From the CDC

Reyes syndrome cases decline

The annual number of cases of Reyes syndrome in the United States has declined dramatically since 1980, researchers at the Centers for Disease Control and Prevention (CDC) report.

Reyes syndrome is a severe neurologic disorder that usually develops after certain viral infections, such as chickenpox and influenza, and occurs almost exclusively in children. The syndrome causes confusion, agitation, and delirium, and it can result in long-term neurologic complications, coma, and death in as many as a third of patients affected by the disorder.

Researchers examined data by local or state health departments or practicing physicians to CDC's National Reye Syndrome Surveillance System. A total of 1207 cases of Reyes syndrome in children younger than 18 years were reported to CDC from 1981 to 1997. After a high of 555 cases were documented in 1980, the number of cases declined, and since 1987, fewer than 37 cases have been reported each year.

About 40% of all cases were in children younger than 5 years; more than 90% of all cases were in children younger than 15 years. Most patients had been ill at least once during the 3 weeks before the onset of Reyes syndrome, and most appeared to have taken aspirin. Nearly a third of the identified patients with Reyes syndrome died.

The CDC continues to caution against using aspirin to treat children suffering from chickenpox or influenza-like illnesses.

A complete article with the findings appears in the May 6 issue of the *New England Journal of Medicine.*

Reducing arthritis' impact

In 1997, arthritis accounted for 744,000 hospital discharges and about 4 million hospital days of care. Arthritis accounted for about 44 million ambulatory care visits to physicians' offices, hospital outpatient departments, and emergency departments in 1997. Interventions to prevent arthritis from occurring, to provide early diagnosis and appropriate management, and to reduce complications and disability can help to reduce the impact of arthritis on the healthcare system and on society as a whole.

The "National Arthritis Action Plan—A Public Health Strategy," available from the CDC, describes ways the public health and healthcare systems can work together to lessen the impact.

Newborn screening prevents mental retardation

The routine screening of newborns for specific metabolic disorders is highly effective in preventing childhood mental retardation caused by these disorders, but the United States currently has no program that monitors the progress of children who screen positive for these diseases.

Certain metabolic disorders such as congenital hypothyroidism and galactosemia compromise the normal breakdown of foods, resulting in toxic metabolites that affect brain development. These disorders can cause irreversible mental retardation if not detected and treated early. Neonatal testing for several of these rare conditions is now routine practice in most US hospital obstetric units.

To determine the effectiveness of the testing protocol, researchers at the CDC and Emory University in Atlanta examined the medical histories of all Atlanta-area children with developmental disabilities born between 1981 and 1991.

About 148 of the more than 360,000 infants born in the Atlanta area during this period would have been at risk for mental retardation caused by a metabolic disorder, researchers estimate. However, only two children from these birth cohorts were identified. Each of those two cases involved the presence of a rare but correctable enzyme deficiency that went undetected at the time of delivery.

The complete report appears in the May 7 *Morbidity and Mortality Weekly Report.*

Chickenpox vaccine required for children before school entry

The CDC recommends that children be vaccinated against the chickenpox virus before entering childcare facilities and elementary schools.

States should require children to have proof of chickenpox vaccination or other evidence of immunity to the virus, such as a physician's diagnosis of the infection, the CDC's Advisory Committee on Immunization Practices recommends.

In addition, states should consider the same requirements for children entering middle school in order to prevent older children from entering adulthood without immunity to the chickenpox virus. The committee also recommended vaccinations for persons 13 years of age and older who are at high risk of exposure or transmission.

The report is printed in the May 28 issue of *Morbidity and Mortality Weekly Report.*

Teen sex declines in several cities

Teenagers in several US cities reported a decline in sexual activity between 1991 and 1997, and those teens who were sexually active were more likely to report using a condom.

The findings are from a survey of thousands of high school students living in eight cities: Boston, Chicago, Dallas, Fort Lauderdale, Jersey City, Miami, Philadelphia, and San Diego.

Between the early 1990s and 1997, the proportion of sexually experienced teens declined by anywhere from 7% to 16% in Chicago, Dallas, Fort Lauderdale and Boston. Condom use increased by 25% in Dallas and 52% in Jersey City.

CDC officials attribute the changes to several factors including HIV prevention efforts at the family, community, and local government levels.

Overweight children and adolescents at risk for cardiovascular problems

More than half of the overweight children and adolescents participating in a study in Bogalusa, La., have at least one additional risk factor for cardiovascular health problems.

The study included more than 9100 5- to 17-year-olds, during seven studies conducted between 1973 and 1994 by the Bogalusa Heart Study in Louisiana. The study's key findings include:

- Fifty-eight percent of the overweight school children, including children 5 to 10 years old, were found to have at least one additional cardiovascular risk factor.
- Twenty percent of the overweight children and adolescents had two or more additional cardiovascular risk factors.

As compared with average weight children and adolescents, overweight youth were found to be:

- 2.4 times more likely to have an elevated level of total cholesterol.
- 2.4 times more likely to have elevated diastolic blood pressure.
- 4.5 times more likely to have higher systolic blood pressure.
- 3 times more likely to have adverse high-density lipoprotein (HDL) cholesterol.
- 7 times more likely to have elevated triglyceride levels.
- 12.6 times more likely to have elevated fasting insulin levels.

The complete study results titled "The Relation of Overweight to Cardiovascular Risk Factors Among Children and Adolescents: the Bogalusa Heart Study" is published in the June issue of *Pediatrics* and can also be found on the American Academy of Pediatic's web site www.pediatrics.org.

From the NHTSA

Shift workers, teens most vulnerable to fatigue-related crashes

Shift workers and teens are the most likely drivers to be involved in a fatigue-related crash, says a report issued by the US Department of Transportation's National Highway Traffic Safety Administration (NHTSA).

The NHTSA in collaboration with the National Center on Sleep Disorders Research (NCSDR) at the National Institute of Health's National Heart, Lung and Blood Institute is working on reducing the risks caused by fatigue and sleepiness on driving safety.

The two federal agencies estimated that 40,000 injuries and 1,550 fatalities annually are attributable to fatigued and drowsy drivers. Between 1985 and 1997, the number of people working on an evening, night, rotating or split shift rose 30%, while the overall workforce increased 23%. Though factory workers account for the largest number of shift workers, the largest gains are in service occupations such as 24-hour computer support lines or mail order catalogs.

In addition, the number of teens aged 15 to 19 is expected to increase from 18.5 million in 1996 to 26.5 million by 2050, the Census Bureau estimates.

NHTSA's program targets shift workers and young males, while the NCSDR is focusing on teens. The report to Congress, titled "The NHTSA & NCSDR Program to Combat Drowsy Driving: A Report to Congress on Collaboration Between the NHTSA and the NCSDR," is available on NHTSA's web site at http://www.nhtsa.dot.gov.

From the FDA

FDA issues health advisory on Trovan

The Food and Drug Administration (FDA) issued a public health advisory to physicians concerning the risks of liver toxicity associated with the use of trovafloxacin (Trovan, an oral antibiotic) and alatrofloxacin (Trovan-IV, the intravenous formulation of the drug). This action follows postmarketing reports of rare but severe liver injuries leading to transplants and deaths.

The FDA is informing physicians that trovafloxacin and alatrofloxacin should be reserved for use only in patients who meet all of the following criteria:

- ☐ patients who have at least one of several specified infections such as nosocomial (hospital-acquired) pneumonia or complicated intra-abdominal infections that, in the judgment of the treating physician, is serious and life- or limb-threatening;
- ☐ patients who begin their therapy in inpatient healthcare facilities (hospitals or long-term nursing care facilities); and
- ☐ patients for whom the treating physician believes that even given the new safety information, the benefit of the product outweighs the potential risk.

In addition, the FDA cautions that therapy with trovaloxacin and alatrofloxacin should not continue for more than 14 days. Therapy should be discontinued sooner if the patient presents any signs of liver dsyfunction, including fatigue, loss of appetite, yellowing of the skin and eyes, severe stomach pain with nausea and vomiting, or dark urine.

More information is available, including the FDA's public health advisory, on the agency's web site, www.fda.gov/cder/news/trovan/default/ htm. And from Pfizer, the manufacturer of the drug at 800-438-1985. Adverse effects should be reported to the FDA through MedWatch by calling 800-332-1088 or fax 800-332-0178.

Arthritis drug Enbrel linked to serious infections

The recently approved arthritis drug etanercept (Enbrel) may increase the chance of potentially life-threatening infections in some patients with rheumatoid arthritis (RA). The Food and Drug Administration (FDA) recommends that physicians refrain from prescribing the drug to patients with sepsis or any active infection, including chronic and localized infections.

The drug, a genetically engineered protein, was approved last November for the treatment of moderate to severe, active RA, but it is also known to suppress tumor necrosis factor, an infection-fighting protein produced by immune system cells.

Since etanercept's approval, 30 of the estimated 25,000 patients treated with it have been reported to have had serious infections develop, including sepsis; six of these patients died within 2 to 16 weeks after starting treatment.

All cases of serious infection or sepsis

occurring in patients taking etanercept should be reported to the agency through MEDWATCH by calling 1-800-FDA-1088, or fax to 1-800-FDA-0178.

Sunscreen regulations finalized

New regulations provide for streamlined labels for over-the-counter (OTC) sunscreen products. The regulations, recently finalized by the FDA, list the sunscreen active ingredients that can be used as well as labeling and testing requirements.

Regulation highlights include: similar labeling requirements for all OTC products including sunscreen-cosmetic combinations; list of 16 allowed sunscreen active ingredients; required sun protection factor (SPF) testing; a new SPF category of "30" plus; reduction of five product sun categories to "minimum," "moderate," or "high"; a "sun alert" statement reflecting the role sunscreens play in reducing the harmful effects of the sun.

Manufacturers will have 24 months to comply with the new requirements. Manufacturers of cosmetic tanning preparations not containing sunscreen will have 12 months to include the required warning statement.

Vioxx approved for osteoarthritis and menstrual pain

Rofecoxib (Vioxx), a new drug for treatment of osteoarthritis and menstrual pain and for the management of acute pain in adults, was recently approved. Rofecoxib is a non-steroidal anti-inflammatory drug (NSAID), and is the second approved version in the cyclooxygenase 2-inhibitor class of drugs.

NSAIDs temporarily relieve pain by blocking the body's production of prostaglandins, which are believed to be associated with the pain and inflammation of injuries and immune reactions.

In clinical trials of about 3600 people, rofecoxib was found to be an effective treatment for the symptoms of osteoarthritis. It was also found to be effective for management of acute pain in adults, in studies conducted in people with postoperative pain after dental extractions or orthopedic surgery; and for pain management related to the menstrual cycle.

A few cases of serious gastrointestinal bleeding and one case of obstruction occurred among patients taking rofecoxib in clinical studies. Additional studies need to be done to see whether rofecoxib causes fewer serious gastrointestinal complications than older NSAID products. Until the studies are done, labeling for rofecoxib will include a warning for physicians and their patients about the risks associated with NSAIDs, including risk of gastrointestinal ulceration, bleeding, and perforation. Patients are advised to report signs and symptoms of gastrointestinal ulceration or bleeding, skin rash, unexplained weight gain, or swelling to their physicians

Dialysis equipment safety alert

The FDA has issued a safety alert over dialysis equipment that may have exposed patients to each others' blood and their bloodborne disease.

Small amounts of blood that leaked inside dialysis machines have been found at treatment centers in Arizona, Florida, New Jersey, and Pennsylvania. The risk that patients were exposed to others' blood is remote. Traces of blood were found in tubing inside the machines, and the manufacturer is recalling 154,000 sets of the tubing.

Recommendations include

☐ having qualified personnel inspect all machines, including the internal pressure tubing set and pressure-sensing port for possible blood contamination;

☐ using an external transducer protector and pressure alarm capabilities;

☐ if the external transducer protector becomes wetted, replace it immediately and inspect it; and

☐ if contamination has occurred, the machine must be taken out of service and disinfected.

Frequent blood line pressure alarms or frequent adjusting of blood drip chamber levels may indicate there is a problem.

FDA to increase new drug monitoring

The US Food and Drug Administration (FDA) plans to bolster its surveillance of new drugs and devices in response to criticism that its speedier reviews are compromising patient safety.

It plans to better analyze information that is currently collected about patients' reactions to products. The new measures were prompted by an internal review to investigate how drug safety had changed since the agency began streamlining its reviews in 1990.

Despite a record number of new drug approvals in recent years, the percentage of recalls had not changed significantly during the past two decades. Between 1% and 3.5% of drugs have been recalled for safety reasons each year since 1979.

Consumer groups have charged that five drug withdrawals in the past 2 years shows the agency has acted too quickly in some cases. One study estimated that about 100,000 people die each year from drug reactions.

The task force recommended reexamining clinical trials used to evaluate drugs and, in some cases, restricting the numbers and types of patients using a drug immediately after it is approved.

FDA warns about sleep aids

Dietary aids marketed as sleep aids or "party drugs" may contain potentially life-threatening chemicals similar to gamma butryolactone (GBL) and gamma hydroxybutyric (GHB), which have been associated with serious side effects including three deaths.

The FDA considers the products unapproved drugs and has seized products that are advertised over the Internet, in muscle-building magazines, and in health food stores as dietary supplements.

GHB has been implicated as a "date rape" drug and cannot be legally marketed in the United States. One related chemical, 1,4 butanediol (BD), can cause complications such as breathing difficulties, unconsciousness, vomiting, seizures, and death. Products that contain BD are sold under the brand names Revitalize Plus, Serenity, Enliven, GHRE, SomatoPro, NRG3, Thunder Nectar, and Weight Belt Cleaner. It might list BD, tetramethylene glycol, GBL, or 2 (3H)-furanone di-hydro on the label.

Avandia approved to treat type 2 Diabetes

The Food and Drug Administration (FDA) approved Avandia (rosiglitazone), a new drug in the thiazolidinedione class of drugs to treat type 2 diabetes. It is approved for patients with type 2 or adult-onset diabetes who are not taking insulin. Patients

should also maintain proper weight and a careful diet.

In clinical trials, rosiglitazone was shown to improve patients' ability to utilize insulin produced in the body. The trials involved more than 4000 patients previously treated with diet alone or with metformin. Adverse effects reported included infection, pain, and headache, but at rates comparable to those in the placebo-treated patients.

Another drug of the same class Rezulin (troglitazone) has been associated with liver failure. In clinical studies of patients treated with avandia, there was no evidence of drug-induced hepatoxicity.

However, the FDA is recommending that liver enzymes be checked at the start of avandia therapy and every two months for the first year.

From the USDA

Scientists discover alternative hypoallergenic latex

Scientists may have found an alternative hypoallergenic latex for medical, industrial, and home products. The milky latex from a native southwestern shrub, guayule, is free of allergens that can cause severe reactions such as anaphylactic shock or death, claim scientists at the Agricultural Research Service in Albany, Calif.

Approximately 20 million Americans are allergic to the latex in gloves, catheters, condoms, or other products traditionally made from Brazilian rubber trees. So, the ARS has focused research on producing guayule latex as a cost-effective alternative.

Composed of rubber particles in a water-based suspension, latex is a higher value product than solid rubber. This, plus the need for hypoallergenic alternatives to conventional latex, has made guayule's latex the focus of research.

Children's preventive health improves with pick-up program

Well-child visits, vaccinations, and preventive services improve when parents are required to show a child's immunization record when they pick up Supplemental Nutrition Program for Women, Infants and Children (WIC) vouchers.

The WIC program, which is funded by the US Department of Agriculture (USDA), provides food and nutritional counseling to low-income women.

Healthcare workers identified underimmunized children in the Milwaukee WIC program and required those families to present the child's immunization record when they picked up their monthly vouchers at a local WIC center.

Vaccination rates in the low-income children studied improved by 20% 12 months after the program started. The children in the monthly voucher pick-up program had two more well-child visits and more screenings for lead, anemia, and tuberculosis compared with the children not enrolled in the program.◆