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**Public release date: 30-Sep-2008**

## **News media often do not report potential sources of bias in medical research**

An analysis of news media coverage of medical studies indicates that news articles often fail to report pharmaceutical company funding and frequently refer to medications by their brand names, both potential sources of bias, according to a study in the October 1 issue of JAMA.

New articles represent an important source of medical information for many patients, and even some physicians. "An increasingly recognized source of commercial bias in medical research is the funding of studies by companies with a financial interest in the results," the authors write. Little is known about how frequently news articles report the funding sources of the medical research they report on, or how frequently news articles use brand medication names instead of generic names, which could create commercial bias.

Michael Hochman, M.D., of the Cambridge Health Alliance and Harvard Medical School, Cambridge, Mass., and colleagues reviewed U.S. news articles from newspaper and online sources about pharmaceutical-funded medication studies to determine how frequently and prominently they indicate the funding source and how often they refer to medications by their brand vs. generic names. The studies were published in five major general medical journals (JAMA, New England Journal of Medicine, Lancet, Archives of Internal Medicine and the Annals of Internal Medicine). The researchers also surveyed editors at the 100 most widely circulated newspapers in the U.S. about their publications' practices on the reporting of company funding and the use of generic medication names.

**The authors identified 306 news articles, of which 175 were from newspapers and 131 were from online sources. Among the 306 news articles about company-funded medication studies, the funding source for the studies was not reported in 42 percent of the articles. There was no significant difference in nonreporting rates between articles obtained from newspaper and online sources. Of the 306 news articles, 277 concerned medications with both generic and brand names. Among these 277 articles, 38 percent used only brand names and 67 percent used brand names in at least half of the medication references.**

The survey of newspaper editors found that 88 percent indicated that his/her publication often or always reported company funding in articles about medical research, and that 77 percent reported

that they often or always referred to medications by the generic names in articles about medical research. Three percent of editors indicated that their publication had a written policy stating that company funding should be reported in articles about medical research, while the editor at two percent of newspapers responded that his/her publication had a written policy stating that medications should be referred to predominantly by their generic names.

However, the editors' perceptions diverged from their publications' actual performances. **A total of 104 newspaper articles were analyzed from publications for which editors reported always identifying company funding. Of these articles, 45 percent failed to cite company funding. Additionally, a total of 75 newspaper articles were analyzed from publications for which the editors reported always using generic names. Of these articles, 76 percent used brand names in at least half of the medication references.**

"Our findings raise several concerns. For patients and physicians to evaluate new research findings, it is important that they know how the research was funded so they can assess whether commercial biases may have affected the results. Additionally, the use of generic medication names by the news media is preferable so that physicians and patients learn to refer to medications by their generic names, a practice that is likely to reduce medication errors and may decrease unnecessary health care costs," the authors write.

**Public release date: 30-Sep-2008**

## **Danish study provides new information on hormone replacement therapy and the risk of heart attacks**

Danish study provides new information on hormone replacement therapy and the risk of heart attacks. It's not what you take but the way that you take it that can produce different results in women who take hormone replacement therapy (HRT), according to new research on the association between HRT and heart attacks, published online in Europe's leading cardiology journal, the European Heart Journal [1] today (Wednesday 1 October).

The study is the largest to look at the effects of HRT since the Women's Health Initiative trial was stopped early after finding that HRT increased the risk of women developing a range of conditions including breast cancer and thromboembolism.

The research is an observational study of 698,098 healthy Danish women, aged 51-69, who were followed between 1995-2001. It has found that overall there was no increased risk of heart attacks in current users of HRT compared to women who had never taken it.

**However, it did find that in younger women (aged 51-54) who were taking HRT during the period of the study, their risk of heart attacks was about a quarter (24%) more than in women who had never taken HRT. In addition, in younger women there was an increasing risk with longer duration of HRT, which was not seen in the older age groups.**

The study also found that the type of HRT and the way that the women took it made a difference to the risk of heart attacks. **Continuous HRT (a continuous combination of oestrogen and progesterone) carried a 35% increased risk of heart attacks compared with women who had never used HRT.** But if HRT was taken on a cyclical basis (oestrogen, followed by a combination of oestrogen and progesterone) there was a tendency for these women to have a reduced risk of heart attacks compared to women who had never used HRT, and this was also seen if a synthetic hormone, tibolone, was used. If the method of taking the oestrogen was via a patch or gel on the skin or in

the vagina, the risk of heart attack reduced by more than a third (38% and 44% respectively).

Dr Ellen Løkkegaard, a gynaecologist at the Rigshospitalet in Copenhagen, Denmark, who led the study, said: "Our finding of lower risk with a cyclic combined regimen, which gives monthly bleeding, than with continuous combined oestrogen/progesterone therapy, which does not cause bleeding, is potentially of great clinical importance. Also, the decreased risk of myocardial infarction with vaginal treatment is a very interesting finding that has not been tested before in large scale observational studies."

She said that the study produced similar results to the WHI study (a randomised controlled trial) for comparable HRT treatments, and that this suggested that the results from her study for the other, non-comparable treatments were valid.

"Our study does not change indications and duration recommendations for HRT. But the main message is that when hormone therapy is indicated for a woman, then a cyclic combined regimen should be preferred, and that application via the skin or the vagina is associated with a decreased risk of myocardial infarction.

"From the previous studies on HRT we have no reason to believe that these recommendations increase the risk of other diseases influenced by hormone therapy, such as breast cancer, venous thromboembolism and stroke. Actually, we believe they could reduce the risk."

Since the WHI trial was stopped, no further randomised controlled trials of HRT have been started.

"This study is the first, big observational study that addresses the influence of various regimens, doses and routes of administration," said Dr Løkkegaard. "In this 'post randomised era' where randomised studies on HRT are not easily performed, it provides important new information

### **Public release date: 30-Sep-2008**

## **During exercise, the human brain shifts into high gear on 'alternative energy'**

New article in the FASEB Journal shows that the brain uses lactate not glucose as fuel  
Alternative energy is all the rage in major media headlines, but for the human brain, this is old news.  
According to a study by researchers from Denmark and **The Netherlands published in the October 2008 print issue of The FASEB Journal, the brain, just like muscles, works harder during strenuous exercise and is fueled by lactate, rather than glucose.** Not only does this finding help explain why the brain is able to work properly when the body's demands for fuel and oxygen are highest, but it goes a step further to show that the brain actually shifts into a higher gear in terms of activity. This opens doors to entirely new areas of brain research related to understanding lactate's specific neurological effects.

"Now that we know the brain can run on lactate, so to speak, future studies should show us when to use lactate as part of a treatment," said Gerald Weissmann, MD, Editor-in-Chief of The FASEB Journal. "From an evolutionary perspective, the result of this study is a no-brainer. Imagine what could have or did happen to all of the organisms that lost their wits along with their glucose when running from predators. They were obviously a light snack for the animals able to use lactate."

To reach their conclusion, the researchers looked at research that compared the blood running to and from the heads of volunteers undergoing strenuous exercise. They found that the blood on its way to the brain contained considerably more lactate than blood flowing from the brain. Further investigation showed that the brain was not storing the lactate which had come from the muscles during exercise, but rather using it as fuel. In fact, the brain helped to clear lactate from the circulation, thereby leaving glucose to the muscles that need it for the hard work they were performing.

### **Public release date: 2-Oct-2008**

## Too many calories send the brain off kilter

An overload of calories throws critical portions of the brain out of whack, reveals a study in the October 3rd issue of the journal *Cell*, a Cell Press publication. **That response in the brain's hypothalamus—the "headquarters" for maintaining energy balance—can happen even in the absence of any weight gain, according to the new studies in mice.**

**The brain response involves a molecular player, called IKK $\beta$ /NF- $\kappa$ B, which is known to drive metabolic inflammation in other body tissues.** The discovery suggests that treatments designed to block this pathway in the brain might fight the ever-increasing spread of obesity and related diseases, including diabetes and heart disease.

"This pathway is usually present but inactive in the brain," said Dongsheng Cai of the University of Wisconsin-Madison. Cai said he isn't sure exactly why IKK $\beta$ /NF- $\kappa$ B is there and ready to spring into action in the brain. He speculates it may have been an important element for innate immunity, the body's first line of defense against pathogenic invaders, at some time in the distant past.

"In today's society, this pathway is mobilized by a different environmental challenge—overnutrition," he said. Once activated, "the pathway leads to a number of dysfunctions, including resistance to insulin and leptin," both important metabolic hormones.

Earlier studies showed that overnutrition can spark inflammatory responses in the peripheral metabolic tissues, including the muscles and liver, and therefore cause various metabolic defects in those tissues that underlie type 2 diabetes. As a result, scientists identified IKK $\beta$  as a target for an anti-inflammatory therapy that was effective against obesity-associated diabetes.

Yet whether metabolic inflammation and its mediators played a role in the central nervous system remained uncertain. Now, the researchers show that a chronic high-fat diet doubles the activity of this inflammatory pathway in the brains of mice. Its activity is also much higher in the brains of mice who are genetically predisposed to obesity, they found.

The researchers report that that increased activity of the IKK $\beta$ /NF- $\kappa$ B pathway can be divorced from obesity itself -- infusions of either glucose or fat into the brains of mice alone led to this inflammatory brain reaction.

Further studies revealed that this activity in the brain leads to insulin and leptin resistance. Insulin lowers blood sugar by causing cells of the body to take it up from the bloodstream. Leptin is a fat hormone important for appetite control.

Moreover, the researchers found that treatments preventing the activity of IKK $\beta$ /NF- $\kappa$ B in the animals' brains protected them from obesity.

While chronic inflammation is generally considered a consequence of obesity, the new results suggest the inflammatory reaction might also be a cause of the imbalance that leads to obesity and associated diseases, including diabetes. As Cai says, it appears that inflammation and obesity are "quite intertwined." An abundance of calories itself promotes inflammation, while obesity also feeds back to the neurons to further promote inflammation in a kind of vicious cycle.

The findings could lead to treatments that might stop this cycle before it gets started.

"Our work marks an initial attempt to study whether inhibiting an innate immune pathway in the hypothalamus could help to calibrate the set point of nutritional balance and therefore aid in counteracting energy imbalance and diseases induced by overnutrition," the researchers said. "We recognize that the significance of this strategy has yet to be realized in clinical practice; currently, most anti-inflammatory

therapies have limited direct effects on IKK $\beta$ /NF- $\kappa$ B and limited capacity to be concentrated in the central nervous system. Nonetheless, our discoveries offer potential for treating these serious diseases."

If realized, such a strategy would likely offer a safe approach given that the critical pathway appears to be unnecessary in the hypothalamus under normal circumstances, they noted.

**Public release date: 2-Oct-2008**

## **Second lumpectomy for breast cancer reduces survival rates**

SACRAMENTO, Calif.) — A majority of women with breast cancer today are candidates for lumpectomy, allowing for conservation of most of their breast tissue. Results of a UC Davis study, however, show that a number of women whose cancer recurs in the same breast are treated with a second lumpectomy rather than a mastectomy, defying current treatment recommendations and cutting the number of years those women survive in half.

"We were surprised to find that so many women in our study — almost a quarter of them — had received another lumpectomy rather than a mastectomy," said Steven Chen, a UC Davis Cancer Center surgical oncologist and lead author of the study, which appears in the October issue of the American Journal of Surgery. "It's likely that patients are asking for lumpectomies when their cancer is diagnosed a second time, and their doctors are simply complying with that request. Whatever the reason, that decision can shorten life spans."

Chen and study co-author, Steve Martinez, also a UC Davis Cancer Center surgical oncologist, gathered data from the National Cancer Institute's Surveillance, Epidemiology and End Results database, which includes information on all cancers diagnosed in selected regions throughout the nation. Their study included 747 patients who previously received breast-conservation therapy and were diagnosed with cancer a second time in the same breast between 1988 and 2004.

The authors found that women who had mastectomies had a 78 percent survival rate after five years, while those who had second lumpectomies had a 67 percent survival rate. The 10-year survival rates were 62 percent for those who had mastectomies and 57 percent for those who had second lumpectomies. In all, 24 percent of women with recurrent breast cancer in the same breast had second lumpectomies.

The researchers went on to calculate the risk of dying for mastectomy patients compared to lumpectomy patients. They found that, after adjusting for factors that affect survival, there will be half as many survivors at any given time in the lumpectomy group versus the mastectomy group.

Chen explained that a mastectomy is the generally accepted surgical treatment for a second cancer because whole breast radiation, which typically accompanies a lumpectomy, is not usually recommended twice in a lifetime. This new study shows as well that there is a survival advantage to those who choose a mastectomy.

According to Martinez, knowledge of breast cancer and its treatments are continuously advancing, and second lumpectomies could at some point become a viable option.

"As therapy for breast cancer becomes more targeted and researchers come closer to identifying those factors that make some breast cancers more aggressive than others, we may have the option of recommending second and even third lumpectomies in select cases in the future. Until then, mastectomy remains the best option for women experiencing a same-breast recurrence of their breast cancer," he said.

**Public release date: 2-Oct-2008**

## **DNA of good bacteria drives intestinal response to infection**

A new study shows that the DNA of so-called "good bacteria" that normally live in the intestines may help defend the body against infection.

The findings, available Oct. 2 online in the journal *Immunity*, are reported by Yasmine Belkaid, Ph.D., and her colleagues in the Laboratory of Parasitic Diseases at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

A person normally has 300 to 500 species of beneficial bacteria, known as commensals, in their intestines. These bacteria are not harmful and, in fact, help an individual maintain his or her digestive health. Typically, the immune system does not attack gut commensals, even though they are bacteria.

"Within the body of a healthy adult, microbial cells vastly outnumber human cells. Research to understand these microbial communities is an exciting scientific frontier," says Anthony S. Fauci, MD, NIAID director. "Among many opportunities related to the so-called 'microbiome,' targeting beneficial bacteria may offer new avenues for therapy against infectious and immune-mediated diseases."

Just how commensals protect against harmful bacteria, known as pathogens, is a complex question. "Pathogens often behave similarly to gut commensals," Dr. Belkaid says. Because the body needs commensals but also has to rid itself of disease-causing microbes, the immune system must distinguish the good bugs from the bad ones.

One mechanism of protection is through the interaction between the commensals and certain immune cells in the intestines. This interaction occurs through the binding of the commensals to receptors on the T cells known as Toll-like receptors (TLRs).

In healthy individuals, some intestinal T cells (known as Tregs) play a regulatory role, recognizing commensals and keeping the immune system from attacking them. During an infection, however, T cells shift into attack mode to fight the infection. The factors controlling this shift from defense to offense have not been well understood.

Dr. Belkaid's team describes a novel way in which the Tregs are regulated to facilitate an immune response to a pathogen. They found that during an infection, the DNA of the body's beneficial bacteria binds to a specific receptor on the intestinal immune cells, called TLR9. The binding of commensal DNA to TLR9 in the presence of a pathogen prevents the generation of Tregs in favor of the generation of protective T cells. These protective T cells can then clear the body of the invading pathogen.

In effect, the commensal DNA acts as a natural adjuvant by boosting the activity of T cells so they can destroy the invading pathogen.

"There is a balance of regulatory immune signals in the body," notes Dr. Belkaid. "During an infection, we've found that commensals can break this balance in favor of an infection-fighting response."

While the immune system must react to invading pathogens to maintain health, an immune response to commensals can cause problems. For example, certain inflammatory bowel diseases, such as Crohn's disease, are thought to be caused in part by immune reactions against commensal bacteria.

**Understanding how commensals interact with the immune system opens up the possibility of using beneficial bacteria as targets for future oral therapies against infections or autoimmune diseases.**

**Public release date: 2-Oct-2008**

**New Study on Effects of Disclosing Financial Interests on Participation**

## **in Medical Research**

Baltimore, MD. - Knowing how an investigator is paid for running a research study surprisingly plays a small role in patients' willingness to take part in clinical trials. However, according to a new Johns Hopkins University study more participants are troubled when they are told that the investigator could profit or lose money depending on the results.

In an effort to learn more about the effects of disclosing an investigator's financial interests on potential study participants, researchers from the Johns Hopkins Berman Institute of Bioethics, Duke University Medical Center, and Wake Forest University surveyed 470 patients from an outpatient cardiology clinic. Each of these patients, who were diagnosed with coronary artery disease, agreed to go through a consent process over the phone for a hypothetical clinical trial.

The study, published in the October issue of the *American Heart Journal*, found that simply revealing an investigator's financial interest in a study does little to affect the patient's decisions to enroll in a hypothetical clinical trial. What the study did find was that patients were more concerned about certain types of financial interests, especially when the investigator owned stock in the company financing the study.

“Disclosure of investigators' financial interests in research does not substantially affect a person's willingness to participate,” says Jeremy Sugarman, M.D., senior author of the study and Harvey M. Meyerhoff Professor of Bioethics and Medicine at the Johns Hopkins Berman Institute of Bioethics, however, “ethically it's important that the patient's 'right to know' is respected before they consent to enroll in research.”

“What seems to be important in the decision-making process was the patients' pre-existing level of trust in medical research in general,” says Dr. Kevin Weinfurt, a medical psychologist at Duke and the lead author of the study.

The team of researchers first assessed the patients' overall level of trust in medical research. Investigators then randomly assigned them to one of three disclosure groups: Members of one group were told the clinic involved in the study would receive per capita payments per enrollee that would be used to cover the costs of the trial, including the doctor's salary. Participants in a second group were told that the investigator held stock in the company sponsoring the research. There were no disclosure statements made to members of the third group.

When asked how likely they would be to join a clinical trial, members of all three groups expressed a moderate degree of willingness to do so. Still, there were some important differences between the groups.

Patients who heard about stock ownership were less willing than those in the other two groups to indicate that they would participate in the study. In addition, they spontaneously offered three times the number of negative comments about the relationship than participants in the other groups, using words like, “disingenuous,” “unacceptable,” and “unethical.” In addition, ten members of the group that were told about stock ownership in the company sponsoring the trial, spontaneously said they would not take part in the trial compared with only one such comment from the other two groups.

In general, members of the per capita group felt that a financial arrangement that helped cover costs of the trial was acceptable, saying, “OK, that sounds more appropriate. So there's no payment to him, but through the university. OK, I'm good.”

But some members in the group that was told about stock ownership found positive things to say about that arrangement, too. One person volunteered that “It looks like he'd have this real incentive for this thing to go real well, and I guess that's all to the good.”

“The findings of this study make it clear that policy makers need to continue to address the issue of

conflicts of interest in research conducted by investigators who stand to profit from the results of clinical trials,” says Sugarman. When it comes to financial disclosure between investigators and research participants Sugarman says, “Policy makers may want to consider more restrictive policies for equity relationships than for other financial interests in research.”

It's important to note that participants in the study were disproportionately middle-to higher income white men, and the researchers say lower income participants from other racial groups might feel differently about financial relationships between researchers and sponsoring companies.

Ralph's Note - Why are we doing studies on how they patient perceives a conflict of interest? A conflict of interest is wrong period. This seems to be more of an experiment into determining the tolerance of the public. Especially when seeing how much conflict the patient can endure before refusing to be part of an experiment

**Public release date: 5-Oct-2008**

## **Disinfectants can make bacteria resistant to treatment**

Chemicals used in the environment to kill bacteria could be making them stronger, according to a paper published in the October issue of the journal Microbiology. Low levels of these chemicals, called biocides, can make the potentially lethal bacterium *Staphylococcus aureus* remove toxic chemicals from the cell even more efficiently, potentially making it resistant to being killed by some antibiotics.

Biocides are used in disinfectants and antiseptics to kill microbes. They are commonly used in cleaning hospitals and home environments, sterilizing medical equipment and decontaminating skin before surgery. At the correct strength, biocides kill bacteria and other microbes. However, if lower levels are used the bacteria can survive and become resistant to treatment.

"Bacteria like *Staphylococcus aureus* make proteins that pump many different toxic chemicals out of the cell to interfere with their antibacterial effects," said Dr Glenn Kaatz from the Department of Veterans Affairs Medical Center in Detroit, USA. "These efflux pumps can remove antibiotics from the cell and have been shown to make bacteria resistant to those drugs. We wanted to find out if exposure to biocides could also make bacteria resistant to being killed by the action of efflux pumps."

The researchers exposed *S. aureus* taken from the blood of patients to low concentrations of several biocides and dyes, which are also used frequently in hospitals. They looked at the effect of exposure on the bacteria and found that mutants that make more efflux pumps than normal were produced.

"We found that exposure to low concentrations of a variety of biocides and dyes resulted in the appearance of resistant mutants," said Dr Kaatz. "The number of efflux pumps in the bacteria increased. Because the efflux pumps can also rid the cell of some antibiotics, pathogenic bacteria with more pumps are a threat to patients as they could be more resistant to treatment."

If bacteria that live in protected environments are exposed to biocides repeatedly, for

example during cleaning, they can build up resistance to disinfectants and antibiotics. Such bacteria have been shown to contribute to hospital-acquired infections.

"Scientists are trying to develop inhibitors of efflux pumps. Effective inhibitors would reduce the likelihood of additional resistance mechanisms emerging in bacteria," said Dr Kaatz. "Unfortunately, inhibitors evaluated to date do not work on a wide range of pathogens so they are not ideal to prevent resistance."

"Careful use of antibiotics and the use of biocides that are not known to be recognised by efflux pumps may reduce the frequency at which resistant strains are found," said Dr Kaatz. "Alternatively, the combination of a pump inhibitor with an antimicrobial agent or biocide will reduce the emergence of such strains and their clinical impact."

**Public release date: 6-Oct-2008**

## **Flu vaccine not associated with reduced hospitalizations or outpatient visits among young children**

Use of the influenza vaccine was not associated with preventing hospitalizations or reducing physician visits for the flu in children age 5 and younger during two recent seasons, perhaps because the strains of virus in the vaccine did not match circulating strains, according to a report in the October issue of Archives of Pediatrics & Adolescent Medicine, one of the JAMA/Archives journals.

Influenza causes substantial illness among young children; therefore, the United States and other countries have expanded their childhood vaccination requirements, according to background information in the article. As of June 2006, U.S. health officials recommend annual vaccinations for all children age 6 to 59 months. "An inherent assumption of expanded vaccination recommendations is that the vaccine is efficacious in preventing clinical influenza disease," the authors write.

Peter G. Szilagyi, M.D., M.P.H., of the University of Rochester School of Medicine and Dentistry and Strong Memorial Hospital, Rochester, N.Y., and colleagues studied 414 children age 5 and younger who developed influenza during the 2003-2004 or 2004-2005 seasons (245 seen in hospitals or emergency departments, and 169 seen in outpatient practices). Their vaccination status was compared with that of more than 5,000 children from the same three counties who did not have influenza during those seasons.

Before the researchers considered any other factors, children with influenza appeared to have lower vaccination rates than children without influenza. **"However, significant influenza vaccine effectiveness could not be demonstrated for any season, age or setting after adjusting for county, sex, insurance, chronic conditions recommended for influenza vaccination and timing of influenza vaccination (vaccine effectiveness estimates ranged from 7 percent to 52 percent across settings and seasons for fully vaccinated 6- to 59-month olds)," the authors write.**

A suboptimal match between the strain of influenza in the vaccine and that circulating in the public during those two seasons may have contributed to the poor effectiveness, the authors note. In 2003-2004, 99 percent of circulating influenza strains were caused by the influenza A virus, **but only 11 percent of influenza A strains across the United States were similar to those in the vaccine.** "The 2004-2005 season was less severe and the vaccine was a better match to circulating strains than in 2003-2004, but still only 36 percent of virus isolates were antigenically similar to vaccine strains," they write.

This study comparing cases with controls adds important information about vaccine effectiveness in children but should be combined with additional research, including studies of years with good vaccine match, they conclude. "Further studies of influenza vaccine effectiveness are needed using a variety of study designs (that adjust for confounders) to assess the yearly impact of influenza vaccination programs for children, particularly as higher rates of vaccination are achieved in the study population," the authors write.

**Public release date: 6-Oct-2008**

## **Vitamin D deficiency common in patients with IBD, chronic liver disease**

Vitamin D replacement may be necessary to reverse deficiency-related bone loss  
Orlando, FL, Oct 6, 2008 – New research presented at the 73rd Annual Scientific Meeting of the American College of Gastroenterology in Orlando found patients with inflammatory bowel disease or chronic liver disease were at increased risk of developing Vitamin D deficiencies. Two separate studies highlight the importance of regular Vitamin D checkups in the evaluation of patients with certain digestive diseases.

For IBD Patients, Vitamin D Deficiency Associated with Lower Quality of Life and Higher Disease Activity

Researchers at the Medical College of Wisconsin investigated whether Vitamin D deficiency in patients with IBD is associated with a lower quality of life or higher disease activity independent of other known risk factors and medication use.

Disease activity and quality of life were assessed using validated questionnaires, which were administered at every clinic visit. The researchers also looked at the prevalence and seasonality of Vitamin D deficiency in this inflammatory bowel disease population, as well as its association with IBD-related hospitalizations, surgeries and medication use.

This retrospective cohort study conducted by Dr. Alex Ulitsky and his colleagues analyzed vitamin D levels of 504 inflammatory bowel disease patients. They recorded the patients' lowest Vitamin D measurements and date when each low measurement was taken.

Dr. Ulitsky and his team found almost 50 percent of the patients were Vitamin D deficient at some point, with 11 percent being severely deficient. Vitamin D deficiency was not significantly associated with being hospitalized for IBD or having IBD-related surgeries. However, in both Crohn's disease (CD) and ulcerative colitis (UC) patients, vitamin D deficiency was independently associated with having increased disease activity scores compared to those with normal levels of Vitamin D. Vitamin D deficient CD patients, but not UC patients, had worse quality of life when compared to patients who were not Vitamin D deficient.

According to Dr. Ulitsky, "All IBD patients, irrespective of their disease, disease location or nature should have their Vitamin D levels checked regularly and corrected aggressively when insufficiency is found."

#### Vitamin D Deficiency Prevalent in Patients with Chronic Liver Disease

Researchers from the University of Tennessee in Memphis measured the vitamin D levels of 118 chronic liver disease patients. Researchers found 92.4 percent of chronic liver patients had some degree of vitamin D deficiency and at least one third were severely deficient. Severe vitamin D deficiency was more common among cirrhotics.

"Since deficiency is common among these patients, Vitamin D replacement may hopefully prevent osteoporosis and other bone complications related to end stage liver disease," said lead researcher Dr. Satheesh P. Nair.

The study included 43 hepatitis C patients with cirrhosis; 57 hepatitis C patients without cirrhosis; 18 cirrhosis patients without hepatitis C. The severity of vitamin D deficiency was divided into three groups: mild (between 20-32 ng/ml), moderate (between 7-20 ng/ml), and severe (less than 7 ng/ml).

#### Importance of Vitamin D and Bone Health

Vitamin D, a fat-soluble vitamin, helps the body absorb calcium and plays a crucial role in the growth and maintenance of strong, healthy bones. A lack of vitamin D causes calcium-depleted bone, which can weaken the bones and increase the risk of fractures resulting from osteoporosis.

A diet rich in vitamin D, such as fish, eggs, fortified milk, and cod liver oil, is essential to maintaining good bone health.

#### **Public release date: 6-Oct-2008**

### **New studies examine the effectiveness of probiotics in IBS**

Orlando, FL, October 6, 2008 – Several studies presented at the American College of Gastroenterology's 73rd Annual Scientific Meeting in Orlando highlight the safety and efficacy of probiotics in improving symptoms and normalizing bowel movement frequency in patients suffering from constipation or diarrhea related to Irritable Bowel Syndrome (IBS).

#### New Systematic Review of Probiotics in IBS

**A systematic review of the efficacy of probiotics in IBS that included 19 randomized controlled trials in 1,628 IBS patients found that "probiotics are effective in IBS,** but we do not have enough information to be sure whether there is one probiotic that is particularly effective or whether combinations of probiotics are required," according to Dr. Paul Moayyedi, the study's lead researcher. Moayyedi and co-investigators at Mayo Clinic in Jacksonville, FL and Rochester, MN; McMaster University in Ontario, Canada; University College in Cork, Ireland and Montefiore Medical Center in New York City, conducted this meta-analysis presented at the ACG Annual Scientific Meeting in Orlando.

#### Multi-Strain Probiotic for IBS Patients with Diarrhea

Dr. Gerald Friedman of The Mount Sinai School of Medicine in New York and co-investigator Greg Biancone conducted a multi-center analysis to determine if a multi-strain probiotic was effective in reducing the frequency of diarrhea in 84 IBS patients (IBS-D). **In this small study, a multi-strain probiotic administered daily for 28 days normalized bowel habits in IBS patients compared to those who received the placebo. The average number of daily diarrheal episodes in the probiotic group significantly decreased from day 1 to day 28 compared to slight decreases in the placebo group**

**during the same period.**

Analysis of Probiotics in Children with IBS

In a placebo-controlled, double-blinded, cross-over study conducted at seven pediatric GI centers in the United States, Italy, and India, Dr. Stefano Guandalini of the University of Chicago and his research team randomly assigned 59 pediatric IBS patients to receive either a probiotic agent (VSL#3®) or a placebo for six weeks. At the end of six weeks, patients switched to the other arm of the study and underwent six more weeks of treatment. Patients filled out a questionnaire to assess their symptoms and overall quality of life before and after treatment. Researchers found the probiotic agent was safe and significantly more effective than the placebo in alleviating IBS-related symptoms (abdominal pain/discomfort, bloating, stool dysfunction) in children and teenagers.

**Public release date: 6-Oct-2008**

## **Oral vitamin D may help prevent some skin infections**

A study led by researchers at the University of California, San Diego School of Medicine suggests that use of oral Vitamin D supplements bolsters production of a protective chemical normally found in the skin, and may help prevent skin infections that are a common result of atopic dermatitis, the most common form of eczema.

The study – led by Richard Gallo, M.D., Ph.D., professor of medicine and chief of the Division of Dermatology at the UCSD School of Medicine and the Dermatology section of the Veterans Affairs San Diego Healthcare System, and Tissa R. Hata, M.D., associate professor of medicine at UC San Diego – found that use of oral vitamin D appeared to correct a defect in the immune systems in patients with this skin disease. Their findings will be published in the October 3 edition of the *Journal of Allergy & Clinical Immunology*

The researchers studied a small number of patients with moderate to severe atopic dermatitis, a chronic skin disease that affects 10 to 20 percent of children and one to three percent of adults. Atopic dermatitis is characterized by areas of severe itching, redness and scaling. Over time, chronic changes can occur due to constant scratching and rubbing. The condition puts patients at increased risk for skin infections by Staph aureus and the herpes and small pox viruses.

It had previously been shown that defects in the immune system interfere with the skin's ability to produce a peptide called cathelicidin, which is protective against microbial invasion. In many skin diseases, including eczema, a deficiency of cathelicidin correlates with increased infection.

Study participants (14 with atopic dermatitis and 14 without) were all given 4000 IUs of oral Vitamin D3 (cholecalciferol) per day for 21 days. Skin lesions were biopsied before and after the 21-day period. The researchers found that oral vitamin D use by the patients appeared to correct the skin's defect in cathelicidin.

"These results suggest that supplementation with oral vitamin D dramatically induces cathelicidin production in the skin of patients with atopic dermatitis," said Hata. "It also slightly elevated its production in normal skin in this study."

However, the researchers caution that this was a small study and that further research is needed to evaluate the long-term effects of vitamin D supplementation, and to determine if this may be an adequate way to prevent infections in patients with atopic dermatitis. In the past several years, vitamin D deficiency has been linked to increased rates of multiple cancers and diabetes, among other diseases, notably in studies published by UC San Diego researcher, Cedric Garland, Dr. P.H., professor with Moores UCSD Cancer Center and the Department of Family and Preventive Medicine at UC San Diego.

**Public release date: 7-Oct-2008**

## **Olive oil ingredient ups the time between meals**

A fatty acid found in abundance in olive oil and other "healthy" unsaturated fats has yet another benefit: it helps keep the body satisfied to prolong the time between meals.

A new study in the October Cell Metabolism, a publication of Cell Press, reveals that once this type of fat, known as oleic acid, reaches the intestine, it is converted into a lipid hormone (oleoylethanolamide, or OEA) that wards off the next round of hunger pangs. The researchers said it may be the first description of an ingredient in food that directly provides the raw materials for a hormone's production.

The findings in rats may yield insight into the precise dietary makeup of fat and protein for optimal hunger control, the researchers said. (Protein plays an important role in limiting hunger as well, but by different means.) The newly discovered signaling pathway might also be tapped into with drugs designed to control appetite by supplementing OEA levels or blocking its breakdown. Similarly, in conditions where people don't eat enough, the researchers speculate that treatments targeting this system might improve the appetite.

Importantly, diets high in processed foods that are riddled with saturated fats might throw a wrench into this system of metabolic control, the researchers said.

"Eating is one of the most important things animals do," said Daniele Piomelli of the University of California, Irvine. "This is just one of many things that control it. That said, a system like this could be forced to inactivation by inappropriate feeding," he said, noting that saturated fats generally lack in oleic acid.

While such diets may lead people to overeat, Piomelli said it will also be of interest to see if this mechanism may be defective in some who tend to eat in excess.

Previous studies had shown that feeding stimulates cells in the intestinal lining to produce OEA, which, when administered as a drug, decreases meal frequency by engaging receptors called peroxisome proliferator-activated receptors (PPARs).

Piomelli's team now reports that infusion of fat into the small intestine stimulates the release of OEA, whereas infusion of protein or carbohydrate does not. They also demonstrate that OEA production uses dietary oleic acid and is disrupted in mutant mice lacking the membrane fatty-acid transporter CD36. Treatments that disrupt CD36 or PPARs undermine the hunger control otherwise driven by fat.

Overall, the results suggest that activation of small-intestinal OEA release, enabled by CD36-mediated

uptake of oleic acid from the diet, serves as a molecular sensor linking fat consumption to satiety. (Piomelli said satiety is perhaps best described as the opposite of hunger.)

" In conclusion," the researchers wrote, "our studies identify OEA as a key physiological signal that specifically links dietary fat ingestion to across-meal satiety. Nutritional and pharmacological strategies aimed at magnifying this lipid-sensing mechanism, such as inhibitors of OEA degradation, might be useful in the treatment of obesity and other eating disorders."

**Public release date: 7-Oct-2008**

## **Red wine may lower lung cancer risk**

PHILADELPHIA – Moderate consumption of red wine may decrease the risk of lung cancer in men, according to a report in the October issue of *Cancer Epidemiology, Biomarkers & Prevention*, a journal of the American Association for Cancer Research.

"An antioxidant component in red wine may be protective of lung cancer, particularly among smokers," said Chun Chao, Ph.D., a research scientist at Kaiser Permanente Department of Research and Evaluation in Pasadena, California.

Chao analyzed data collected through the California Men's Health Study, which linked clinical data from California's health system with self-reported data from 84,170 men aged 45 to 69 years. Researchers obtained demographics and lifestyle data from surveys computed between 2000 and 2003, and identified 210 cases of lung cancer.

Researchers measured the effect of beer, red wine, white wine and liquor consumption on the risk of lung cancer. Adjustments were made for age, race/ethnicity, education, income, body mass index, history of chronic obstructive pulmonary disease or emphysema, and smoking history.

Among the study participants, there was on average a two percent lower lung cancer risk associated with each glass of red wine consumed per month. The most substantial risk reduction was among smokers who drank one to two glasses of red wine per day. The researchers reported a 60 percent reduced lung cancer risk in these men. Researchers warned men to stop smoking as the best way to reduce lung cancer risk; noting that even men who drank one to two glasses of red wine per day still face higher lung cancer risk than do non-smokers.

No clear associations with lung cancer were noted for consumption of white wine, beer, or liquor. "Red wine is known to contain high levels of antioxidants. There is a compound called resveratrol that is very rich in red wine because it is derived from the grape skin. This compound has shown significant health benefits in preclinical studies," Chao said.

Chao said their findings should not be construed to recommend heavy alcohol consumption.

**Public release date: 7-Oct-2008**

## **Honey helps to heal wounds**

Honey may reduce healing times in patients suffering mild to moderate burn wounds. A systematic review by Cochrane Researchers concluded that honey might be useful as an alternative to traditional wound dressings in treating burns.

"We're treating these results with caution, but it looks like honey can help speed up healing in some burns,"

says lead researcher Dr Andrew Jull, of the Clinical Trials Research Unit at the University of Auckland, New Zealand.

Honey has been used in wound treatment since ancient times. The mechanism of action is unclear. While honey may help the body remove dead tissue and provide a favourable environment for the growth of new, healthy tissue, current interest in medicinal honey focuses largely on its antibacterial effects.

The review brings together data from 19 clinical trials involving 2554 patients with a range of different wounds. **Honey was more effective in reducing healing time compared to some gauze and film dressings that are often used to treat moderate burns.** However, the researchers were unable to show any clear benefits for the healing of grazes, lacerations, surgical wounds and leg ulcers.

The researchers don't advise using honey to treat other types of wounds. "Health services should invest in treatments that have been shown to work," says Dr Jull. "But, we will keep monitoring new research to try and establish the effect of honey."

**Public release date: 7-Oct-2008**

## **Herbal Menopause Therapy a Good Fit for Breast Cancer Patients?**

COLUMBIA, Mo. – When it comes to understanding the effectiveness and safety of using herbal therapies with other drugs, much is unknown. Now, a University of Missouri researcher will study how black cohosh - an herbal supplement often used to relieve hot flashes in menopausal women - interacts with tamoxifen, a common drug used to treat breast cancer.

As women age and reach menopause, their risk of developing breast cancer increases. Many women who have, or are at risk, for breast cancer take tamoxifen. The drug prevents approximately 50 percent of breast cancers in women who have an increased risk of developing breast cancer. However, when women take tamoxifen, they cannot take hormone replacement therapies to relieve menopausal symptoms. Their options are limited to taking antidepressants that can have complications, enduring uncomfortable menopausal symptoms, or trying the black cohosh.

“Hopefully, this study will provide evidence that black cohosh is safe to use for breast cancer patients,” said Rachel Ruhlen, a postdoctoral researcher in the MU School of Medicine. “Currently, there is little reliable information guiding women in how they can use foods and botanical supplements to enhance their treatment or improve their quality of life.”

To study how black cohosh and tamoxifen interact, Ruhlen will use a group of rats prone to breast cancer, known as ACI rats. Previous studies have found that human breast cancer is associated with life-time exposure of estrogen. ACI rats, like humans, develop mammary tumors after exposure to estrogen. In a previous study, Ruhlen found that when ACI rats were treated with the human breast cancer drug tamoxifen, mammary tumor mass was reduced by 89 percent.

“Many animal models of breast cancer differ in important ways from humans with breast cancer,” Ruhlen said. “These models are useful in studying how human tumors grow and spread to other parts of the body, but fall short because of the difference in how human tumors begin. However, mammary tumors in ACI rats share several key features with the majority of human breast cancers, particularly in how tumors start. Because the ACI rats develop tumors and can be treated in a way similar to humans, it is a relevant model for human breast cancer.”

Ruhlen’s research on black cohosh and tamoxifen is funded by Susan G. Komen for the Cure. Her paper, “Tamoxifen induces regression of estradiol-induced mammary cancer in ACI.COP-Ept2 rat model,” will be published in *Breast Cancer Research and Treatment*. Ruhlen works with Salman Hyder, a professor of biomedical sciences in the College of Veterinary Medicine and investigator in the Dalton Cardiovascular Research Center.

**Public release date: 8-Oct-2008**

## **Bisphenol A linked to chemotherapy resistance**

CINCINNATI—Exposure to bisphenol A (BPA) may reduce the effectiveness of chemotherapy treatments, say University of Cincinnati (UC) scientists.

The research study, led by UC's Nira Ben-Jonathan, PhD, says that BPA—a man-made chemical found in a number of plastic products, including drinking bottles and the lining of food cans—actually induces a group of proteins that protect cancer cells from the toxic effects of chemotherapy.

The findings are reported in the journal *Environmental Health Perspectives* and appear online Oct. 8, 2008, ahead of print.

"Resistance to chemotherapy is a major problem for cancer patients, especially those with advanced or metastatic disease," says Ben-Jonathan, a professor of cancer and cell biology at UC who has studied BPA for more than 10 years. "Finding out what contributes to that resistance can give us an idea of what to target in order to make chemotherapy as effective as possible."

Researchers have suspected that BPA could play a role in cancer because of the chemical's structural similarities to a cancer-promoting compound called diethylstilbestrol (DES). But Ben-Jonathan's team found that BPA isn't exactly mimicking the action of DES.

"BPA does not increase cancer cell proliferation like DES does," she says. "It's actually acting by protecting existing cancer cells from dying in response to anti-cancer drugs, making chemotherapy significantly less effective."

Ben-Jonathan's team studied human breast cancer cells, subjecting them to low levels of BPA consistent with levels found in the blood of human adults. The team found that BPA is acting in cancer cells similar to the way estrogen does—by inducing proteins that protect the cells from chemotherapy agents.

Estrogen's protein-inducing action has been previously linked to chemotherapy resistance, but researchers have been unable to explain why such resistance still occurs in certain patients with less estrogen. Ben-Jonathan says her team's research has important implications for this subgroup of patients.

"Patients with less circulating estrogen—post-menopausal women, for example—can also suffer from chemotherapy resistance," she says. "Linking BPA to this problem gives us one more avenue to explore in terms of preventing chemotherapy resistance."

"These data," study authors write, "provide considerable support to the accumulating evidence that BPA is hazardous to human health."

Coauthors include Elizabeth LaPensee, Sejal Fox and Traci Tuttle.

**Public release date: 7-Oct-2008**

## **St. John's wort relieves symptoms of major depression**

New research provides support for the use of St. John's wort extracts in treating major depression. A Cochrane Systematic Review backs up previous research that showed the plant extract is effective in treating mild to moderate depressive disorders.

"Overall, we found that the St. John's wort extracts tested in the trials were superior to placebos and as effective as standard antidepressants, with fewer side effects," says lead researcher, Klaus Linde of the Centre for Complementary Medicine in Munich, Germany.

Extracts of the plant *Hypericum perforatum*, commonly known as St. John's wort, have long been used in folk medicine to treat depression and sleep disorders. The plant produces a number of different substances that may have anti-depressive properties, but the whole extract is considered to be more effective.

Cochrane Researchers reviewed 29 trials which together included 5,489 patients with symptoms of major depression. All trials employed the commonly used Hamilton Rating Scale for Depression to assess the severity of depression. In trials comparing St. John's wort to other remedies, not only were the plant extracts considered to be equally effective, but fewer patients dropped out of trials due to adverse effects. The overall picture is complicated, however, by the fact that the results were more favourable in trials conducted in German speaking countries, where St. John's extracts have a long tradition and are often prescribed by doctors.

Despite the favourable findings for St. John's wort, researchers are anxious not to make generalisations about the plant's use as an anti-depressant and recommend consulting a doctor in the first instance, especially as the extracts can sometimes affect the actions of other beneficial drugs.

"Using a St. John's wort extract might be justified, but products on the market vary considerably, so these results only apply to the preparations tested," says Linde.

### **Herbal Menopause Therapy a Good Fit for Breast Cancer Patients?**

COLUMBIA, Mo. – When it comes to understanding the effectiveness and safety of using herbal therapies with other drugs, much is unknown. Now, a University of Missouri researcher will study how black cohosh - an herbal supplement often used to relieve hot flashes in menopausal women - interacts with tamoxifen, a common drug used to treat breast cancer.

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prevents approximately 50 percent of breast cancers in women who have an increased risk of developing breast cancer. However, when women take tamoxifen, they cannot take hormone replacement therapies to relieve menopausal symptoms. Their options are limited to taking antidepressants that can have complications, enduring uncomfortable menopausal symptoms, or trying the black cohosh.

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**Public release date: 9-Oct-2008**

## **Mouse studies suggest daily dose of ginkgo may prevent brain cell damage after a stroke**

Working with genetically engineered mice, researchers at Johns Hopkins have shown that daily doses of a standardized extract from the leaves of the ginkgo tree can prevent or reduce brain damage after an induced stroke.

The scientists, in a report published in *Stroke*, say their work lends support to other evidence that ginkgo biloba triggers a cascade of events that neutralizes free radicals known to cause cell death.

"It's still a large leap from rodent brains to human brains but these results strongly suggest that further research into the protective effects of ginkgo is warranted," says lead researcher Sylvain Doré, Ph.D., an associate professor in the Department of Anesthesiology and Critical Care Medicine. "If further work confirms what we've seen, we could theoretically recommend a daily regimen of ginkgo to people at high risk of stroke as a preventive measure against brain damage."

In the study, researchers gave ginkgo biloba EGb 761 - a lab-quality form of the extract - to normal mice and HO-1 knockout mice, mice lacking the gene that produces the enzyme heme oxygenase-1 (HO-1). HO-1 breaks down heme, a common iron molecule found in blood, into carbon monoxide, iron and biliverdin. HO-1 has been shown to act as an antioxidant and have a protective effect against inflammation in animal models.

Doré and his team gave 100 milligrams per kilogram of EGb 761 extract orally once daily for seven days before inducing stroke in the mice by briefly blocking an artery to one side of the brain.

After stroke induction, the mice were tested for brain function and brain damage. One such test, for example, involves running patterns, another tests reaction to an external stimulus. Similar tests were conducted on mice that did not receive the ginkgo extract.

Neurobehavioral function was evaluated before the study and at 1, 2 and 22 hours after stroke using a four-point scale: (1) no deficit, (2) forelimb weakness, (3) inability to bear weight on the affected side, (4) no spontaneous motor activity.

Results showed that normal mice that were pretreated had 50.9 percent less neurological dysfunction and 48.2 percent smaller areas of brain damage than untreated mice. These positive effects did not exist in the HO-1 knockout mice.

"Our results suggest that some element or elements in ginkgo actually protect brain cells during stroke," says Doré.

Roughly 700,000 people experience a stroke in the United States annually. Of those, 87 percent have an ischemic stroke, which is caused by a blocked artery in the brain. Some brain damage occurs simply from the lack of blood getting to brain cells; however, it is known that an increase in the presence of free radicals at the site of an ischemic stroke - once the clot is cleared and the blood supply returns - is also a major cause of resulting brain cell damage. Free radicals are toxic oxygen molecules that are produced when cells die. According to Doré and his team, ginkgo increases HO-1 levels, and the antioxidant properties of this enzyme eliminate free radicals at the surrounding regions of the stroke site.

The only current treatment for ischemic stroke is to clear the clot with tissue plasminogen activator (tPA) or other means. This, however, offers no real protection against the cell damage that occurs when blood flow is restored.

"Ginkgo has long been touted for its positive effects on the brain and is even prescribed in Europe and Asia for memory loss," says Doré. "Now we have a possible understanding for how ginkgo actually works to protect neurons from damage."

Native to China, the ginkgo tree is grown as an ornamental shade tree in Australia, Southeast Asia, Europe, Japan and North America. It is commercially cultivated in France and the United States. It has a grey bark, reaches a height of 35 meters and a diameter of 3 to 4 meters. It has deciduous, fan-like leaves that are green, grey-yellow, brown or blackish.

**Public release date: 9-Oct-2008**

## **Children with cystic fibrosis not well covered by guidelines for vitamin D needs**

Existing recommendations for treating vitamin D deficiency in children with cystic fibrosis (CF) are too low to cover the serious need, leaving most at high risk for bone loss and rickets, according to researchers at Johns Hopkins Children's Center.

In results of their investigation, published in the October issue of *The Journal of Pediatrics*, the Johns Hopkins team found that nearly half of the 262 children with CF in the study were vitamin D deficient, and the majority of these remained persistently so, despite getting restorative doses equal to or higher than the recommendations set by the Cystic Fibrosis Foundation.

As a result of the findings, Hopkins already has amended its treatment protocol and now treats both adult and pediatric CF patients who have vitamin D deficiency with 50,000 IU daily for four weeks. Growing children with CF are especially vulnerable to vitamin D deficiency because a hallmark of their condition is poor absorption of nutrients and malnutrition. CF, a genetic disorder, is marked by the body's inability to transport chloride in and out of cells, causing mild to life-threatening complications, including recurrent and severe lung infections and delayed growth.

The Cystic Fibrosis Foundation defines vitamin D deficiency in patients as levels lower than 30 nanograms per milliliter and recommends that patients who are vitamin D deficient receive a weekly dose of 50,000 IU of ergocalciferol, a form of vitamin D.

"These findings are a big wake-up call not only because they show that many children with CF are lacking vitamin D, but also because the deficiency persists even in those children who are treated with weekly doses twice or three times as high as the current recommendations," says Hopkins Children's lung specialist Deanna Green, M.D., who led the research. "Clearly there is an urgent need to find more effective ways to restore healthy vitamin D levels."

In the meantime, investigators say, doctors caring for patients with CF should think about increasing the vitamin D intake beyond the current recommendations in those who are vitamin D deficient. They should also check vitamin D levels at least once a year in all CF patients and more frequently in those with abnormally low levels.

In the current study of CF patients treated at Hopkins Children's between 2003 and 2006, investigators found that 86 percent were vitamin D deficient in 2003, 50 percent were deficient in 2004, 54 percent were deficient in 2005, and 46 percent were deficient in 2006.

Comparing different weekly intakes of ergocalciferol, the Hopkins team found that the currently recommended 50,000 IU per week for eight weeks was effective in only 33 percent of the patients with vitamin D deficiency, while increasing the therapy to twice a week was effective in 26 percent of patients. Delivering the same dose three times a week

corrected the deficiency in just 43 percent of children. Vitamin D levels appeared to follow fluctuations in seasonal sun exposure, dropping sharply in the fall and winter and peaking during spring and summer.

Vitamin D deficiency was worst during the fall, with 83 percent of patients testing deficient, while only 41 percent were vitamin D deficient in the summer. Sun exposure is critical for vitamin D synthesis and production. Some doctors recommend sun exposure twice a week for up to 30 minutes at a time, but the debate is ongoing because sun exposure without protection increases the risk of skin cancer.

"Clearly we haven't established an optimal dose for treating vitamin D deficiency and more research is needed to do so," says senior researcher Peter Mogayzel, M.D. Ph.D., director of Hopkins Children's Cystic Fibrosis Center. "But what we know for sure is that the current recommendations are too low, and doctors should treat their patients with vitamin D deficiencies more aggressively,"

New therapies and earlier diagnosis have led to more and more CF patients living longer and well into adulthood, which means that vitamin D deficiency will be increasingly important for CF patients as they age.

"It is a testament to the advances we've made in treating CF, but as more and more patients survive and live longer, they will begin to face chronic conditions usually seen in healthy adults," Mogayzel says. "If we do not treat vitamin D deficiency early on, bone disease and osteoporosis will be increasingly a problem in the aging CF population."

The findings come on the heels of another Hopkins study showing that low levels of vitamin D increased the overall risk of death by 26 percent in the general population.

**Public release date: 9-Oct-2008**

## **Vitamin D a key player in overall health of several body organs, says UC Riverside biochemist**

RIVERSIDE, Calif. – Essential for life in higher animals, vitamin D, once linked to only bone diseases such as rickets and osteoporosis, is now recognized as a major player in contributing to overall human health, emphasizes UC Riverside's Anthony Norman, an international expert on vitamin D.

In a paper published in the August issue of the American Journal of Clinical Nutrition, Norman identifies vitamin D's potential for contributions to good health in the adaptive and innate immune systems, the secretion and regulation of insulin by the pancreas, the heart and blood pressure regulation, muscle strength and brain activity. In addition, access to adequate amounts of vitamin D is believed to be beneficial towards reducing the risk of cancer.

Norman also lists 36 organ tissues in the body whose cells respond biologically to

vitamin D. The list includes bone marrow, breast, colon, intestine, kidney, lung, prostate, retina, skin, stomach and the uterus.

According to Norman, deficiency of vitamin D can impact all 36 organs. Already, vitamin D deficiency is associated with muscle strength decrease, high risk for falls, and increased risk for colorectal, prostate and breast and other major cancers.

"It is becoming increasingly clear to researchers in the field that vitamin D is strongly linked to several diseases," said Norman, a distinguished professor emeritus of biochemistry and of biomedical sciences who has worked on vitamin D for more than 45 years. "Its biological sphere of influence is much broader than we originally thought. The nutritional guidelines for vitamin D intake must be carefully reevaluated to determine the adequate intake, balancing sunlight exposure with dietary intake, to achieve good health by involving all 36 target organs."

Vitamin D is synthesized in the body in a series of steps. First, sunlight's ultraviolet rays act on a precursor compound in skin. When skin is exposed to sunlight, a sterol present in dermal tissue is converted to vitamin D, which, in turn, is metabolized in the liver and kidneys to form a hormone. It was Norman's laboratory that discovered, in 1967, that vitamin D is converted into a steroid hormone by the body.

The recommended daily intake of vitamin D is 200 international units (IU) for people up to 50 years old. The recommended daily intake of vitamin D is 400 IU for people 51 to 70 years old and 600 IU for people over 70 years old. **Norman's recommendation for all adults is to have an average daily intake of at least 2000 IU.**

"To optimize good health you must have enough vitamin D," he said. "Vitamin D deficiency is also especially of concern in third world countries that have poor nutritional practices and religious customs that require the body to be covered from head to toe. Ideally, to achieve the widest frequency of good health by population, we need to have 90 percent of the people with adequate amounts of vitamin D."

About half of the elderly in North America and two-thirds of the rest of the world are not getting enough vitamin D to maintain healthy bone density, lower their risks for fracture and improve tooth attachment.

"There needs to be a sea change by various governmental agencies in terms of the advice they present to citizens about how much vitamin D should be taken," Norman said. "The tendencies of people to live in cities where tall buildings block adequate sunlight from reaching the ground, to spend most of their time indoors, to use synthetic sunscreens that block ultraviolet rays, and to live in geographical regions of the world that do not receive adequate sunlight all contribute to the inability of the skin to biosynthesize sufficient amounts of vitamin D."

Found in minute amounts in food, vitamins are organic substances that higher forms of animals need to grow and sustain normal health. Vitamins, however, are not synthesized

in sufficient amounts to meet bodily needs. Therefore, the body must acquire them through diet or in the form of supplements.

Because it is found in very few foods naturally, milk and other foods (often orange juice) are fortified with vitamin D.

While deficiency of vitamin D impacts health negatively, ingestion of extremely high doses of vitamin D can cause hypercalcemia, a condition in which the blood's calcium level is above normal. **The highest daily 'safe' dose of vitamin D is 10,000 IU.**

"More than ever we need to increase the amount of research on vitamin D, with more funding from government agencies and pharmaceutical companies, to meet the challenge of preserving or improving the health of everyone on the planet," Norman said.

**Public release date: 10-Oct-2008**

**Research shows link between bisphenol A and disease in adults**

A research team from the Peninsula Medical School, the University of Exeter, the University of Plymouth and the University of Iowa, have found evidence linking bisphenol A to diabetes and heart disease in adults

A research team from the Peninsula Medical School, the University of Exeter, the University of Plymouth and the University of Iowa, have found evidence linking Bisphenol A (BPA) to diabetes and heart disease in adults.

Their research paper is to be published in the Journal of the American Medical Association on Wednesday 17 September and it is the first time that evidence has emerged of the association between higher BPA levels and disease in adults.

BPA is a controversial chemical commonly used in food and drink containers. It has previously caused concerns over health risks to babies, as it is present in some baby's bottles.

BPA is used in polycarbonate plastic products such as refillable drinks containers, compact disks, some plastic eating utensils and many other products in everyday use. It is one of the world's highest production volume chemicals, with over 2.2 million tonnes **(6.4 billion pounds) produced in 2003, with an annual growth in demand of between six and 10 per cent each year.**

Many previous studies in laboratory animals have suggested that BPA is safe, but some laboratory studies have raised doubts. Experiments in which mice and rats were exposed to BPA have shown that higher doses of the chemical can lead to liver damage, insulin resistance, diabetes and obesity. The laboratory animal evidence is complicated and controversial. **Some scientists believe that BPA can disrupt the work done by hormones, especially oestrogen, but the full biological effects of BPA in humans is far from clear.**

The research team analysed information from the US government's National Health and Nutrition Examination Survey (NHANES) 2003-2004, the only large-scale data available on BPA concentrations excreted in urine. The research team analysed the results for the 1455 adults aged between 18 and 74 years old for whom measures were available. This study group is representative of the general population of the USA.

The analysis found that the 25 per cent of the population with the highest BPA levels were more than twice as likely to have heart disease and/or diabetes, compared to the 25 per cent with the lowest BPA levels. **Higher BPA levels were also associated with clinically abnormal liver enzyme concentrations.**

While this study has identified a statistical association between BPA and adult diseases for the first time, much more research is needed. Future work needs to exclude the small possibility that the association is due to some other unstudied factor, or that people with these diseases somehow become more exposed to BPA. It is also unclear whether the liver enzyme changes are linked to liver damage.

Professor David Melzer, Professor of Epidemiology and Public Health at the Peninsula Medical School (Exeter, UK), who led the team commented: "Our study has revealed, for the first time, an association between raised BPA loads and two common diseases in adults. At the moment we can't be absolutely sure that BPA is the direct cause of the extra cases of heart disease and diabetes: if it is, some cases of these serious conditions could be prevented by reducing BPA exposure. This is therefore an exciting finding, but it is also just the first step in understanding the role of BPA."

He emphasised that this new possible link does not detract from the existing health advice to people on how to prevent heart disease and diabetes. Professor Melzer also praised the NHANES study and the US Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention, who released these data for analysis by researchers.

Tamara Galloway, Professor of eco-toxicology from the School of Biosciences, the University of Exeter, added: "Our results illustrate how important human bio-monitoring programmes such as NHANES are in providing high quality information on the extent of human exposure to common chemicals such as BPA, allowing us to explore the relationship between exposure and health outcomes more fully."

**Public release date: 12-Oct-2008**

## **Pectin power**

Scientists have found a new possible explanation for why people who eat more fruit and vegetables may gain protection against the spread of cancers.

They have shown that a fragment released from pectin, found in all fruits and vegetables, binds to and is believed to inhibit galectin 3 (Gal3), a protein that plays a role in all stages of cancer progression.

"Most claims for the anticancer effects of foods are based on population studies," says Professor Vic Morris from the Institute of Food Research. "For this research we tested a molecular mechanism and showed that it is viable."

Population studies such as EPIC, the European Prospective Investigation of Cancer, identified a strong link between eating lots of fibre and a lower risk of cancers of the gastrointestinal tract. But exactly how fibre exerts a protective effect is unknown.

Pectin is better known for its jam-setting qualities and as being a component of dietary fibre. The present study supports a more exciting and subtle role.

Interaction between dietary carbohydrates and mammalian proteins, of which this research is an example, may provide an explanation. Other food carbohydrates such as

beta glucans are considered to be bioactive and their anti-cancer action can be attributed to different types of carbohydrate - mammalian protein interactions.

"For a whole combination of different effects it is best to consistently eat a range of fruits, vegetables and high-fibre foods," says Professor Morris. "You don't necessarily have to eat a superfood."

The next stage of Prof Morris' research is to identify how pectin can be taken up by the body and released so it can exert its effect on cancer cells. The research could result in functional foods with added bioactive pectin as well as providing more conclusive evidence for the importance of eating at least your '5-a-day'.

"This first step opens the way to a new and exciting area of research in bioactive carbohydrates", says Professor Morris.

**Public release date: 12-Oct-2008**

## **First evidence that a common pollutant may reduce iodine levels in breast milk**

### **Environmental Science & Technology**

Researchers in Texas are reporting the first evidence from human studies that perchlorate, a common pollutant increasingly found in food and water, may interfere with an infant's availability of iodine in breast milk. Iodine deficiency in infants can cause mental retardation and other health problems, the scientists note. The study also provides further evidence that iodine intake in U.S. mothers is low and that perchlorate may play a key role.

In a study scheduled for the November 1 issue of ACS' semi-monthly Environmental Science & Technology, Purnendu Dasgupta and colleagues note that perchlorate occurs naturally in the soil and is also manufactured as a rocket fuel and explosive ingredient. Past studies showed that perchlorate can inhibit iodine uptake. However, scientists did not know its effects on iodine levels in the milk of nursing mothers.

To find out, the researchers collected breast milk samples from 13 breastfeeding mothers and measured their content of iodine, perchlorate, and thiocyanate, another iodine inhibitor found in certain foods. The study showed that if these breast milk samples were fed to infants, 12 of 13 infants would not have an adequate intake of iodine. It also

showed that nine of the infants would have ingested perchlorate at a level exceeding those considered safe by the National Academy of Sciences. "Even though the number of subjects was not large, in terms of the number of total samples analyzed, this is the most extensive study on the topic," the researchers say, adding that the low iodine levels are "disconcerting." — MTS

**Public release date: 13-Oct-2008**

## **Vitamin K does not stem BMD decline in postmenopausal women with osteopenia**

**\*\*\*\*READ ARTICLE IMPORTANT FINDINGS\*\*\*\***

In a randomized controlled trial called the "Evaluate the Clinical use of vitamin K Supplementation in Postmenopausal Women with Osteopenia" (ECKO) trial, Angela Cheung and colleagues at the University of Toronto found that a high dose daily vitamin K1 supplement did not protect against age-related bone mineral density (BMD) decline. However, as reported in this week's PLoS Medicine, the findings also suggest that vitamin K1 may protect against fracture and cancer in postmenopausal women with osteopenia.

Dr. Cheung and colleagues randomized 440 postmenopausal women with osteopenia to receive either 5 mg of vitamin K1 or a placebo daily for two years. Two hundred and sixty one of these women continued their treatment for two more years to gather information about the long-term effects of vitamin K1 supplementation.

After two years and after four years, lower back and hip measurements of bone mineral density (BMD) had decreased by similar amounts in both the vitamin K and the placebo groups.

**Over the four-year period, fewer women in the vitamin K group had fractures (9 versus 20 women in the placebo group) and fewer women had cancer (3 versus 12). Vitamin K supplementation was well tolerated over the four-year period and adverse health effects were similar in the two treatment groups, report the researchers.** They emphasize that the study was not powered to examine fractures or cancers and the numbers were small, therefore the findings must be interpreted with caution.

The researchers say that larger studies are needed to examine the effect of vitamin K1 on fractures and on cancer and, until these are done, high dose vitamin K1 supplementation should not be recommended for the prevention of osteoporosis.

In the US, 10 million people have osteoporosis and 18 million have osteopenia, a milder condition that precedes osteoporosis.

**Ralph's note - So the study was just based upon BMD, and not fracture risk. What**

**type of convoluted research grant did they receive. A 50% plus reduction in fracture, is a very significant finding. Isn't that the whole point of BMD. The reduction of fractures to begin with?**

**Public release date: 13-Oct-2008**

## **Scientists develop new cancer-killing compound from salad plant**

Researchers at the University of Washington have updated a **traditional Chinese medicine to create a compound that is more than 1,200 times more specific in killing certain kinds of cancer cells than currently available drugs, heralding the possibility of a more effective chemotherapy drug with minimal side effects.**

The new compound puts a novel twist on the common anti-malarial drug artemisinin, which is **derived from the sweet wormwood plant** (*Artemisia annua* L). Sweet wormwood has been used in herbal Chinese medicine for at least 2,000 years, and is eaten in salads in some Asian countries.

The scientists attached a chemical homing device to artemisinin that targets the drug selectively to cancer cells, sparing healthy cells. The results were published online Oct. 5 in the journal *Cancer Letters*.

"The compound is like a special agent planting a bomb inside the cell," said Tomikazu Sasaki, chemistry professor at UW and senior author of the study.

In the study, the UW researchers tested their artemisinin-based compound on human leukemia cells. It was highly selective at killing the cancer cells. The researchers also have preliminary results showing that the compound is similarly selective and effective for human breast and prostate cancer cells, and that it effectively and safely kills breast cancer in rats, Sasaki said.

Cancer drug designers are faced with the unique challenge that cancer cells develop from our own normal cells, meaning that most ways to poison cancer cells also kill healthy cells. Most available chemotherapies are very toxic, destroying one normal cell for every five to 10 cancer cells killed, Sasaki said. This is why chemotherapy's side effects are so devastating, he said.

"Side effects are a major limitation to current chemotherapies," Sasaki said. "Some patients even die from them."

The compound Sasaki and his colleagues developed kills 12,000 cancer cells for every healthy cell, meaning it could be turned into a drug with minimal side effects. A cancer

drug with low side effects would be more effective than currently available drugs, since it could be safely taken in higher amounts.

The artemisinin compound takes advantage of cancer cell's high iron levels. Artemisinin is highly toxic in the presence of iron, but harmless otherwise. Cancer cells need a lot of iron to maintain the rapid division necessary for tumor growth.

Since too much free-floating iron is toxic, when cells need iron they construct a special protein signal on their surfaces. The body's machinery then delivers iron, shielded with a protein package, to these signals proteins. The cell then swallows this bundle of iron and proteins.

**Artemisinin alone is fairly effective at killing cancer cells. It kills approximately 100 cancer cells for every healthy cell, about ten times better than current chemotherapies.** To improve those odds, the researchers added a small chemical tag to artemisinin that sticks to the "iron needed here" protein signal. The cancer cell, unaware of the toxic compound lurking on its surface, waits for the protein machinery to deliver iron molecules and engulfs everything -- iron, proteins and toxic compound.

Once inside the cell, the iron reacts with artemisinin to release poisonous molecules called free radicals. When enough of these free radicals accumulate, the cell dies.

"The compound is like a little bomb-carrying monkey riding on the back of a Trojan horse," said Henry Lai, UW bioengineering professor and co-author of the study.

The compound is so selective for cancer cells partly due to their rapid multiplication, which requires high amounts of iron, and partly because cancer cells are not as good as healthy cells at cleaning up free-floating iron.

"Cancer cells get sloppy at maintaining free iron, so they are more sensitive to artemisinin," Sasaki said.

Cancer cells are already under significant stress from their high iron contents and other imbalances, Sasaki said. Artemisinin tips them over the edge. The compound's modus operandi also means it should be general for almost any cancer, the researchers said.

"Most currently available drugs are targeted to specific cancers," Lai said. "This compound works on a general property of cancer cells, their high iron content."

The compound is currently being licensed by the University of Washington to Artemisia Biomedical Inc., a company Lai, Sasaki and Narendra Singh, UW associate professor of bioengineering, founded in Newcastle, Wash. for development and commercialization. Human trials are at least several years away. Artemisinin is readily available, Sasaki said, and he hopes their compound can eventually be cheaply manufactured to help cancer patients in developing countries.

Other authors of the study are Steve Oh, UW medical student; Byung Ju Kim, UW chemistry instructor; and Singh.

The Washington Technology Center and the Witmer Foundation provided funding for the study.

**Public release date: 13-Oct-2008**

## **More Americans have, get treated for high blood pressure**

*Study highlights:*

- *An analysis of data from two national health studies shows that more U.S. adults have hypertension than ever before.*
- *The percent of those aware of, being treated for and having the disorder under control has increased and as a result more people are living with rather than dying from hypertension.*
- *Researchers say the nation's obesity epidemic is a major factor for the increase in hypertension prevalence.*

DALLAS, Oct. 14, 2008 — First, the bad news: More American adults have hypertension (high blood pressure) and prehypertension than ever before.

Now, the good news: The percentage of those getting treated for and controlling high blood pressure has also increased. As a result, even the bad news has a good news aspect: more people are living with rather than dying from hypertension.

The bad news—good news portrait of the disease — reported in *Hypertension: Journal of the American Heart Association* — emerged from an analysis of data from two national health studies. Researchers at the National Heart, Lung, and Blood Institute (NHLBI), of the National Institutes of Health, said the nation's obesity epidemic is a major factor in the increased prevalence of hypertension.

“That confirms what others have observed based on more limited data and what one would expect, because obesity is an important cause of high blood pressure,” said Jeffrey A. Cutler, M.D., lead author of the study and a consultant to NHLBI's Divisions of Prevention and Population Sciences and Cardiovascular Diseases.

Researchers compared the hypertension findings of the third National Health and Nutrition Examination Survey (NHANES III), which ran from 1988–1994, with data from the first six years (1999–2004) of the current NHANES, which collects information continuously in two-year blocks. They examined data from 16,351 NHANES III respondents and 14,430 surveyed during 1999–2004, all age 18 or older.

The age-standardized prevalence rate for hypertension rose from 24.4 percent to 28.9 percent. Being overweight or obese accounted for part but not all of the increase in high blood pressure among different age and race/ethnicity groups.

Prevalence is an estimate of the total number of cases of a disease existing in a population

during a specified period. Prevalence is often expressed as a percentage of the population.

“We see that much of the magnitude in men is accounted for by obesity, but less so in women, possibly because of some unexplored changes in risk factors for hypertension,” said Paul D. Sorlie, Ph.D., co-author of the study and Epidemiology Branch Chief in the Division of Prevention and Population Sciences.

The most notable change in most race and gender groups was an upward trend in blood pressure categories. **This lowered the percent of Americans with normal pressure (from 55.5 percent to 50.3 percent)**. Prehypertension — defined as readings of 120 to less than 140 systolic and/or 80 to 89 diastolic — increased from 32.3 percent to 36.1 percent. (Systolic is the upper number—the pressure when the heart is beating, while diastolic, the lower number, is the pressure when the heart is relaxing.)

Ralph's Note - WHAT only 50.3% of Americans have normal Blood Pressure now!!!

**Public release date: 14-Oct-2008**

## **Resveratrol prevents fat accumulation in livers of 'alcoholic' mice**

Study shows substance found in grapes, red wine, peanuts, prevents alcoholic fatty liver by coordinating molecules that control fat metabolism

BETHESDA, Md. (Oct. 14, 2008) - The accumulation of fat in the liver as a result of chronic alcohol consumption could be prevented by consuming resveratrol, according to a new study with mice. The research found that resveratrol reduced the amount of fat produced in the liver of mice fed alcohol and, at the same time, increased the rate at which fat within the liver is broken down.

Chronic alcohol consumption causes fat to accumulate and can lead to liver diseases, including cirrhosis and fibrosis of the liver. It can also result in liver failure. The study points to resveratrol as a possible treatment for alcoholic fatty liver disease, and as a way to prevent the disease in those who are at risk, but have not developed it.

Resveratrol is present in grapes, peanuts, berries and in red wine. Other research with mice has suggested resveratrol may have anti-cancer and anti-inflammatory properties. There is also evidence that it has cardiovascular benefits. However, these findings have not been extended to humans.

The study, "Resveratrol alleviates alcoholic fatty liver in mice," was carried out by Joanne M. Ajmo, Xiaomei Liang, Christopher Q. Rogers, Brandi Pennock and Min You, all of the University of South Florida Health Sciences Center, Tampa. The study appears in the American Journal of Physiology-Gastrointestinal and Liver Physiology, published by The American Physiological Society.

Activates cell signalers

The study builds on previous research, which suggests that alcohol inhibits two molecules that play a role in cell signaling and the breakdown of fats in the liver: AMP-activated protein kinase (AMPK) and sirtuin 1 (SIRT1). When alcohol inactivates AMPK and SIRT1, it allows fat to accumulate. Resveratrol does the opposite -- activating AMPK and SIRT1, and helping to clear out fat.

In this study, the authors wanted to find out more about how this happens, at the molecular level. They divided mice into groups and fed all of them a low-fat diet. Some mice had resveratrol in their diet, some had resveratrol plus ethanol (alcohol), some had ethanol alone and some had neither ethanol nor resveratrol. The researchers used two different dose levels of resveratrol. At the end of the experiment, they examined the livers of the mice.

The researchers found, as they had expected, that resveratrol treatment increased the expression of SIRT1 and stimulated the activity of AMPK in the livers of mice fed alcohol. They further found that the increased expression of SIRT1 and AMPK led to:

Reduction of sterol regulatory element binding protein (SREBP-1)

Activation of peroxisome proliferator-activated receptor gamma co-activator alpha (PGC-1 $\alpha$ )

Elevation of circulating adiponectin, a hormone produced by fat cells, which helps control obesity

Enhanced expression of adiponectin receptors in the liver, which increases the effectiveness of the circulating adiponectin.

The findings suggest that resveratrol prevents alcoholic fatty liver by coordinating molecules that control fat metabolism. This prevents accumulation of fat in the mouse liver by both reducing the production of fat and burning off the fat that is there. Interestingly, the combination of alcohol with resveratrol appears to enhance the positive effects of resveratrol, said Dr. You, the study's senior author.

"Our study suggests that resveratrol may serve as a promising agent for preventing or treating human alcoholic fatty liver disease," the authors concluded.

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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.**