

## PSORIATIC ARTHRITIS NEWS AND VIEWS

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### PSORIATIC ARTHRITIS MEDICAL NEWS

#### ZELNORM HAS SERIOUS SIDE EFFECTS

Zelnorm (tegaserod) is a prescription drug for the short-term treatment of women with irritable bowel syndrome (IBS). Zelnorm is intended primarily to treat the constipation that accompanies IBS. (It has never been tested in men.)

Summary: The FDA has added new warning information to the label of the drug Zelnorm. Patients are warned to stop taking Zelnorm immediately if they develop rectal bleeding, bloody diarrhea, or new or worsening abdominal pain. These are symptoms of intestinal ischemia in which the supply of blood and oxygen to the intestines are compromised. Zelnorm rarely causes severe diarrhea that can result in dehydration and a need for intravenous fluids. Therefore, Zelnorm also should be stopped if diarrhea occurs.

Comment: We have been bothered by some of the current Zelnorm advertising. For example, ads on television present a group of very attractive women, all smiling and showing off their trim, tanned, well-toned midsections. One gets the

immediate impression that Zelnorm has something to do with being young, pretty and in great shape. It would not be very glamorous to state on prime time TV that Zelnorm is actually intended to "increase the movement of stools (fecal matter) through the bowels" but that, in fact, is what this drug is intended to do.

Barbara K. Hecht, Ph.D. - Frederick Hecht, M.D. Medical Editors,  
MedicineNet.com

#### FDA UPDATES ZELNORM LABELING WITH NEW RISK INFORMATION

The Food and Drug Administration (FDA) today announced the addition of new risk information to the health professional labeling for Zelnorm (tegaserod maleate). Zelnorm is a prescription medication for the short-term treatment of women with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation. The labeling is being revised to ensure health professionals and patients have the most current and complete information available when prescribing and taking Zelnorm.

The specific revisions include a new warning about the serious consequences of diarrhea associated with the medication; a new precaution about ischemic colitis and other forms of intestinal ischemia (i.e., reduced blood flow to the intestines); changes to the adverse reactions section describing post-marketing reports; and new information in the "Information for the Patient" leaflet. The new warning states, "Serious consequences of diarrhea, including hypovolemia, hypotension and syncope have been reported in the clinical studies and during marketed use of Zelnorm. In some cases, these complications have required

hospitalization for rehydration. Zelnorm should be discontinued immediately in patients who develop hypotension or syncope. Zelnorm should not be initiated in patients who are currently experiencing or frequently experience diarrhea."

The new precaution on ischemic colitis states, "Ischemic colitis, and other forms of intestinal ischemia, has been reported in patients receiving Zelnorm during marketed use of the drug. A causal relationship between Zelnorm use and these events has not been established. Placebo-controlled clinical trials of 7,000 patients for 3-month duration showed no cases of these events, and would suggest the rate of these events is low. Zelnorm should be discontinued immediately in patients who develop symptoms of ischemic colitis, such as rectal

bleeding, bloody diarrhea or new or worsening abdominal pain. Patients developing these symptoms should be evaluated promptly and have appropriate diagnostic testing performed. Treatment with Zelnorm should not be resumed in patients who develop findings consistent with ischemic colitis."

Under the post marketing experience heading in the adverse reactions section, the labeling now states, "Voluntary reports of adverse events occurring with the use of Zelnorm include the following: ischemic colitis, mesenteric ischemia, gangrenous bowel, rectal bleeding, syncope, suspected sphincter of Oddi spasm, bile duct stone, and cholecystitis with elevated transaminases. Because these cases are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. No causal relationship between these events and Zelnorm use has been established. Hypokalemia secondary to diarrhea has also been reported."

The new patient information advises patients who get new or increased stomach pain or blood in their stools to stop taking Zelnorm right away and to immediately contact their doctor to determine if they may have a serious problem. In addition, the new labeling advises patients to stop taking Zelnorm and to call a doctor right away if they experience diarrhea that leads to lightheadedness, dizziness or fainting.

FDA approved Zelnorm on July 24, 2002, following the recommendation for approval made by FDA's Gastrointestinal Drugs Advisory Committee on June 26, 2000.

Zelnorm is the only FDA-approved prescription drug for the short-term treatment of women with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation.

Zelnorm increases the movement of stools (fecal matter) through the bowels. Zelnorm does not cure IBS, nor does it treat diarrhea-predominant IBS. Zelnorm reduces pain and discomfort in the abdominal area, and reduces bloating and constipation. The safety and effectiveness of Zelnorm in men have not been established.

In conjunction with the FDA announcement, the manufacturer of Zelnorm, Novartis Pharmaceuticals Corporation of East Hanover, N.J., has issued a letter to health professionals to highlight the labeling changes.

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## VITAMIN E MAY INCREASE BAD CHOLESTEROL

By Steven Reinberg - HealthDay Reporter (HealthDayNews)

You have probably heard that antioxidants such as vitamin E are good for you, but new research finds antioxidants may actually help produce "bad" cholesterol.

Experiments in cells and mice indicate that oxidation is necessary to reduce the amount of low-density lipoprotein (LDL) cholesterol produced in the liver. That is why polyunsaturated fatty acids, which are oxidants, can reduce cholesterol production.

Oxidation, also called oxidant stress, is a chemical reaction of a substance with oxygen. In the body, oxidant stress releases free radicals that damage cells.

"Not all oxidant stress is bad for you," said lead researcher Dr. Edward A. Fisher, a professor of cardiovascular medicine and cell biology at New York University. "Oxidant stress also has some benefits in terms of the cardiovascular system, by decreasing the liver production of the lipoproteins that cause atherosclerosis."

"Sometimes oxidative stress is good, and sometimes it's bad," said co-researcher Dr. Kevin Jon Williams, a professor of medicine at Jefferson Medical College. For example, humans breathe oxygen because they need oxidation to convert food into energy, and oxidant stress is also how the immune system kills bacteria, he added.

Fisher's team found liver cells under oxidative stress release free radicals made by the normal conversion of polyunsaturated fatty acids to so-called lipid peroxides.

When these free radicals are released, they destroy a critical protein called ApoB100. Without ApoB, the liver cannot make LDL cholesterol, and the amount of cholesterol released into the blood is therefore substantially reduced.

The researchers found that when vitamin E was introduced to these liver cells, it prevented the destruction of ApoB, which lets the liver make more LDL cholesterol, according to their report in the May issue of the *Journal of Clinical Investigation*.

In large studies, "vitamin E has flunked as a protection against coronary artery disease," Fisher said. So the "blanket recommendation for the use of antioxidants, such as vitamin E, for lowering the risk of heart disease is not warranted."

However, the findings also confirm that diets rich in polyunsaturated fatty acids, such as those found in fish, can substantially reduce the amount of bad

cholesterol your body makes, Fisher added.

Williams said the he would "take vitamin E supplements only in circumstances where there has been proven clinical benefit, and that is not the case in cardiovascular disease."

Dr. Ronald Krauss, director of atherosclerosis research at the Children's Hospital Oakland Research Institute, said this study shows how diet can affect blood fat levels.

"This study reminds us that even though there are number of benefits of antioxidants in the diet, we can't assume that all antioxidants will benefit all aspects of health," said Krauss, who wrote an accompanying editorial.

There may be a lack of benefit from antioxidants on blood fat levels, Krauss said. "In order to determine whether antioxidants benefit heart disease, we have to rely on clinical studies," he noted.

"The studies that have been done to date have not shown a benefit from antioxidants. Maybe this study gives us one reason for that negative result," Krauss said.

"If one wants to take advantage of antioxidants, which can have many health benefits, one should rely on eating foods that are rich in antioxidants and not rely on taking supplements to prevent heart disease," Krauss advised.

SOURCES: Edward A. Fisher, M.D., Ph.D., professor, cardiovascular medicine and cell biology, New York University, New York City; Kevin Jon Williams, professor, medicine, Jefferson Medical College, Philadelphia; Ronald Krauss, M.D., director, atherosclerosis research, Children's Hospital Oakland Research Institute, Oakland, Calif.; May 2004 Journal of Clinical Investigation Copyright © 2004 ScoutNews, LLC. All rights reserved.

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#### TOO MUCH VITAMIN C BAD FOR JOINTS By E.J. Mundell - HealthDay Reporter (HealthDayNews)

If a moderate amount of daily vitamin C is good for bone health, then more must be even better, right? Wrong.

"Everybody needs vitamin C in their diet, but taking supplements beyond the recommended daily allowance is probably inadvisable" when it comes to fighting arthritis, said Dr. Virginia Kraus, an associate professor of medicine at Duke University and lead author of a study that challenges the conventional wisdom on diet and osteoarthritis.

Millions of older Americans suffer from the pain and stiffness of osteoarthritis -- a deterioration of bones and cartilage in the joints. Unlike rheumatoid arthritis, which experts know is caused by inflammation brought on by immune system dysfunction, the causes of osteoarthritis remain unclear.

Seeking a deeper understanding of the disease, researchers are now focusing on lifestyle and dietary factors as possible contributors to osteoarthritis. In their study, published in the June issue of *Arthritis & Rheumatism*, Kraus' team of researchers fed guinea pigs low, medium and high doses of vitamin C as part of their daily diet.

"The guinea pig is the ideal animal in which to test this," Kraus explained, "because they require vitamin C in their diet, just like humans, and they get an osteoarthritis of their knees that looks very similar to the type of knee osteoarthritis that humans get."

Arthritis specialists have long recommended that patients consume an adequate daily amount of vitamin C because the nutrient is both a potent antioxidant and a key player in the formation of joint cartilage. But would higher doses of the vitamin make bones even stronger?

Not so, Kraus reports. "More is not better," she said. "We found that the more vitamin C given, the more osteoarthritis is apparent in the joints of these animals that are predisposed to getting osteoarthritis."

Guinea pigs fed low doses of vitamin C showed the least signs of knee arthritis, Kraus said, but since they also tended to weigh much less than the medium- or high-dose animals, reductions in weight might explain that result.

Animals fed a medium dose of vitamin C -- roughly equivalent to the recommended daily allowance in humans -- had slightly more signs of knee damage. But it was the high-dose animals that fared worse, with obvious signs of arthritis and an increase of bony outcroppings on the knee called osteophytes or bone spurs.

The exact links between excess vitamin C and osteoarthritis remains unclear. "One connection that we were able to make was that vitamin C activates a protein called TGF-beta," Kraus said. "When active, this protein seems to increase bone spur or osteophyte formation." Microscopic bone spurs roughen the surface of joints, she explained, triggering the irritation and inflammation that is a hallmark of arthritis.

Dr. John H. Klippel, president of the American Arthritis Foundation, said the findings "are challenging the common wisdom that increased doses of vitamin C may be helpful or protective -- in fact, it seems to be quite the opposite." He believes more study is needed into possible links between diet and bone health, especially since the origins of osteoarthritis remain a mystery.

"This kind of research is so important because osteoarthritis is an extremely common disease," he said. "Therefore, it begs the question, are there other dietary influences that in some way affect this disease?"

The study findings should not alter the standard dietary recommendation that Americans eat five to six servings of fruits and vegetables per day to obtain adequate doses of vitamin C, Kraus said. But for those who can't always be sure they are getting enough vitamin C from their diet, taking a daily

multivitamin might be advisable, as well.

"What I tell my patients is that one multivitamin per day is a prudent thing because it also has the daily allowance of vitamin D and other micronutrients that might be important to bones," she said.

But should folks take an extra vitamin C pill on top of that?

"Absolutely not," Kraus said. "I try and emphasize to my patients that just because something is natural doesn't mean that more is better for you. It just goes to prove that the old adage that moderation is, for most things, the best."

SOURCES: Virginia Kraus, M.D., Ph.D., associate professor, medicine, division of rheumatology, Duke University Medical Center, Durham, N.C.; John H. Klippel, M.D., president and chief executive officer, Arthritis Foundation; June

2004 Arthritis & Rheumatism Copyright © 2004 ScoutNews LLC. All rights reserved.

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#### TOO MUCH OF A GOOD THING: BETTER WATCH YOUR VITAMIN INTAKE OCALA, Fla. (The New York Times News Service)

Vitamin supplements, in large doses, can be too much of a good thing. Research done by the Mayo Clinic states that taking high doses of certain essential vitamins can even be harmful.

So, what are the basics, and which vitamins should you be careful with? And why is taking daily doses of vitamins good?

Vitamins help you to process food and help you to use the energy, or calories, efficiently. If you are not eating healthy, taking a daily dose of vitamins also insures that your body gets the recommended dosage you need to survive.

There are water-soluble vitamins, meaning that your system flushes the excess out of your system in urine. Water-soluble vitamins are mainly vitamins in the B and C families.

However, four vitamins -- A, D, E and K -- are fat-soluble and excesses are stored in fatty tissues in the body. It is possible to accumulate too much of these vitamins -- to the point where they become toxic to your system.

#### DON'T OVER DO IT

VITAMIN A, or retinol, plays a part in maintaining healthy vision, bone growth, reproduction and regulation of your immune system. But the risks associated with taking too much Vitamin A are osteoporosis, liver abnormalities, hair loss and neurological problems. Common sources of Vitamin A are vegetables containing beta-carotene, such as carrots. Check with your doctor before taking additional Vitamin A supplements: The recommended dosage for men is 1,000 retinol equivalent; for women, 800.

VITAMIN D, calciferol, is necessary for the absorption of dietary calcium. Too much Vitamin D can result in excessive urination, high blood pressure, kidney damage and kidney stones. Vitamin D is added to milk and can also be obtained from natural sunlight. The RDA is 200 IU for adults.

VITAMIN E, or d-alpha tocopherol, in excess can cause an increased risk of bleeding, but other than that doesn't generally appear to be harmful in excessive doses. The RDA is 10 IU for men, 8 IU for women.

VITAMIN K forms clots and can thwart blood-thinning medication's actions. Supplements should only be taken under medical supervision. More than 80 micrograms for men or 65 for women is harmful.

#### THE BOTTOM LINE

Taking a basic multivitamin with 100 percent of recommended daily vitamins is usually sufficient, unless a medical condition (determined by a physician) requires that you take additional supplements.

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#### WHY PHYSICAL ACTIVITY AND EXERCISE ARE IMPORTANT

The terms physical activity and exercise may seem synonymous, but there are critical differences between the two.

Physical activity encompasses any movement of the body in which your muscles contract and your metabolism increases. Everything from washing dishes to playing ice hockey falls under this umbrella.

Exercise is a subcategory of physical activity. It refers specifically to a structured program of activity geared toward achieving or maintaining physical fitness.

Levels of physical activity can be viewed on a continuum. At one end of the spectrum is a sedentary lifestyle, an absence of any significant physical activity. On the other end is the peak level of exercise training exhibited by a well-conditioned athlete. How you move along this continuum depends on both your starting point and your exercise goals. If you are currently sedentary, simply upping the amount of physical activity in your daily life is an important push forward.

At a certain point, however, you will need to establish an exercise program to continue making strides. And once you have a program in place, you should periodically review your fitness level and reexamine your personal goals to determine how you can continue to make progress.

#### How Your Body Responds To Physical Activity And Exercise

When you call on your body to perform any type of physical work — even something as simple as walking across the room — your cells are jolted out of their

resting state of balance. What follows is a complicated set of physical processes that supply the cells with the extra energy they need.

First and foremost, the cells require additional oxygen to fuel the metabolic functions necessary for sustained activity. To meet this demand, the respiratory and circulatory systems gear up to deliver oxygen-rich blood to the working muscles. This accelerated metabolism, in turn, produces greater amounts of waste products. These products are transported back to waste-removal sites, such as the lungs and kidneys, for expulsion from the body.

It is because of these processes that you breathe more rapidly and your heart pumps more vigorously when you exert yourself. Another byproduct of increased energy production is heat. Sweating is a telltale sign of strenuous exertion is your body's way of cooling your skin and keeping your body temperature at a safe level.

#### The Benefits Of Physical Activity And Exercise

Physical activity (and exercise) is a cornerstone of a healthy lifestyle. Not only does physical activity make you look and feel better, but it is also critical for improving your health and extending your life. Being active significantly lowers your chances of developing potentially fatal illnesses, including heart disease, diabetes and cancer. In addition, remaining active throughout your life can help you stay healthy as you age.

Here's a rundown on the benefits you can expect from regular activity:

- Lower risk of early death
- Lower risk of heart disease
- Lower risk of high blood pressure (If your blood pressure is already elevated, you can expect it to drop.)
- Better weight control
- Lower risk of diabetes
- Lower risk of colon cancer
- Increased bone strength
- Improved balance
- Lower risk of depression and anxiety
- Increased energy level
- Overall sense of well-being

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#### RHEUMATOID ARTHRITIS RELIEF FROM RITUXAN

Background: Rituxan (rituximab) is a monoclonal (man-made) antibody. It attaches to a structure called the CD20 receptor on the surface of B-lymphocytes

and selectively knocks them out. Rituxan was the first monoclonal antibody approved in the US for the treatment of cancer, namely B-cell non-Hodgkin lymphoma (NHL).

Summary: A trial of Rituxan has been completed in patients with poorly controlled rheumatoid arthritis. (Treatment with methotrexate had not controlled

their disease). A single IV course of Rituxan provided significant improvement in the symptoms of rheumatoid arthritis.

Comment: Rituxan is an intriguing new drug for alleviating symptoms in rheumatoid arthritis and it may hold promise for the treatment of other autoimmune diseases such as lupus. However, the use of Rituxan in this trial led to some serious infections (because it is immunosuppressive).  
Barbara K. Hecht, Ph.D. Frederick Hecht, M.D. Medical Editors,  
MedicineNet.com

## CANCER DRUG RELIEVES RHEUMATOID ARTHRITIS By Serena Gordon - HealthDay Reporter (HealthDayNews)

Long-term relief from the pain of rheumatoid arthritis may soon be a reality.

In the June 17 issue of the New England Journal of Medicine, researchers from University College London report that the cancer drug rituximab, when taken alone or in combination with other rheumatoid arthritis drugs in a single course of two infusions, provided relief from the symptoms of rheumatoid arthritis for as long as 48 weeks.

"I think rituximab is going to be a promising addition to the treatments we have available for people with rheumatoid arthritis," said Dr. Leonard Serebro, a senior staff rheumatologist at the Ochsner Clinic Foundation Hospital in New Orleans.

Dr. Jonathan Edwards, lead author of the study and a professor of connective tissue medicine at University College London, said what's most exciting about this work is that it "completely changes our understanding of the cause of rheumatoid arthritis in that it shows that B cells are critically involved in the underlying process."

B cells, which are also known as lymphocytes, are an integral part of the body's immune system. When working properly, the immune system is only supposed to attack foreign matter, such as invading bacteria or viruses. In autoimmune diseases like rheumatoid arthritis, the body's immune system mistakenly turns against itself and begins attacking healthy tissue.

"The cycle underlying autoimmune diseases such as rheumatoid arthritis may be similar to a bug in a computer that makes it loop and crash," Edwards said in a statement. "B-cell targeted therapy is like rebooting the computer of your immune system to sidestep the bug."

More than 2 million people in the United States have rheumatoid arthritis, according to the Arthritis Foundation. Symptoms of the disease include joint pain and stiffness, fever, fatigue, limited range of motion, and redness of the skin.

Rituximab, sold under the brand name Rituxan, is what's known as a monoclonal antibody, which is a drug that targets a specific cell that's causing trouble. It is typically used to treat non-Hodgkin's lymphoma.

For the new study, Edwards and his colleagues randomly assigned 161 people with active rheumatoid arthritis to one of four treatments: oral methotrexate; rituximab; rituximab plus cyclophosphamide; or rituximab plus methotrexate. All of the study volunteers had taken methotrexate, a common rheumatoid arthritis medication, but had not achieved relief from their symptoms. Also, all were given a 17-day course of corticosteroids.

The researchers found that rituximab, when taken alone or in combination, provided greater relief of symptoms than methotrexate alone at both 24 and 48 weeks. For example, after 24 weeks, 43 percent of those on the rituximab-methotrexate combination and 41 percent on the rituximab-cyclophosphamide combination reported at least a 50 percent improvement in their symptoms compared to only 13 percent of the methotrexate group.

Edwards said the biggest benefit from this treatment was the long-lasting relief without a need for repeated treatments, which is standard with current therapies.

"On average, our patients need treatment every 15 months. For the most successful responders, it is every two to three years. Continued treatment in the sense of regular re-dosing is what this approach is designed to avoid."

Rituximab was well tolerated. The only serious side effect was respiratory infection, but Serebro said that people with rheumatoid arthritis already have an elevated risk of infection because of the disease.

"The responses that were seen and the duration of the responses, coupled with the low side effects that were seen, were extremely encouraging," said Dr. Clifton O. Bingham III, a rheumatologist and director of the Seligman Center for

Advanced Therapeutics at NYU-Hospital for Joint Disease. "In general, there's a lot of excitement surrounding rituximab for rheumatoid arthritis."

The experts caution, however, that this treatment needs more study. Serebro also noted that until it is FDA-approved for the treatment of rheumatoid arthritis, many insurance companies likely won't pay for the medication, which is expensive.

Bingham said the new study left several questions unanswered. First, he pointed out that fairly high doses of corticosteroids were given in this study. He

said another trial needs to be done to see if rituximab needs to be given in combination with corticosteroids to be so effective, or if it could be given without the additional medication. Also, he said that while the people in this study achieved symptom relief, no objective measure, such as X-rays, were taken to assure that the disease was not continuing to progress.

Bingham and Serebro pointed out another exciting aspect of this therapy -- its potential for treating other autoimmune diseases, such as lupus.

"This has tremendous promise for all autoimmune diseases," said Bingham.

SOURCES: Jonathan Edwards, M.D., professor of connective tissue medicine,

University College London; Leonard Serebro, M.D., senior staff rheumatologist, Ochsner Clinic Foundation Hospital, New Orleans; Clifton O. Bingham III, M.D., rheumatologist and director, Seligman Center for Advanced Therapeutics, NYU-Hospital for Joint Disease, and assistant professor of medicine, New York University School of Medicine, New York City; June 17, 2004, New England Journal of Medicine - Copyright © 2004 ScoutNews LLC. All rights reserved.

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A PUBLIC DRUG REGISTRY? IT'S ABOUT TIME  
AMA'S EFFORTS TO PUBLISH RESULTS OF ALL STUDIES ARE LONG OVERDUE  
By Arthur Caplan, Ph.D. June 22, 2004

#### COMMENTARY

Listen very carefully. Do you hear the sounds of ice cracking in the fiery domain where sinners are said to go upon their deaths? Has hell in fact frozen over? Can it be true? Has the American Medical Association broken away from a long history of concern about protecting its members' self-interest and pushed forward an idea that is sound, bold and in the public interest? Hell, yes!

On June 17, the AMA voted to ask the federal government to create a registry that would make publicly available the results of all drug experiments conducted on humans. This means that anyone could look and see what drugs have worked, which ones are duds and which ones are known to have possibly dangerous side effects.

#### Limited access to information

Such a move would help solve the problem of limited access to accurate drug information in the United States, an issue that stems from several sources. First off, academic researchers have a hard time getting research published if it does not show positive results. Negative studies don't get past most journal editors. Even if experiments that don't pan out do get published in the academic literature, you are not likely to hear about it. "Common cold still not cured" is a headline you are unlikely to ever read.

More troubling than the problems academic researchers have in getting negative results published is the behavior of private companies that sponsor studies.

Pharmaceutical and biotechnology companies sponsor the overwhelming majority of late-stage tests of new drugs and medical devices. Even if private drug companies know there are negative results or even injuries and deaths associated with their products, they are under no obligation to make that information known to you or the medical profession. The companies consider this data proprietary. They have lobbied to ensure that only the Food and Drug Administration gets this information and, even then, some drug companies simply prematurely squash studies they don't think will reflect favorably on their product.

The most recent example of hiding negative results concerns children. Studies

conducted by drug companies showed evidence linking the use of antidepressant drugs to an increased risk of suicide in children. But the pharmaceutical companies chose not to disclose this evidence. It was only when Elliott Spitzer,

New York State's take-no-bull attorney general, began hauling the offending drug companies into court that the damaging evidence was released.

The physicians of the AMA realized that without ready access to all experimental data — good, bad and indifferent — they cannot hope to know what is the best treatment for their patients. And they understand that without public access to negative data all they can go on is what the marketing departments of the drug companies tout as the best drug to prescribe.

#### Broken contracts

There is another reason to make sure that every bit of data produced in testing new drugs and devices on human beings is made public: It is part of the tacit contract the researcher and sponsor of the study have with each and every subject.

If you agree to be in an experiment or to participate in a clinical trial to find new ways to treat your cancer, diabetes, Parkinsonism, asthma, depression, migraines or whatever, you are told that the chance of directly benefiting from your participation in a study is at best unknown. Research simply often does not pan out. But, you are also told that if you choose to enter a study then even if it does not work, and most studies do not, doctors will learn from the results and future generations will benefit from that knowledge.

That is a great reason to participate in medical research. But if negative results are not published, if bad outcomes or deaths are swept under the rug, then nothing is learned. And the promise that was made to those who put up with the risk, inconvenience and hassle of research is broken.

Medicine will be much much better off if commercial concerns take a back seat to society's need to know. All data from every experiment — regardless of who pays for it — should be kept in a national registry that is accessible to anyone who wants to see it. Not just because such a registry will make medicine more effective, cheaper and safer, but also because it is what every subject in a medical experiment has the right to expect.

Arthur Caplan is director of the Center for Bioethics at the University of Pennsylvania.

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With this issue, I will have published 70 newsletters to our website. The whole process started August 21st of 2001.

I will be taking a mini break from the daily routine of checking medical publications, newspapers, magazines, journals, researching additional sites and publishing two times each month. Therefore, there will be no newsletters during July and August.

I will resume publishing the newsletter beginning Sept. 15th. Hope everyone has a great summer with as many pain free days as possible.

Good Health to All,

Jack Nicholas  
Newsletter Editor  
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