

Shorts

briefed by Jule Klotter

Drug Trial Cut-Offs

Tens of thousands of patients – some for altruistic reasons, many in hope of a cure – take part in clinical drug trials each year. When a trial ends, patients who have benefited from a test drug often lose access to the new treatment. The government has special programs for patients who want to continue taking an experimental drug after a trial ends, but these programs require the consent of the drug's manufacturer and the patient's doctor. Most drugs fail clinical trials, and companies save money by producing limited amounts. Sometimes, drug manufacturers only produce enough of the test drug for the trial itself. Even if companies do have additional supplies of a test drug, hospital boards, which are responsible for regulating clinical trials, are reluctant to ask manufacturers for additional doses. They fear alienating these companies since clinical trials bring money and prestige to a hospital.

In other cases, researchers are reluctant to let patients continue taking a test drug after a trial ends because negative side effects may arise. *The Wall Street Journal* reported the case of a 12-year-old boy with an aggressive brain tumor that shrunk by a third after he received three injections of a radioactive Novartis drug. When the trial ended, the researcher who led the trial refused to give the boy another dose. She suggested that the parents take the boy to Europe where a similar treatment was undergoing testing. Unlike in the US, patients taking part in European drug trials pay for the treatment. In this case, it would cost \$10,000 plus travel expenses. The boy's father began lobbying the FDA, Novartis, congressmen, and the media for help. The combined pressure led the researcher to agree to a fourth dose of the drug. She later admitted that she was afraid that the FDA would shut down her on-going trial if the boy reacted badly to additional doses. Like this boy's father, it is often up to patients and their families to push for continued access to an experimental drug.

An international physician's group that sets ethical standards, the World Medical Association, has stated that clinical trial participants should be able to continue treatments that benefit them. However, an advisor to hospital boards and drug companies, New York lawyer Mark Barnes, says that the cost of providing experimental drugs to patients for free could mean less money for the development of other drugs.

Anand, Geeta. How Some Patients in New-Drug Trials Can Get Cut Off. *The Wall Street Journal*, December 8, 2003

English Health Care Change

The National Health Service (NHS) of England is spending \$17 billion to develop and implement a nationwide computerized health care information system. Over the next couple of years, the health records of each of England's 50 million NHS clients will be stored in a central database, accessible to medical practitioners. The system will allow health care appointments and referrals to be made online. Doctors will also be able to e-mail prescriptions directly to pharmacies. The computerized system will also allow attending physicians, practitioners, and therapists to follow a patient's care over time and document when each phase of a person's treatment is scheduled to take place. Officials expect the system to conduct five billion transactions a year by the end of 2008.

To protect patient privacy, NHS is allowing patients to prevent general access to potentially damaging information (eg., an abortion or a mental health problem) and to designate which

medical practitioners can see their complete medical records. The NHS system will also include an 'audit trail' that will show who has accessed which parts of a patient's record.

Naik, Gautam. England Plans Major Revamp of Health Care. *The Wall Street Journal* 3 December 2003

Hospital Discounts for Uninsured

Responding to criticism from patient advocates, labor unions, and lawmakers, hospitals are beginning to revise how they bill and collect payment from the nation's 43.6 million uninsured patients. Medicare regulations require hospitals to set and adhere to a list of charges for each of their treatments and services. The list is supposed to keep hospitals from overcharging the agency or certain groups of patients. When Medicare was first initiated in the 1960s, hospital charges were based on actual cost plus a reasonable profit, and Medicare/Medicaid patients received a discount. As HMOs became powerful enough to demand and receive discounts for their clients, hospitals began to raise their listed charges in order to start from a higher bargaining position. Without an insurer or the government to act as their advocate, uninsured patients are usually charged the full list price. When uninsured patients fail to pay their bills, hospitals have put liens on their homes, garnished wages, seized bank accounts, and even had debtors who miss court dates, arrested.

The American Hospital Association has agreed to ask its 4,800 member hospitals to adopt new voluntary guidelines for billing and collection, but the organization says the guidelines must first be approved by Medicare. In a letter to the Department of Health and Human Services, the group states that Medicare regulations "make it far too difficult and frustrating" to offer uninsured patients discounts. Tom Gustafson, deputy director of the center for Medicare Management, told *The Wall Street Journal* that Medicare does let hospitals give people, who can prove financial need, discounts on a case-by-case basis. Medicare officials will have to determine whether a unilateral discount for uninsured patients is permitted by current regulations. In the meantime, the American Hospital Association has asked its members to make their billing charges public and easily understandable and to provide financial counseling that includes available charity care or financial aid.

Lagnado, Lucette. Hospitals Will Give Price Breaks to Uninsured, if Medicare Agrees. *The Wall Street Journal*, 17 December 2003

Low-Dose Naltrexone Therapy

Naltrexone, a drug used to treat heroin and opium addicts, can boost the immune system when taken at low doses, according to the Low Dose Naltrexone Homepage (www.lowdosenaltrexone.org). The drug, FDA-approved in 1984, blocks opioid receptors. At high doses, it blocks the effect of heroin or opium. At low doses naltrexone inhibits the action of endogenous opioid hormones (eg, beta-endorphin and met-enkephalin). Research in the last 20 years has shown that most immune cells have receptors for these opioid hormones that are believed to help "orchestrate" the immune system. A review article on opioid-induced immune modulation in the *New England Journal of Medicine* (November 13, 2003) said: "Preclinical evidence indicates overwhelmingly that opioids alter the development, differentiation, and function of immune cells, and that both innate and adaptive systems are affected. Bone marrow

progenitor cells, macrophages, natural killer cells, immature thymocytes and T cells, and B cells are all involved.”

New York physician Bernard Bihari, MD, found that low-dose naltrexone (LDN) taken once a day at bedtime enhanced the immune system of his HIV patients. Apparently, the body responds to a nightly blockage of opioid receptors by producing more endorphin and enkephalin. In his clinical practice, Dr. Bihari has found that LDN helps patients with autoimmune disease and cancer as well as those with HIV/AIDS. The progression of autoimmune disease – including multiple sclerosis, rheumatoid arthritis, celiac disease, CFIDS, and lupus – ceased in all of the patients taking LDN. Many experienced a remission. Among the 350 AIDS patients (as of September 2003) that Dr. Bihari treats, over 85% showed no detectable levels of HIV during the past 7 years. Some of these patients are on LDN only and others are using LDN along with accepted AIDS therapies. Low-dose naltrexone is now being studied at Penn State's College of Medicine. Dr. Jill Smith leads the 4-month study to test LDN's effectiveness in relieving the symptoms of Crohn's disease.

The Low Dose Naltrexone Homepage, sponsored by Advocates for Therapeutic Immunology, emphasizes that the low-dose naltrexone must be taken in an unaltered form – not time-release. The therapeutic dose is around 3 to 4.5 mg. Since naltrexone usually comes in 50 mg doses, doctors may need the services of a reputable compounding pharmacy.

The Low Dose Naltrexone Homepage www.lowdosenaltrexone.org
Penn State Colon & Rectal Surgery Research: www.hmc.psu.edu/colorectal/research/naltrexone.htm

Selenium Supplements & Keep Hope Alive

The essential trace mineral selenium has several uses including antioxidant protection, immune system stimulation, and cancer prevention. In Keep Hope Alive's *Journal of Immunity* (Spring 2003), Mark Konlee urges people to include Brazil nuts and seafood – both selenium-rich – in their diets. He recommends that people avoid supplements with sodium selenite because of toxic effects and L-selenomethionine, the most common form sold in health food stores.

After studying research literature, Konlee says he found no evidence that daily usage of L-selenomethionine as high as 1800 mcg for several weeks produced any positive effects other than a “small decline in mercury levels.” Patient reports to Keep Hope Alive support these results. As of September 2002, fourteen people had found no benefit from selenium supplements containing L-selenomethionine. Lab tests indicated no increases in WBC, CD4, or CD8 counts; and viral loads failed to decrease. In addition, half of these people experienced adverse effects. One person with CFIDS reported a numbing sensation on the right side of his body that disappeared a few days after he discontinued selenomethionine. Another experienced pain in the kidney area. Lung congestion and skin problems are other possible negative effects.

In contrast, Keep Hope Alive has received over 20 cases in which a plant-based selenium supplement has “completely resolved many cases of long standing candidiasis and, [has] reduced fatigue, increased T cell counts and WBCs, restored the ability to sweat and restored pure whiteness to the whites of the eyes. Not one case of adverse effects has been reported in the past year from using plant-based selenium supplements at dosages up to 1800 mcg daily.” These supplements are made from high-selenium mustard greens (e.g., Ecological Formulas's “Selenium Cruciferate” or Solaray's “Bio-Active Selenium”), high-selenium broccoli (e.g., Jarrow Formulas “Activated Selenium”), or selenium-yeast (Source Natural's “Selenomax”). The L-selenomethionine supplements, promoted as an amino acid chelate, are actually “an inorganic selenium in a base of L-

methionine,” according to Konlee's conversation with one company's employee.

Keep Hope Alive is a 501 (C) 3 non-profit organization, dedicated to researching and informing the public about low-cost effective treatments for people with compromised immune systems. The organization does not receive any funding from government or corporations, depending instead on small contributions from individuals to pay for lab tests of various supplements and foods. The group's website, www.keepphope.net, has over 1000 pages of information on nutritional and immune-based therapies. The web site also has a Message Board for sharing information, asking questions, and presenting diverse views. *The Journal of Immunity* (published quarterly) gives updates on the information in Mark Konlee's newest book, *Immune Restoration Handbook*. A worldwide list of health care practitioners who subscribe to the newsletter or have bought Konlee's current or past books is available under Quicklinks on the Keep Hope Alive home page. Keep Hope Alive can be contacted at P.O. Box 270041, West Allis, Wisconsin 53227; phone 414-548-4344 fax 414-329-0653.

Konlee, Mark. *Journal of Immunity* Spring 2003

Painkiller Abuse

As drug companies produce new formulations of opioid painkillers, the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) are seeking ways to curtail the drugs' illegal use. Potent narcotic painkillers with a time-release mechanism, such as OxyContin, have been especially attractive to abusers, who have learned how to override the time-release action and get the drug's effect all at once. OxyContin's manufacturer, Purdue Pharma LP, is seeking FDA approval for another time-release opioid, called Palladone, that is even stronger than OxyContin. Among other painkilling drugs in development are an asthma-style inhaler containing morphine and fentanyl (a synthetic opioid) from Aradigm Corp and new painkiller patches from Johnson and Johnson, producer of the Duragesic fentanyl patch.

FDA is asking manufacturers to include abuse-management programs, which include physician education, as part of the drugs' approval process. Doctors will be asked to identify patients who have a higher risk of addiction. Labels on existing painkillers as well as new ones will include more detailed guidelines for prescribing them appropriately. For its part, the DEA plans to work with medical boards to develop required continuing-education courses for physicians on the use of opioids. The agencies are trying to find ways to lessen abuse and still make these powerful painkillers available for patients with severe pain.

Mathews, Anna Wilde & Fields, Gary. Federal Agencies Seek to Curb Abuse of Potent Painkillers. *The Wall Street Journal* 3 December 2003.

Stress & Illness

In her article “Enough to Make You Sick?”, published in *The New York Times* (12 October 2003), Helen Epstein examines why inhabitants of some of America's poor urban minority neighborhoods have so many health problems. She writes, “Some of these neighborhoods have the highest mortality rates in the country, but this is not, as many believe, mainly because of drug overdoses and gunshot wounds. It is because of chronic diseases...that include stroke, diabetes, kidney disease, high blood pressure and certain types of cancer....” Two New York doctors in their 1990 study reported that young African-American men in Harlem had such a high incidence of heart

Copyright of Townsend Letter for Doctors & Patients is the property of Townsend Letter Group and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.