative method which can inhibit H. pylori infection efficiently without antibiotics associated side effects.

A research team from China investigated the potential anti-H. pylori and anti-inflammation in vivo effects of two lactobacillus strains from human stomach. Their study will be published on January 28, 2010 in the World Journal of Gastroenterology.

Their results illustrated that both lactobacillus strain Lactobacillus fermenti (L. fermenti) and Lactobacillus acidophilus (L. acidophilus), showed significant anti-H. pylori activity, while strain L. fermenti displayed more efficient antagonistic activity in vivo whose efficacy is close to the standard triple therapy, thus significantly improving the H. pylori-associated Balb/c gastritis.

Their study provided a new clue for the therapy of H. pylori associated diseases, which could be prevented and treated by regulating the balance of flora in stomach. Thus lactobacillus can be a choice to replace antibiotics or as an adjuvant to antibiotics in treating H. pylori-infected diseases.

**Public release date: 11-Feb-2010**

## **Researchers develop dietary formula that maintains youthful function into old age**

HAMILTON, ON. February 11, 2010 – Researchers at McMaster University have developed a cocktail of ingredients that forestalls major aspects of the ageing process.

The findings are published in the current issue of Experimental Biology and Medicine.

"As we all eventually learn, ageing diminishes our mind, fades our perception of the world and compromises our physical capacity," says David Rollo, associate professor of biology at McMaster. "Declining physical activity—think of grandparents versus toddlers—is one of the most reliable expressions of ageing and is also a good indicator of obesity and general mortality risk."

The study found that a complex dietary supplement powerfully offsets this key symptom of ageing in old mice by increasing the activity of the cellular furnaces that supply energy—or mitochondria—and by reducing emissions from these furnaces—or free radicals—that are thought to be the basic cause of ageing itself.

Most of the primary causes of human mortality and decline are strongly correlated with age and free-radical processes, including heart disease, stroke, Type II diabetes, many cancers, neurodegenerative diseases, and inflammatory and autoimmune conditions. Successful intervention into the ageing process could consequently prevent or forestall all of these.

Using bagel bits soaked in the supplement to ensure consistent and accurate dosing, the formula maintained youthful levels of locomotor activity into old age whereas old mice that were not given the supplement showed a 50 per cent loss in daily movement, a similar dramatic loss in the activity of the cellular furnaces that make our energy, and

declines in brain signaling chemicals relevant to locomotion. This builds on the team's findings that the supplement extends longevity, prevents cognitive declines, and protects mice from radiation.

Ingredients consists of items that were purchased in local stores selling vitamin and health supplements for people, including vitamins B1, C, D, E, acetylsalicylic acid, beta carotene, folic acid, garlic, ginger root, ginkgo biloba, ginseng, green tea extract, magnesium, melatonin, potassium, cod liver oil, and flax seed oil. Multiple ingredients were combined based on their ability to offset five mechanisms involved in ageing.

For Rollo, the results go beyond simply prolonging the lifespan.

"For ageing humans maintaining zestful living into later years may provide greater social and economic benefits than simply extending years of likely decrepitude," he says. "This study obtained a truly remarkable extension of physical function in old mice, far greater than the respectable extension of longevity that we previous documented. This holds great promise for extending the quality of life of "health span" of humans."

Development of new and hopefully more effective supplements is ongoing.

### **Public Release: 16-Feb-2010**

## **One in Two Children Has Chronic Health Issues**

TUESDAY, Feb. 16 (HealthDay News) -- One in every two U.S. children now grapples at some time with a chronic health condition, such as asthma, attention-deficit hyperactivity disorder (ADHD) or obesity, new research suggests.

The good news is that for many of those children, their chronic childhood illness won't persist. Just over 7 percent of those who reported a chronic condition at the beginning of the study still had the condition six years later.

"Over time, we found the rates of chronic conditions and obesity in U.S. children increased, but quite a few of these conditions resolved on their own," said study author Dr. Jeanne Van Cleave, a pediatrician at MassGeneral Hospital for Children in Boston.

The findings are published in the Feb. 17 issue of the Journal of the American Medical Association.

A chronic health condition is one that lasts at least 12 months, according to the study. Some of the conditions included asthma, type 1 diabetes, type 2 diabetes, epilepsy, cystic fibrosis, heart problems, allergic conditions, learning disabilities, hyperactivity, sinus infections, ear infections and more. Obesity was defined as a body-mass index in the 95th

percentile or higher for the child's gender and age.

The researchers conducted the study using three different groups of children. The first cohort, which included 2,337 children, was interviewed during 1988 to 1994; the second, which included 1,759 children, was interviewed during 1994 to 2000 and the final group, which included 905 children, was interviewed from 2000 to 2006.

At the beginning of each period, the children were between the ages of 2 and 8; chronic conditions were confirmed by reports from parents.

At the end of each study, the prevalence of chronic illness or obesity was 12.8 percent in the first (earliest) group, 25 percent for the second group and 26.6 percent for the third (and most recent) group. The third group also had the highest prevalence of reporting a chronic condition at any time during the six-year study period, with 51.5 percent reporting a chronic condition at some point during the study.

The risk of having a chronic condition was higher for males, and for children who were black or Hispanic. Kids who had overweight mothers were far more likely to be overweight themselves, according to the study.

What surprised the authors, however, was that the chronic conditions weren't always lasting. Overall, only 7.4 percent of the children who had a chronic condition at the start of the study still had that same condition at the end of the research period.

"We've always thought of chronic conditions as quite permanent, so these findings give a lot of hope for kids with chronic conditions and obesity," said Van Cleave.

She said these findings also raise a number of research questions, as well as point to the need for good health care, including prevention and education services.

"It's likely that a lot of these conditions resolved because families made lifestyle changes, such as eating healthier foods, reducing screen time and becoming more physically active," she said.

"The burden of chronic disease in children is pretty high," said Dr. Geetha Raghuvver, a cardiologist and an associate professor at Children's Mercy Hospital in Kansas City, Mo.

Raghuvver said she isn't sure how much of the fluctuation in chronic conditions is real, because they're based on parental reports. "Some of the major issues here, like established childhood obesity, don't fluctuate and go away in our experience without a rigorous attempt. Although it's probably reassuring that at least some of these conditions may go

away in time," she said.

But the bottom line, she said, is that U.S. children need better health habits. "This is just another study emphasizing what many already knew. And, if we don't eradicate the root causes, such as bad eating and little exercise, we'll continue to see a lot more morbidity in children," Raghuveer said.

"I'm seeing more and more kids with high cholesterol and insulin resistance that already have blood vessel damage in them. **They're already like a 45-year-old in terms of blood vessel health. We need a basic change in how we live and how we eat. Prevention is key,**" she stressed.

**Public Release: 16-Feb-2010**

## **High levels of vitamin D in older people can reduce heart disease and diabetes**

Middle aged and elderly people with high levels of vitamin D could reduce their chances of developing heart disease or diabetes by 43%, according to researchers at the University of Warwick.

A team of researchers at Warwick Medical School carried out a systematic literature review of studies examining vitamin D and cardiometabolic disorders. Cardiometabolic disorders include cardiovascular disease, type 2 diabetes mellitus and metabolic syndrome.

Vitamin D is a fat-soluble vitamin that is naturally present in some foods and is also produced when ultraviolet rays from sunlight strike the skin and trigger vitamin D synthesis. Fish such as salmon, tuna and mackerel are good sources of vitamin D, and it is also available as a dietary supplement.

Researchers looked at 28 studies including 99,745 participants across a variety of ethnic groups including men and women. The studies revealed a significant association between high levels of vitamin D and a decreased risk of developing cardiovascular disease (33% compared to low levels of vitamin D), type 2 diabetes (55% reduction) and metabolic syndrome (51% reduction).

The literature review, published in the journal *Maturitas*, was led by Johanna Parker and Dr Oscar Franco, Assistant Professor in Public Health at Warwick Medical School.

Dr Franco said: "We found that high levels of vitamin D among middle age and elderly populations are associated with a substantial decrease in cardiovascular disease, type 2 diabetes and metabolic syndrome.

"Targeting vitamin D deficiency in adult populations could potentially slow the current

epidemics of cardiometabolic disorders.”

All studies included were published between 1990 and 2009 with the majority published between 2004 and 2009. Half of the studies were conducted in the United States, eight were European, two studies were from Iran, three from Australasia and one from India.

**Public release date: 18-Feb-2010**

### **New evidence that green tea may help fight glaucoma and other eye diseases**

Scientists have confirmed that the healthful substances found in green tea — renowned for their powerful antioxidant and disease-fighting properties — do penetrate into tissues of the eye. Their new report, the first documenting how the lens, retina, and other eye tissues absorb these substances, raises the possibility that green tea may protect against glaucoma and other common eye diseases. It appears in ACS's bi-weekly Journal of Agricultural and Food Chemistry.

Chi Pui Pang and colleagues point out that so-called green tea "catechins" have been among a number of antioxidants thought capable of protecting the eye. Those include vitamin C, vitamin E, lutein, and zeaxanthin. Until now, however, nobody knew if the catechins in green tea actually passed from the stomach and gastrointestinal tract into the tissues of the eye.

Pang and his colleagues resolved that uncertainty in experiments with laboratory rats that drank green tea. Analysis of eye tissues showed beyond a doubt that eye structures absorbed significant amounts of individual catechins. The retina, for example, absorbed the highest levels of gallic catechin, while the aqueous humor tended to absorb epigallocatechin. **The effects of green tea catechins in reducing harmful oxidative stress in the eye lasted for up to 20 hours.** "Our results indicate that green tea consumption could benefit the eye against oxidative stress," the report concludes.

**Public release date: 19-Feb-2010**

### **Progesterone for traumatic brain injury tested in phase III clinical trial**

Researchers at 17 medical centers across the country soon will begin using the hormone progesterone to treat patients who experience traumatic brain injury (TBI). The treatment is part of a randomized, double-blind Phase III clinical trial that will enroll approximately 1,140 people over a three- to six-year period beginning in March, 2010. The trial is funded by a grant to Emory University from the National Institutes of Health.

The clinical trial is led by David Wright, MD, associate professor of emergency medicine at Emory University School of Medicine. Atlanta's Grady Memorial Hospital will serve as the lead center, with faculty from Emory School of Medicine and Morehouse School

of Medicine.

Wright will discuss progress in clinical trials using progesterone for TBI at the American Association for the Advancement of Science (AAAS) Annual Meeting in San Diego. His presentation takes place in a panel discussion about traumatic brain injury at 1:30 p.m. PST, Friday, Feb. 19, 2010.

Emory researchers concluded in an earlier three-year clinical trial conducted in 100 patients that giving progesterone to trauma victims shortly after a brain injury appears to be safe and may reduce the risk of death and long-term disability. That clinical trial was called ProTECT I (Progesterone for Traumatic brain injury – Experimental Clinical Treatment). The current trial is named ProTECT III.

The earlier trial found evidence that progesterone is safe for use in patients suffering from traumatic brain injuries. Results also showed a 50 percent reduction in mortality in those patients treated with progesterone. The treatment improved functional outcomes and reduced disability in patients with moderate brain injury.

Progesterone is naturally present in small but measurable amounts in the brains of males and females. Human brain tissue is loaded with progesterone receptors. Laboratory studies suggest that progesterone is critical for the normal development of neurons in the brain and exerts protective effects on damaged brain tissue.

Donald G. Stein, PhD, Asa G. Candler Professor of Emergency Medicine, Emory School of Medicine, and director of Emory's Department of Emergency Medicine Brain Research Laboratory, pioneered discoveries regarding the effect of progesterone following traumatic brain injury – first discovering the neuro-protective properties of progesterone in the laboratory more than 25 years ago.

Every 15 seconds, someone in the United States sustains a significant traumatic brain injury. Approximately 2 million adults and children in the United States suffer from traumatic brain injuries each year - leading to 50,000 deaths and 80,000 new cases of long-term disability, according to the Centers for Disease Control and Prevention. Despite the enormity of the problem, scientists have failed to identify effective medications to improve outcomes following a traumatic brain injury.

"No new treatment for severe TBI has been approved in over 30 years," says Wright. "With such promising success in laboratory testing and in our previous clinical trial, we hope to conclude in this national trial that progesterone—along with standard medical trauma care—works better than standard medical care alone in reducing brain damage caused from a TBI." Site principal investigators for the proTECT III trial at Grady Memorial Hospital in Atlanta will be Michael Frankel, MD, Emory professor of neurology, and Jeffrey Salomone, MD, Emory associate professor of surgery. The trial will be conducted through the Neurological Emergencies Treatment Trial (NETT) network coordinated by the University of Michigan. Data analysis will occur at the Medical University of South Carolina.

## Exception from Informed Consent (EFIC)

As part of the trial, patients who are enrolled in the study may be provided the progesterone hormone without consent of family members or next-of-kin, in large part because success of the drug is highly dependent on its being administered to the patient as quickly as possible after sustaining a brain injury.

According to Wright, researchers normally get permission (consent) before a person participates in a clinical study. If that person is unconscious, such as in a traumatic brain injury (TBI), they will be unable to consent for themselves. In these cases researchers will ask for permission from a person's legal guardian (usually next of kin). However, since TBI must be treated quickly, there might not be enough time to locate and talk to someone about the study before the medication is started.

"In ProTECT III, a person might very well be enrolled in the study without a legal guardian's or family member's consent," explains Wright. "The U.S. Food and Drug Administration (FDA) has, in fact, created a set of special rules, called "Exception from Informed Consent" (EFIC). These rules allow research studies in certain emergency situations to be conducted without consent."

EFIC applies only when all of the following apply: A. The person is in a life-threatening situation; B. Current treatments are unproven or unsatisfactory; C. The study might provide direct benefit to the person; D. It is not possible to obtain informed consent from: 1) the person because of his or her medical condition or 2) the person's guardian because there is a very short amount of time required to treat the medical condition.

### **Public release date: 22-Feb-2010**

## **New study shows sepsis and pneumonia caused by hospital-acquired infections kill 48,000 patients**

Cost \$8.1 billion to treat

Washington D.C. – Two common conditions caused by hospital-acquired infections (HAIs) killed 48,000 people and ramped up health care costs by \$8.1 billion in 2006 alone, according to a study released today in the Archives of Internal Medicine.

This is the largest nationally representative study to date of the toll taken by sepsis and pneumonia, two conditions often caused by deadly microbes, including the antibiotic-resistant bacteria MRSA. Such infections can lead to longer hospital stays, serious complications and even death.

"In many cases, these conditions could have been avoided with better infection control in hospitals," said Ramanan Laxminarayan, Ph.D., principal investigator for Extending the Cure, a project examining antibiotic resistance based at the Washington, D.C. think-tank Resources for the Future.

"Infections that are acquired during the course of a hospital stay cost the United States a staggering amount in terms of lives lost and health care costs," he said. "Hospitals and other health care providers must act

now to protect patients from this growing menace."

Laxminarayan and his colleagues analyzed 69 million discharge records from hospitals in 40 states and identified two conditions caused by health care-associated infections: sepsis, a potentially lethal systemic response to infection and pneumonia, an infection of the lungs and respiratory tract.

The researchers looked at infections that developed after hospitalization. They zeroed in on infections that are often preventable, like a serious bloodstream infection that occurs because of a lapse in sterile technique during surgery, and discovered that the cost of such infections can be quite high: For example, people who developed sepsis after surgery stayed in the hospital 11 days longer and the infections cost an extra \$33,000 to treat per person.

Even worse, the team found that nearly 20 percent of people who developed sepsis after surgery died as a result of the infection. "That's the tragedy of such cases," said Anup Malani, a study co-author, investigator at Extending the Cure, and professor at the University of Chicago. "In some cases, relatively healthy people check into the hospital for routine surgery. They develop sepsis because of a lapse in infection control—and they can die."

The team also looked at pneumonia, an infection that can set in if a disease-causing microbe gets into the lungs—in some cases when a dirty ventilator tube is used. They found that people who developed pneumonia after surgery, which is also thought to be preventable, stayed in the hospital an extra 14 days. Such cases cost an extra \$46,000 per person to treat. In 11 percent of the cases, the patient died as a result of the pneumonia infection.

According to the authors, HAIs frequently are caused by microbes that defy treatment with common antibiotics. "These superbugs are increasingly difficult to treat and, in some cases, trigger infections that ultimately cause the body's organs to shut down," said Malani.

In 2002, the Centers for Disease Control and Prevention estimated that all hospital-acquired infections were associated with 99,000 deaths per year. While the Extending the Cure study looked at only two of the most common and serious conditions caused by these infections, it also calculated deaths actually caused by, rather than just associated with, infections patients get in the hospital.

Based on their research, study authors were able to estimate the annual number of deaths and health care costs due to sepsis and pneumonia that is actually preventable.

"The nation urgently needs a comprehensive approach to reduce the risk posed by these deadly infections," he added. "Improving infection control is a clear way to both improve patient outcomes and lower health care costs

**Public release date: 23-Feb-2010**

## **Bitter melon extract attacks breast cancer cells**

### **Early Saint Louis University research points to promising area of research**

ST. LOUIS -- The extract from a vegetable that is common in India and China shows promise in triggering a chain of events that kills breast cancer cells and prevents them from multiplying, a Saint Louis University researcher has found.

Ratna Ray, Ph.D., professor in the department of pathology at Saint Louis University and lead researcher, said she was surprised that the extract from the bitter melon she cooks in stir fries inhibits the growth of breast cancer cells.

"To our knowledge, this is the first report describing the effect of bitter melon extract on cancer cells," Ray

said. **"Our result was encouraging. We have shown that bitter melon extract significantly induced death in breast cancer cells and decreased their growth and spread."**

Ray said she decided to study the impact of bitter melon extract on breast cancer cells because research by others have shown the substance lowers blood sugar and cholesterol levels. Bitter melon extract is commonly used as a folk medicine to treat diabetes in China and India, she said.

Ray conducted her research using human breast cancer cells in vitro – or in a controlled lab setting. The next step, she says, is to test bitter melon extract in an animal model to see if it plays a role in delaying the growth or killing of breast cancer cells. If those results are positive, human trials could follow.

While it's too early to know for sure whether bitter melon extract will help breast cancer patients, the question is worth studying, Ray said.

"There have been significant advances in breast cancer treatment, which have improved patient survival and quality of life. However women continue to die of the disease and new treatment strategies are essential," Ray said.

**"Cancer prevention by the use of naturally occurring dietary substances is considered a practical approach to reduce the ever-increasing incidence of cancer. Studying a high risk breast cancer population where bitter melon is taken as a dietary product will be an important area of future research," Ray said.**

She cautioned against seeing bitter melon extract as a miracle cure for breast cancer.

"Bitter melon is common in China and India, and women there still get breast cancer," Ray said.

**Public release date: 24-Feb-2010**

## **Vitamin B3 shows early promise in treatment of stroke**

An early study suggests that vitamin B3 or niacin, a common water-soluble vitamin, may help improve neurological function after stroke, according to Henry Ford Hospital researchers.

When rats with ischemic stroke were given niacin, their brains showed growth of new blood vessels, and sprouting of nerve cells which greatly improved neurological outcome.

Now research is underway at Henry Ford to investigate the effects of an extended-release form of niacin on stroke patients. Henry Ford is the only site nationally conducting such a study.

"If this proves to also work well in our human trials, we'll then have the benefit of a low-cost, easily-tolerable treatment for one of the most neurologically devastating conditions," Michael Chopp, Ph.D., scientific director of the Henry Ford Neuroscience Institute.

Dr. Chopp will present results from the animal model study at the International Stroke Conference in San Antonio.

According to the National Stroke Association, stroke is the third-leading cause of death in America and a leading cause of disability.

Ischemic strokes occur as a result of an obstruction within a blood vessel supplying blood to the brain. Ischemic stroke accounts for about 87 percent of all cases. One underlying condition for this type of obstruction is the development of fatty cholesterol deposits lining the vessel walls.

Niacin is known to be the most effective medicine in current clinical use for increasing high-density lipoprotein cholesterol (HDL-C), which helps those fatty deposits.

Dr. Chopp and his colleagues found that in animals niacin helps restore neurological function in the brain following stroke.

In 2009, stroke physicians at Henry Ford Hospital published research which showed that HDL-C is abnormally low at the time stroke patients arrive at the hospital.

**Dr. Chopp's research found that in animals, niacin increased "good" cholesterol (HDL-C), which increased blood vessels in the brain and axonal and dendritic growth leading to a substantial improvement in neurological function.**

"Niacin essentially re-wires the brain which has very exciting potential for use in humans," says Dr. Chopp. "The results of this study may also open doors in other areas of neurological medicine, including brain injury."

Andrew Russman, D.O., is the principal investigator of the team at Henry Ford Hospital who will evaluate in clinical trials whether niacin improves recovery for human stroke patients.

"If we are able to prove that treating patients with niacin helps to restore neurological function after stroke, we're opening a whole new avenue of treatment for the leading cause of serious long-term disability in adults," says Dr. Russman.

**Public release date: 25-Feb-2010**

## **Why BPA leached from 'safe' plastics may damage health of female offspring**

Yale scientists show how bisphenol A induces epigenetic changes in pregnant mice that cause hormonal imbalance in the later life of female progeny

Here's more evidence that "safe" plastics are not as safe as once presumed: New research published online in The FASEB Journal (<http://www.fasebj.org>) suggests that exposure to Bisphenol A (BPA) during pregnancy leads to epigenetic changes that may cause permanent reproduction problems for female offspring. BPA, a common component of plastics used to contain food, is a type of estrogen that is ubiquitous in the environment.

"Exposure to BPA may be harmful during pregnancy; this exposure may permanently affect the fetus," said Hugh S. Taylor, Ph.D., co-author of the study from Yale University School of Medicine in New Haven, Connecticut. "We need to better identify the effects of environmental contaminants on not just crude measures such as birth defects, but also their effect in causing more subtle developmental errors."

Taylor and colleagues made this discovery by exposing fetal mice to BPA during pregnancy and examining gene expression and DNA in the uteruses of female fetuses. Results showed that BPA exposure permanently affected the uterus by decreasing regulation of gene expression. These epigenetic changes caused the mice to over-respond to estrogen throughout adulthood, long after the BPA exposure. **This suggests that early exposure to BPA genetically "programmed" the uterus to be hyper-responsive to estrogen. Extreme estrogen sensitivity can lead to fertility problems, advanced puberty, altered mammary development and reproductive function, as well as a variety of hormone-related cancers.** BPA has been widely used in plastics and other materials. **Examples include use in water bottles, baby bottles, epoxy resins used to coat food cans, and dental sealants.**

"The BPA baby bottle scare may be only the tip of the iceberg." said Gerald Weissmann, M.D., Editor-in-Chief of The FASEB Journal. "Remember how diethylstilbestrol (DES) caused birth defects and cancers in young women whose mothers were given such hormones during pregnancy. We'd better watch out for BPA, which seems to carry similar epigenetic risks across the generations. "

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**These reports are done with the appreciation of all the Doctors, Scientist, and other Medical Researchers who sacrificed their time and effort. In order to give people the ability to empower themselves. Without the base aspirations for fame, or fortune. Just honorable people, doing honorable things.**