

PSORIATIC ARTHRITIS NEWS AND VIEWS

VOLUME- 4 ISSUE- 13

September 15, 2004

PSORIATIC ARTHRITIS MEDICAL NEWS

AMA TO WEIGH INFLUENCE OF DRUG COMPANIES

CHICAGO (AP) -- Drug companies' influence on medical research and on doctors themselves will be under the microscope as the nation's largest group of physicians gathered for its annual meeting in June.

Proposals facing the American Medical Association include a measure seeking to make all drug study results public, even unpublished research funded by pharmaceutical companies that might reflect poorly on their products.

The measure stems partly from concern over unpublished data linking some antidepressants with suicidal behavior in children. Government officials are investigating the potential link.

Another measure would strengthen a policy the AMA adopted last year on "shadowing," the practice of drug company representatives sitting in on patients' visits with their doctors.

Critics say the practice is an attempt to influence what medicines are prescribed. Drug companies say the practice is educational, but they sometimes pay hundreds of dollars a day to the doctors for these visiting rights -- money the new measure says doctors should refuse.

The more than 250 proposals prepared for the meeting, also asked the AMA to take a stand on issues that include the obesity epidemic, the execution of juvenile criminals and the harvesting of organs from patients who haven't explicitly given consent.

The generally cautious AMA frequently avoids taking bold stands on controversial issues, and many proposals at the five-day meeting will be rejected or revised before being sent to the group's delegates, who begin voting on policies to adopt.

A new financial report touts the group's fiscal health, showing a \$20.1 million operating profit in 2003 -- the fourth consecutive year of operating in

the black. The increase from \$11.7 million in 2002 was attributed partly to revenues from publishing and sources other than AMA dues, which have been declining along with membership.

The AMA had 250,830 members in 2003, down from 260,455 in 2002, representing about a third of the nation's doctors and medical students.

Still, any AMA support could lend credence to the meeting's proposals,

including the move to make all drug study results public.

As drafted, the measure would ask the U.S. Department of Health and Human Services to consider forming a national registry of all drug studies, possibly available over the Internet.

Alan Goldhammer of the industry group Pharmaceutical Research and Manufacturers of America said a public research registry could lead to misinterpretation.

"Those are the kinds of things that we'd have to look at and discuss before endorsing or rejecting any proposal," Goldhammer said.

Calls for publicizing all drug studies also have come from the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry and bioethicists concerned about industry influence on doctors.

"It would be good to see the AMA get on board," said Merrill Goozner of the Center for Science in the Public Interest. "Medical professionals who are after all the prescribers and the primary users of these tools ... should be the guys in the forefront" of the issue, Goozner said.

It is critical for doctors to have all information on tested drugs so they can make informed prescribing decisions, said Dr. David Fassler, a Vermont psychiatrist.

Drug companies aren't required to publish study results, and medical journal editors "are at the mercy of what is sent in the mail," said Dr. Catherine DeAngelis, editor of the Journal of the American Medical Association.

Drug company-funded submissions more often than not have positive results, a phenomenon called publication bias.

DeAngelis voiced support for the push for a national registry, as did Dr. Jeffrey Drazen, editor of the New England Journal of Medicine. Copyright 2004 The Associated Press. All rights reserved.

**CONSUMER GROUP URGES BAN OF CHOLESTEROL DRUG
CONCERN OVER SIDE EFFECTS OF CRESTOR GROWS**
By Robert Bazell-Correspondent NBC News

Otis Elliott started taking the cholesterol-lowering drug Crestor and developed severe muscle pains within days.

"I just couldn't stand it anymore, the pain was too severe," says Elliott. However, by then it was nearly too late; Elliott went into kidney failure, which doctors say almost killed him.

In a recently published letter published in the medical journal The Lancet, a consumer advocacy group warns that the danger of such life-threatening side

effects is unacceptably high with Crestor, a statin that was approved by the Food and Drug Administration last August.

"So everywhere you turn there are ads for Crestor and there is no question that those ads help to sell drugs, but what patients have not known and what I think a lot of doctors have not known is that the drug has unique risks," says Dr. Sidney Wolfe of the nonprofit group Public Citizen. All statins carry a slight risk of muscle damage, but the consumer group says the danger is higher with Crestor, and only Crestor threatens the kidneys.

Ever since Crestor was approved by the FDA, the manufacturer, AstraZeneca, has been heavily advertising the drug.

AstraZeneca says the concern about side effects is just flat-out wrong. "We believe the safety profile for Crestor has been very, very extensively studied and we're confident that it is comparable to the other statins," says David Brennan, the company's CEO.

What is at stake is a potential portion of an enormous market and human lives. Sales of statin drugs in the United States now total \$14 billion a year,

with 13 million people taking them. In addition, experts say the number of people who should be taking the drugs is triple the numbers who are currently taking them.

FDA officials say they agree with the manufacturer that Crestor is safe and effective, but add that they will continue to study reports of harmful side effects, such as Elliott's case, to see if they reveal an unusual pattern.

2004 MSNBC Interactive

YOUR GENES CAN AFFECT DRUG ACTIVITY

By Ed Edelson - HealthDay Reporter

A study showing that an individual's genetic makeup affects the response to a cholesterol-lowering drug heralds a new medical discipline, researchers say: pharmacogenetics.

It's not something that will change medical practice just yet, says Dr. Paul M. Ridker, chief of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital in Boston and lead author of a new study appearing

in the June 16 Journal of the American Medical Association. But "over the next 10 years we will see a lot of studies of this kind that will help address the issue of how we treat our patients."

"Burgeoning" is the word Ridker used for the field of pharmacogenetics, while Susanne B. Haga, project director of human genetics at the Center for the

Advancement of Genomics, a private research group, said knowledge about the interaction between genes and drugs "is growing by leaps and bounds."

Over the long run, said Haga, co-author of an editorial accompanying the report, "information on how genetic variation affects drug efficacy and drug safety will become a basic part of drug development." But right now, she said, "the commercial ability to test for these variations is not available."

Still, the study "will be a real eye-opener for physicians and patients," Ridker said.

He and his colleagues did detailed genetic studies of 1,563 people taking pravastatin (Pravachol), one of several statin medications being prescribed to lower cholesterol levels. The researchers looked for individual variations called single-nucleotide polymorphisms (SNPs) in genes that play a role in the metabolism of cholesterol and other lipids.

One of those genes produces a molecule called HMG-CoA reductase. Two common and closely linked SNPs in that gene "were significantly associated with a 22 percent smaller reduction in total cholesterol and a 19 percent smaller reduction in LDL cholesterol following 24 weeks of pravastatin therapy," the report said.

That gene-based reduced activity was found in about 8 percent of the people studied, Ridker said, adding that the finding was more or less expected.

"We've known for some time that some patients get a greater reduction than others," he said. "We were looking for evidence that genetic variation played a role. We found it on the basis of genes that are the target of the drug itself."

The finding doesn't call for any major change in treatment of patients with the specific SNPs, at least now, Ridker said. "It could well be that just a higher dose will overcome this problem," he said.

What is important is that the effect of genetic variation on the effects of drugs used to treat cancer now has been verified for at least one drug used in cardiology, Ridker said. It's not known yet whether genetic variation acts in the same way on other statins, he said, and many more studies are needed to determine the role played by pharmacogenetics in drug therapy.

"This paper is important because it is a first demonstration, but we are in no way there yet," Ridker said.

SOURCES: Paul M. Ridker, M.D., MPH, director, Center for Cardiovascular Disease Prevention, Brigham and Women's Hospital, Boston; Susanne B. Haga, Ph.D,

project director of human genetics, Center for the Advancement of Genomics, Rockville, Md.; June 16, 2004 Journal of the American Medical Association. Copyright © 2004 ScoutNews LLC.

BLOOD CLOT RISK NOT TREATED PREVENTIVELY, STUDY FINDS

DURHAM, NC — In a nationwide study of hospitalized patients, researchers at Duke University Medical Center and Brigham and Women's Hospital found that individuals at risk for developing deep vein thrombosis (DVT) -- a disorder characterized by the formation of blood clots in the deep veins of the legs --

often fail to receive preventive medications. DVT can cause death when leg clots break free and lodge in the lungs, a condition known as pulmonary embolism.

The study found that, of more than 5,000 patients who developed DVT, the majority failed to receive prophylactic therapy in the 30-day period prior to their diagnosis. What's more, said the researchers, in patients with DVT, physicians often failed to prescribe the drugs proven most effective for treating the disorder, opting instead for older treatment methods.

"Clearly, there is a disconnect between evidence and execution as it relates to DVT prevention and treatment," said co-lead investigator Victor Tapson, M.D., associate professor of medicine at Duke University Medical Center. "The bottom line is that every patient admitted to a hospital ought to be considered for preventive measures."

Tapson and study first author Samuel Goldhaber, M.D., of Brigham and Women's Hospital, report their findings in the Jan. 15, 2004, issue of *The American Journal of Cardiology*. The study was supported by Aventis Pharmaceuticals, which manufactures low molecular weight heparin, a drug that can treat and prevent DVT. Tapson is a paid consultant and has conducted research for Aventis.

Those who most often develop DVT include patients with cancer, obesity and heart failure. Also at increased risk for DVT are elderly patients and those who have had surgery within the previous three months or who have been immobile in the previous 30 days.

Symptoms of DVT can be mild to severe, and include swelling and discomfort in the extremities. Administration of low-dose anticoagulants, including unfractionated heparin, low molecular weight heparin and warfarin, have been found to significantly reduce the risk of DVT. Once clots have formed, higher doses of the drugs act as effective treatments.

Left untreated, leg vein clots can enter the bloodstream and travel to the lungs causing pulmonary embolism, a condition that can affect lung function. Pulmonary embolism is responsible for more than 100,000 deaths in the U.S. each year -- more than the number of breast cancer deaths, highway fatalities or deaths from AIDS, Tapson noted.

For the study, over a period of six months, physicians at 183 sites nationwide enrolled 5,451 patients with DVT in the registry. The study investigators obtained information about patients' histories from medical records.

Less than 30 percent of patients enrolled in the registry received preventive blood thinning drugs within 30 days prior to their diagnosis of DVT. Of the 2,726 patients who developed DVT while in the hospital, 42 percent failed to receive prophylaxis within 30 days prior to diagnosis, the team reported.

Furthermore, said Tapson, physicians often treated patients diagnosed with DVT with unfractionated heparin rather than low molecular weight heparin,

despite clear advantages of the latter drug. For example, low molecular weight heparin is administered by subcutaneous injection, while unfractionated heparin

generally requires intravenous infusion. Patients receiving low molecular weight heparin can often be discharged while receiving treatment, he added, while those receiving unfractionated heparin require longer hospital stays.

"Studies like this allow us to look at real life in terms of the treatment that patients are receiving," Tapson said. "Clearly, anticoagulants proven to aid in the prevention of DVT are being underused by physicians in the United States for both medical and surgical patients, despite a very low risk of side effects."

The solution, said Tapson, is to educate physicians that all hospitalized patients should be evaluated with regard to their DVT risk and those at risk provided prophylaxis. Source: Duke University Medical Center news release.

CAN AUTOIMMUNE DISEASE BE DETECTED EARLY?

By Steven Reinberg HealthDay Reporter

Study: Antibodies can foretell problems long before symptoms

For many autoimmune diseases, such as type 1 diabetes, lupus, multiple sclerosis, Addison's disease and rheumatoid arthritis, antibodies to the diseases appear years before symptoms.

Knowing that antibodies are present before the disease develops, doctors can alert patients to symptoms to watch out for, and researchers may be able to develop early treatments, according to a report in the May 8 issue of The Lancet.

Antibodies are specific proteins made by the body's immune system to fight infection or harmful foreign substances.

However, in autoimmune disease, the body makes autoantibodies that attack the body itself, said study author Dr. Hal Scofield, an associate member of the

Oklahoma Medical Research Foundation.

"It is now clear that these antibodies, which are markers of autoimmune diseases, appear in people's blood long before the clinical illnesses begin," he added.

These autoantibodies are preclinical markers to the disease, and that appears to be true for almost every autoimmune disease, Scofield explained.

"It may be possible to identify people with the potential of developing these diseases before they get sick," Scofield said. "As we can identify many of

these diseases before people get sick, you can imagine prevention trials taking place."

This approach is being done now in a trial of type 1 diabetes in children with autoantibodies that are markers for the disease. The children are being administered nasal insulin to try to prevent diabetes from developing, Scofield said.

In addition, Scofield believes, if patients knew they were at risk for an autoimmune disease, they could be told what to watch out for. They might also be able to avoid some of the most serious complications, such as diabetic coma or Addisonian crisis, a life-threatening condition that happens when the adrenal gland fails to produce enough of the hormone cortisol.

The next step, according to Scofield, is to study large groups of people with autoantibodies to various diseases to see how predictive these autoantibodies are in determining who develops a disease and how long it takes symptoms to appear.

Scofield cautioned that right now the benefit of identifying autoantibodies has little practical application. "There is the potential in the next few years to identify people who go on to get an autoimmune disease, and that kind of identification may lead to preventive therapies," he said.

"I am very enthusiastic about this approach," said Dr. Noel Rose, director of the Center for Autoimmune Disease Research at Johns Hopkins University. "This is an extremely important report."

"These autoantibodies are a warning sign of impending disease, and it opens the possibility of predicting disease and possibly benefiting patients by early treatment or even interrupting the autoimmune responses," he added.

"Antibodies in diseases such as lupus, rheumatoid arthritis, multiple sclerosis, diabetes and others can be measured and should allow the development of patient-specific therapies," said Dr. Paul J. Utz, an assistant professor of medicine at Stanford University School of Medicine.

"As newer technologies are developed, we will be able to measure thousands of unique antibodies at one time. Their measurement will be an important component of future drug development for biotechnology and pharmaceutical companies," Utz said.

"This paper really shows the importance of early screening, particularly in people with early symptoms," said Virginia Ladd, the president of the American Autoimmune Related Diseases Association.

Earlier diagnosis will lead to preventing major organ damage, she added.

Today, even when patients have autoantibodies, doctors dismiss them, Ladd said, "but this paper says that it is important to follow patients who have low levels of autoantibodies."

SOURCES: Hal Scofield M.D., associate member, Oklahoma Medical Research

Foundation, and professor, medicine, University of Oklahoma Health Science Center, Oklahoma City; Noel Rose, M.D., Ph.D., director, Center for Autoimmune Disease Research, Johns Hopkins University, Baltimore; Paul J. Utz, M.D., assistant professor, medicine, Stanford University School of Medicine, Palo Alto, Calif.; Virginia Ladd, president, American Autoimmune Related Diseases Association, Detroit; May 8, 2004, The Lancet. Copyright © 2004 ScoutNews, LLC. All rights reserved.

DRUG PRICES OUTSTRIP MEDICARE DISCOUNTS

Discounts: A report from the AARP Public Policy Institute presents the results of a study of changes in manufacturers' prescription drug prices from

2000-2003 for the nearly 200 brand name prescription drugs most widely used by Americans age 50 and older. This report compares price changes to the rate of general inflation. It focuses on the price that drug manufacturers charge wholesalers because that is a substantial component of the final retail price. A

change in the price the drug manufacturers charge to wholesalers generally results in a similar percentage change in the price that the consumer pays.

On average, prices charged by drug manufacturers for widely used brand name prescription drugs in 2003 increased three times the rate of inflation. Ranked by their volume of sales, the price for Fosamax (alendronate) was up 5.6%, the price for Lipitor (atorvastatin) was up 6.0% and the price for Plavix (clopidogrel) was up 7.8%.

Comment: This report is more evidence that drug prices are continuing to escalate and that they are not even being kept within the rate of overall inflation. The report also confirms what we all already know. Something has to be done to control the ever-increasing prices of drugs in the US. Barbara K. Hecht, Ph.D., Frederick Hecht, M.D., Medical Editors, MedicineNet.com

DRUG PRICE INCREASES TRIPLE THE RATE OF INFLATION

By Karen Pallarito, HealthDay Reporter

(HealthDayNews) -- Prices for the most popular brand-name medications used by older Americans increased at three times the rate of inflation last year, claims a new AARP study.

"That's a pretty substantial increase," said study co-author Steven W. Schondelmeyer, head of the department of pharmaceutical care and health systems at the University of Minnesota.

The study, released Tuesday, measured changes in the prices that drug manufacturers charged wholesalers over a four-year period starting in the year 2000. The authors said the underlying price fluctuations are significant because

they affect the actual prices seniors pay at their local drugstore or by mail.

"These price increases typically pass straight through to the consumer," Schondelmeyer said.

Prices for widely used brands rose 4.1 percent, on average, in 2000, and 6.9 percent in 2003, while inflation fell from 3.3 percent to 2.2 percent over the same period, the report said.

And the average cost to consumers for top brands nearly doubled from 2000 to 2003 -- rising from \$33.76 to \$60.38, the authors estimate. This means the typical older American who takes three drugs would have paid \$101 more in 2000 and \$181 more in 2003 if the higher prices were passed along, AARP noted.

When it came to individual brand names, a 10-milligram dose of the cholesterol medication Lipitor rose 6 percent in 2003, almost triple the 2.2 inflation rate that same year. A 75-milligram dose of the blood thinner Plavix rose 7.8 percent each year covered by the study.

Large increases were also seen in estrogen drugs and thyroid medications, checking in at 10 times and six times the rate of inflation, respectively, in 2003.

Pharmaceutical Research and Manufacturers of America, the brand name drug industry's lobbying group, did not respond to a request for comment on the findings.

AARP's Public Policy Institute tracked prices for the top 200 drugs used by seniors, based on both annual sales volume and the number of prescriptions dispensed each year. The analysis yielded a combined list of the 291 most widely used drugs, including 197 brands -- the focus of this report.

At some future date, AARP said it intends to issue a separate report examining price changes for the top 94 generic drugs used by seniors.

The new report is the latest step in a larger campaign by the senior citizen advocacy group to put pressure on the pharmaceutical industry to lower drug prices. The effort comes in the wake of sharp criticism of AARP leaders for supporting last year a Medicare prescription drug benefit program that bars the federal government from negotiating lower prices from drug makers.

As part of that legislation, seniors may take advantage of a new drug discount card program effective June 1. Federal Medicare officials say the program will give cardholders price breaks averaging 11 percent to 18 percent off average retail prices. But critics of the program say the discounts are meaningless if drug prices continue to escalate.

"The new prescription benefit in Medicare was an important step, but our members have made it clear that they want AARP to continue to push for affordable drugs," AARP Chief Executive Officer Bill Novelli said in a statement.

Earlier this year, AARP asked the pharmaceutical industry to hold its price increases to the rate of general inflation. The new data provide a benchmark

against which to monitor the industry's future performance, the group said.

Overall, the new prescription drug report showed the average rate of growth in manufacturers' drug prices has accelerated in recent years, said study co-author David J. Gross, a senior policy adviser with AARP's Public Policy Institute.

On a cumulative basis, prices for the 155 brand-name drugs on the market for the entire four-year period rose 27.6 percent, on average. That compares with a general inflation rate of 10.4 percent for the four-year period, the report said.

Only four drugs had price increases below the four-year average rate of inflation, according to the report.

The rapid price increases for estrogens and thyroid hormones may be due to the fact that few generics have cropped up to compete against these drugs, the study authors said.

These medications have been on the market since World War II, noted Schondelmeyer, who suspects drug makers are raising prices to reflect current pricing trends. "They're drugs that have not had the same kind of generic competition that we see (elsewhere)," he added.

Also Tuesday, AARP unveiled a new quarterly report to consumers on prescription drug prices. The "Rx Watchdog Report" will update consumers on drug maker activities, their pricing policies, quarterly profits and spending on lobbying and advertising, the group said.

SOURCES: David J. Gross, senior policy adviser, AARP Public Policy Institute, Washington, D.C.; Steven W. Schondelmeyer, Pharm.D., Ph.D., professor, pharmaceutical management and economics, head, department of pharmaceutical care and health systems, and director of Prime Institute, College of Pharmacy, University of Minnesota; May 25, 2004, AARP report, Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 Through 2003
- Copyright © 2004 ScoutNews LLC. All rights reserved.

LACK OF VITAMIN D LINKED TO PAIN
By Salynn Boyles WebMD Medical News Reviewed By Brunilda Nazario, MD

Study Shows Limited Sun Exposure Has Health Benefits

There is new evidence that small amounts of unprotected sun exposure could be good for you. Earlier studies have linked vitamin D deficiency with an increased risk for several cancers. Now comes word that it may also be a major cause of unexplained muscle and bone pain.

In a study involving 150 children and adults with unexplained muscle and

bone pain, almost all were found to be vitamin D deficient; many were severely deficient with extremely low levels of vitamin D in their bodies.

Humans tend to get most of their vitamin D from exposure to sunlight, so those who avoid the sun completely or who always wear sunscreen to protect themselves against skin cancers are at risk for vitamin D deficiencies, says Michael Holick, MD. Holick runs the Vitamin D Research Lab at Boston University Medical Center.

"I think the current message that all unprotected sun exposure is bad for you is too extreme," he tells WebMD. "The original message was that people should limit their sun exposure, not that they should avoid the sun entirely. I

do believe that some unprotected exposure to the sun is important for health."

Dermatologists Disagree

Holick claims there is now a strong epidemiological case linking vitamin D deficiency with a host of cancers including those of the prostate, colon, and breast; and he says vitamin D may also help protect against heart disease, autoimmune diseases, and even type 1 diabetes.

He will present the evidence in a book scheduled for publication next spring, but the nation's largest dermatology group remains unconvinced. In a recent press release, American Academy of Dermatology officials wrote that they were "deeply concerned" that the message that unprotected sun exposure may have health benefits could "mislead the public about the very real danger of sun exposure, the leading cause of skin cancer."

Patients Should Be Tested

In the latest study, Gregory A. Plotnikoff, MD, of the University of Minnesota Medical School found a much higher incidence of vitamin D deficiency in the patients with unexplained muscle and skeletal pain than expected, regardless of their ages.

All of the African Americans, East Africans, Hispanics, and Native Americans who participated in the study were vitamin D deficient, as were all of the patients under the age of 30.

The researcher says it was a big surprise that the worst vitamin D deficiencies occurred in young people -- especially women of childbearing age. The findings are reported in the December issue of the journal Mayo Clinic Proceedings.

"The message here is that unexplained pain may very well be linked to a vitamin D deficiency," Plotnikoff tells WebMD. "My hope is that patients with unexplained pain will be tested for vitamin D status, and treated, if necessary."

Food and Pills

Although it is possible to get vitamin D through foods or supplements, both researchers say it is not easy. A glass of fortified milk or fortified orange

juice has about 100 international units (IU) of vitamin D and a multivitamin typically has 400 IU. Holick believes most people need about 1000 IU of vitamin D each day. The recommended dietary allowance (RDA) for vitamin D varies

with age, sex, and various medical conditions but in general is 200-600 IU per day. Other sources of vitamin D include:

Cod Liver Oil. 1 tablespoon=1360 IU of vitamin D

Salmon. 3 ounces=425 IU of vitamin D

Herring. 3 ounces=765 IU of vitamin D

Sardines. Canned, 3 ounces=255 IU of vitamin D

Multivitamin supplements commonly provide 200-400 IU of vitamin D daily.

He says a light-skinned person wearing a swimsuit at the beach will have absorbed about 20,000 IU of vitamin D in the time it takes their skin to get lightly pink.

The amount of sun exposure needed to get the proper dose of vitamin D depends on a person's skin type, where they live, and time of year, and time of day

the exposure occurs. Holick says it is difficult for people living in northern climates to get the vitamin D they need from the sun in the winter, but in

the summer a light-skinned person at the beach should get all the vitamin D they need in about five minutes.

"The trick is getting just enough sun to satisfy your body's vitamin D requirement, without damaging the skin," he says. "It is difficult to believe that

this kind of limited exposure significantly increases a person's risk of skin cancer."

SOURCES: Plotnikoff, G. Mayo Clinic Proceedings, December 2003; vol. 78: pp. 1463-1470. Gregory A. Plotnikoff, MD, MTS, departments of internal medicine and pediatrics, University of Minnesota Medical School, Minneapolis. Michael Holick, MD, department of medicine, Boston University School of Medicine, Boston. News release, American Academy of Dermatology, July 3, 2003; "Vitamin D

+ Sunshine + Bad Medicine." © 2003 WebMD Inc. All rights reserved.

FDA SAYS REMICADE USERS SUFFER AILMENTS

August 24, 2004 - WASHINGTON (AP)

The Food and Drug Administration and manufacturer Centocor are warning doctors that patients receiving the drug Remicade to treat rheumatoid arthritis

and Crohn's disease have suffered sometimes-fatal blood and central nervous system disorders.

Centocor's Aug. 11 warning letter to doctors said the "causal relationship" between the ailments and Remicade therapy "remains unclear."

The Malvern, Pa.-based company, working with the federal drug regulatory agency, revised its label for the monoclonal antibody.

Patients receiving the drug suffered reductions in their red and white blood cell, granulocyte and platelet counts, leaving them more vulnerable to abnormal bleeding and infections. In some instances, patients died. In rare instances, patients suffered central nervous system disorders, including confusing immune system responses that swelled, then decayed, blood vessels.

Remicade was approved for use in the United States on Aug. 24, 1998. Worldwide, 509,000 patients have taken it. In late July, a European advisory committee approved expanding its use for treating people with psoriatic arthritis.

Copyright 2004 The Associated Press. All rights reserved.

My â€œtime awayâ€ this summer was just what the doctor ordered, however I am glad to be back in the newsletter business.

My computer has so many news items, articles, studies, etc, saved on it, I could write newsletters forever. Since I havenâ€™t published since June, some information you may have already seen or heard about from other sources, however I will be including news item that could be vital knowledge for our membership, particularly new members.

Good Health to All,

Jack Nicholas
Newsletter Editor
Cornishpro@aol.com (mailto:Cornishpro@aol.com)

Issue 2004 09/15/04 -13