Federal update

From the FDA

FDA approves Relenza for influenza treatment

The FDA has approved zanamivir (Relenza), an inhaled antiviral drug, for adults and adolescents aged 12 years and older for the treatment of uncomplicated influenza virus.

This product is approved to treat type A and B influenza, although the principal trials enrolled more than 1000 patients with type A influenza, a much smaller number had type B influenza.

In clinical studies, patients with influenza who received zanamivir had shorter times to improvement in influenza symptoms. More than 1500 patients with influenza-like illness, including fever, headache, muscle aches, cough, and sore throat, were enrolled in studies assessing efficacy.

FDA gives nod to new sleeping pill

The FDA has approved zaleplon (Sonata), a new prescription sleeping pill that can be taken in the middle of the night without producing a groggy feeling in the morning.

It should become available at pharmacies in about a month. Users must be able to stay in bed for 4 or more hours to avoid a feeling of being “hungover,” which is often associated with use of sleeping aids, drugmaker American Home Products said.

FDA issues Final Rule on drug products containing colloidal silver

The FDA has issued a Final Rule declaring that all over-the-counter drug products containing colloidal silver or silver salts are not recognized as safe and effective.

In recent years, colloidal silver preparations of unknown formulation have begun to appear in stores. These products are labeled with indications to treat adults and children for diseases including the human immunodeficiency virus, the acquired immune deficiency syndrome, cancer, tuberculosis, malaria, lupus, syphilis, scarlet fever, shingles, herpes, pneumonia, typhoid, tetanus, and others.

According to the Final Rule, a colloidal silver product for any drug use will first have to be approved by the FDA under the new drug application procedures. The indiscriminate use of colloidal silver solutions has resulted in argyria.

FDA issues guidelines for drug broadcast ads

Pharmaceutical manufacturers advertising drugs on television or radio will need to include four different vehicles for informing consumers how to get information about product risks and uses.

Advertisers need to include the following: a toll-free telephone number; reference to a print ad in a concurrently running print publication, or distribution of product brochures in convenient outlets; referral to a healthcare provider; and an Internet address.

Broadcast drug advertisers are currently required to disclose all major risks associated with the product and provide consumers with directions on how to access detailed information about a drug’s risks and uses.

Blood donations from travelers limited

The FDA imposed a ban on blood donations by anyone who has traveled to or lived in Britain for a total of 6 months since 1980. This is the period when mad cow disease swept through Britain’s cattle.

The donor ban is a precaution as there is no evidence that any mad cow-type illness has been spread through blood transfusions. However, the mad cow disease has been linked to a human brain-destroying illness, and both illnesses are so mysterious that scientists simply cannot rule out the possibility that they could infect blood.

Some Americans who traveled frequently to Britain during its mad cow disease crisis are being banned from donating blood back home. The ban covers travel to or residence in England, Scotland, Wales, Northern Ireland, the Isle of Man, and the Channel Islands.

New drug approved for brain cancer

The FDA has approved temozolomide (Temodar), a cancer treatment for adult patients in whom anaplastic astrocytoma has been diagnosed and who have had a relapse after chemotherapy.

Temozolomide has been granted accelerated approval, a regulatory mechanism that allows early approval for a product for the treatment of serious or life-threatening conditions for which no acceptable alternative treatments exist. Accelerated approval is based on surrogate markers of effectiveness such as shrinkage of a tumor rather than a documented effect on clinical benefit such as survival or quality of life.

The agent’s approval was supported by a multicenter trial in 162 patients who had anaplastic astrocytoma at first relapse and who had received previous radiation therapy and may also have received chemotherapy. In the patients with tumors resistant to previous chemotherapy, 7 of 54 patients had partial shrinkage of their tumors, whereas 5 (9%) of 54 patients had a complete response.

Possible side effects include headache,
nausea, vomiting, fatigue, and low blood cell counts.

FDA approves new use of seizure drug

Topiramate (Topamax), an epilepsy drug used by adults, was approved for use as an add-on therapy for young patients with partial-onset seizures.

Drugs already are prescribed to treat pediatric epilepsy patients, but topiramate is the first of a new generation of antiepileptic drugs approved for partial-onset seizures for patients as young as 2 years. About 750,000 pediatric patients have partial-onset seizures.

The drug's most common side effects, when used as an add-on therapy with other drugs, include drowsiness, loss of appetite, fatigue, nervousness, weight loss, aggressive reaction, and difficulty with concentration and memory.

FDA cautions about medication mixup

The Food and Drug Administration (FDA) has urged Pfizer Inc and Monsanto Co to make sure physicians and pharmacists understand the difference between the trade name Celebrex (celecoxib), the new arthritis drug, and its sound-alike Celexa (citalopram), a depression treatment, and Cerbyx (fosphenytoin sodium), an antiepileptic drug.

Since Celebrex was launched in January, federal regulators have received 95 reports of errors by physicians and pharmacists dispensing Celebrex. None of the cases involve serious injury or death.

Of the 95 medication mixups reported to the FDA, only 22 cases involved a patient actually taking the wrong drug. In the other cases, someone caught the error in time.

From the CDC

Obesity increases risk of colon cancer

Obesity is a risk factor for colon cancer in both men and women, reports a researcher in the August 15 issue of the American Journal of Epidemiology.

As part of the first National Health and Nutrition Examination Survey, a federal researcher examined 1971 through 1992 data on more than 13,000 Americans. During the study period, colon cancer developed in 222 of the participants.

Study subjects were categorized into groups based on their body mass index (BMI). Persons with a BMI of 24 to 26 faced an 86% higher risk of colon cancer compared with those with a BMI of 22. Risks for persons with BMIs of between 26 to 28, or 28 to 38, were more than double or triple those of individuals with a BMI of 22.

Life expectancy up 30 years

Antibiotics, clean drinking water, and advances that have helped control infectious disease are the key reasons that Americans can expect to live nearly 30 years longer than they did at the turn of the century.

Overall death rate from diseases including pneumonia and tuberculosis has declined from 797 per 100,000 in 1990 to 59 per 100,000 in 1996, the CDC said.

From 1990 to 1996, life expectancy has increased from 47.3 years to 76.1 years. In 1900, pneumonia, tuberculosis, and diarrhea/enteritis were the leading causes of death. In 1996, the leading causes were heart disease, cancer, and stroke.

CDC announces antituberculosis plan

Federal health officials have announced a plan that calls for new methods of treating and preventing tuberculosis (TB).

The US TB rate is at an all-time low of 7 cases per 100,000 people. Physicians are worried that the possibility of the spread of drug-resistant strains of TB combined with complacency and global TB outbreaks could all cause a resurgence.

Since 1992, TB cases in the United States have decreased 31%. But between 1992 and 1997, the number of TB cases increased 6% among people outside the United States. Drug-resistant strains were reported in 43 states and Washington DC.

A federal advisory council report to the CDC says a new vaccine is crucial as are long-term sources of private and public money to support vaccine research. In addition, the report says that strategies targeting high-risk groups, including people with the human immunodeficiency virus and prison inmates, have been poorly applied and that treatment measures are often underused.

Radon places smokers at high cancer risk

Smokers are at the highest risk of exposure to radon and are the least likely to test their homes for the presence of the carcinogenic gas.

According to the CDC, about 10% to 14% of all US lung cancer deaths are attributed to radon exposure, making it the second leading cause of lung cancer death after smoking. In their current study, the CDC examined National Health Interview Study data on nearly 41,000 US homes.

During 1993-1994, an overall mean of 5.5 million (6.7%) households tested for radon. Households with smokers were less likely to be tested than households without smokers.

The findings of federal researchers can be found in the August 13 issue of Morbidity and Mortality Weekly Report.

CDC reports on drug-resistant Staphylococcus

Federal health officials are warning physicians about a drug-resistant bacteria, Staphylococcus aureus, which has killed four people and sickened scores of others in the Midwest.

Prompted by the deaths of four previously healthy children in Minnesota and North Dakota from the bacteria, the CDC is instituting an investigation. The children, two from Minnesota and two from North Dakota, ranged in age from 1 to 13 years. Two were white, one was black, and one was American Indian. They died between 1997 and 1999.

In the two states, 200 people have become ill in the past 2 years after con-
tracting staphylococcal infections resistant to penicillin and cephalosporin. The overall overuse of antibiotics may account for one reason the bacteria may be resistant to some drugs.

**Drug-resistant bacteria on the rise**

The bacteria that cause pneumonia, meningitis, and other serious illnesses are becoming increasingly resistant to penicillin.

The number of cases of *Streptococcus pneumoniae* infections that proved resistant to antibiotics increased from 14% in 1993-1994 to 25% in 1997, the CDC said.

According to the CDC, one of the leading factors in the increase is overuse of antibiotics.

**From the DHHS**

**Gaps still exist in vaccination rates**

Nearly a quarter of youngsters still lack complete protection against polio, tetanus, and other illnesses, according to findings of the National Vaccine Advisory Committee, a panel of 15 experts convened by the US Department of Health and Human Services.

After a serious measles outbreak in 1989-1991, the federal government created the Childhood Immunization Initiative to increase immunization rates among US children. Many of the Initiative's goals have been met.

To improve the nation's vaccination rate, the team recommends that:

- All health insurance plans provide full coverage for the costs of immunization.
- Physicians, healthcare workers, and other public and private immunization providers operate recall and reminder systems alerting parents to their child's immunization status.
- Public and private organizations work together to set up in each state computerized immunization registries that keep track of a child's immunization status.
- Immunization be linked to federal assistance programs like Women Infants and Children with delivery of benefits tied to the child vaccination process.

The report can be found in the July 28 issue of *JAMA*.

**Opiates take lead over cocaine in treatment admissions**

The Substance Abuse and Mental Health Services Administration's (SAMHSA) latest study of substance abuse treatment admissions revealed that the number of admissions for opiate, primarily heroin, surpassed admissions for cocaine use in 1997.

Opiates account for 16% of the 1.5 million substance abuse treatment admissions that were reported in 1997 by the states to SAMHSA, an agency of the US Department of Health and Human Services.

The study, "National Admissions in Substance Abuse Treatment Services: The Treatment Episode Data Set (TEDS) 1992-1997," also revealed that alcohol continues to lead all other substances as the cause for treatment admissions. Almost half, or 48%, of treatment admissions in 1997 were for alcohol abuse, with 44% of these alcohol admissions involving another substance as well.

The 1997 TEDS also shows a continuing trend in rising treatment admissions for stimulants, primarily amphetamine, with admissions increasing from 1.5% of all admissions in 1992 to 4.5% of all admissions in 1997. Treatment admissions also continued to rise for substance abusers aged 17 years or younger, with admissions increasing from 6.3% of all admissions in 1993 to 8.9% of all admissions in 1997. Substance abusers, aged 19 years and younger, accounted for more than 49% of all treatment admissions for marijuana use.

For more information, visit the agency's Web site at [www.samhsa.gov](http://www.samhsa.gov).