Medication Use and Older Adults
8 Getting Ready for Another Flu Season
More vaccine should be available for the 2006–2007 season, and experts have prepared new recommendations for who should get flu shots.

10 A Focus on Vision
Surgical developments and advances in corrective eyewear provide many options for improving vision.

18 Some Cold Medicines Move Behind Counter
Find out why you may have to show your ID to a pharmacist to buy over-the-counter decongestants.

Cover Story
20 Medication Use and Older Adults
Older adults, their family members, and caregivers can partner with health professionals to improve medication management.

27 Artificial Sweeteners: No Calories ... Sweet!
Here's a tasty look at the artificial sweeteners approved by the FDA.

29 The FDA Approves New Drug for Smoking Cessation
Chantix acts at sites in the brain affected by nicotine.

30 Protecting the Public Health: More Than a Full-Time Job for Many at the FDA
From doing dental work in El Salvador in 90-degree heat to tracking missing persons in Maryland on horseback, FDA employees continue to make a difference outside of their regular workdays.
Managers estimate that between 100 million and 120 million doses of flu vaccine will be produced for the season ahead.

Some cold medicines are now behind pharmacy counters as part of the war on illegal drugs.

Artificial sweeteners can help reduce calories and aid in the management of diabetes.

Many FDA employees promote public health in volunteer activities outside of their regular jobs.
Observations

The risks of high blood pressure, heart disease, arthritis, and diabetes increase with age. So do the number of medications that Americans use to treat these conditions. An estimated 25 percent of Americans take three or more medications each day, according to The Graying of America: An Encyclopedia of Aging, Health, Mind, and Behavior, by Donald H. Kauser and Barry C. Kauser.

In addition, the percentage of people taking multiple prescription drugs increases after age 65. For example, a Medicare beneficiary with drug coverage filled an average of 19 drug prescriptions annually in 1999, according to the National Institute for Health Care Management.

Of course, taking a drug exactly as prescribed is critical to its safety and effectiveness. For example, an antibiotic stopped prematurely because a person feels better could allow an infection to recur with bacteria resistant to the drug. Taking a drug at the wrong time, taking the wrong dosage, or forgetting to take a drug altogether could cause serious problems or limit the effectiveness of the treatment.

A variety of alarms, labeled trays, blister packs, and other aids are available to help ensure that older people who have trouble tracking their medicines take them as prescribed. For more on the importance of taking drugs properly and for some strategies on how to do so, see our cover story titled “Medication Use and Older Adults,” beginning on page 20.

Optical defects that cause light to not focus properly on the retina of the eye cause refractive errors—one of the most frequent eye problems in the United States, according to the National Eye Institute (NEI).

The two most common refractive errors are nearsightedness (myopia) and farsightedness (hyperopia). People who are nearsighted see close objects clearly, but distant objects are blurred. It’s just the reverse for those who are farsighted—nearby objects are blurry, while distant objects are sharp.

Other refractive errors include uneven focus (astigmatism) and an age-related problem with focusing on near objects called presbyopia. Researchers aren’t sure why refractive errors develop, according to the NEI, but treatments range from glasses and contact lenses to specially designed lasers that reshape the cornea, changing its focusing power. For more on vision correction, including the latest on FDA-approved products, read our feature article titled “A Focus on Vision,” beginning on page 10.

Like others nationwide, many FDA employees don’t stop working when they leave their job for the day. Some volunteer. Some coach. Others use their expertise and passion to help people in need. We take a look at six dedicated FDA employees who continue to make a difference outside of their regular job in our feature story titled “Protecting the Public Health: More Than a Full-Time Job for Many at the FDA,” beginning on page 30.

We also take a look at the preparations being made for the upcoming flu season, the reasons why some cold medicines have been moved behind the pharmacy counter, and an update on artificial sweeteners.

Raymond Formanek Jr.
Editor

Updates

New Drug Helps Prevent Heart Transplant Rejection

A new drug that suppresses the body’s immune reaction for the prevention of graft rejection in heart transplant recipients has been approved by the FDA.

Prograf (tacrolimus), available in capsule form and as an injectable, was previously approved for the prevention of graft rejection in people receiving liver and kidney transplants. Prograf acts by a mechanism similar to cyclosporine, another immunosuppressant used to prevent transplant rejection.

Prograf offers an alternative to cyclosporine for use in certain combination immunosuppressive regimens in liver, kidney, and heart transplantation.

“This approval is another example of the benefits of our agency’s ‘orphan’ drugs program,” says Steven Galson, M.D., director of the FDA’s Center for Drug Evaluation and Research, “which seeks to answer the medical needs of small groups of patients.”

In a U.S. study, patient and graft survival at 12 months after transplantation in the Prograf group was similar to that of the cyclosporine group.

The use of Prograf is associated with increased risk of neurotoxicity, renal function impairment, infection, and post-transplant diabetes mellitus. Like most combination drugs used in organ transplants, the Prograf-based combination is associated with an increased risk of malignancies, especially non-melanoma skin cancers. Prograf is manufactured by Astellas Pharma US Inc., Deerfield, Ill.
Generic Capsule Form of HIV/AIDS Drug

The FDA has approved the first generic capsule dosage form of zidovudine to treat HIV/AIDS to be marketed in the United States. The tablet and oral solution forms of zidovudine were previously approved for sale in the United States when the patent on those dosage forms expired in September 2005.

The approval of the capsule form of the drug, which is manufactured by Aurobindo Pharma Ltd. in Hyderabad, India, follows the expiration of GlaxoSmithKline's patent on its capsule form of the product marketed under the trade name Retrovir.

“This is a significant generic approval,” says Acting Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D. “Retrovir, which was initially approved in March 1987, was the first of a group of breakthrough medications that have transformed what was then a disease with a very dismal prognosis into one with a much more hopeful prognosis. Approval of this additional dosage form of zidovudine should help reduce the cost of this therapy for American patients.”

Zidovudine is in the class of drugs called nucleoside reverse transcriptase inhibitors, which help keep the AIDS virus from reproducing. This anti-retroviral drug is intended to be used with other anti-retroviral agents for the treatment of HIV-1 infection.

Humanitarian Device Treats Rare Twin Syndrome

The FDA has approved a Humanitarian Device Exemption (HDE) for Fetoscopy Instrument Sets used to treat fetuses with a rare disorder of the placenta, called twin-to-twin transfusion syndrome (TTTS), under the Humanitarian Use Device (HUD) program.

TTTS sometimes occurs when women are pregnant with identical twins. During development, blood vessels in the fetuses’ shared placenta connect their blood circulations. In most cases, the blood flows properly through these vessels. In TTTS, however, the blood begins to flow unevenly, with one fetal twin receiving too much blood (the recipient) and one receiving too little (the donor). This condition can cause heart failure in the recipient twin and life-threatening anemia in the donor twin. Many of these TTTS babies do not survive delivery or are born with severe handicaps.

The Fetoscopy Instrument Sets give doctors a new option for treating TTTS, and can help prolong the mother’s pregnancy and improve the odds of survival for both twins. Complications also are reduced for one or both twins.

The instrument sets are intended to be used for the treatment of TTTS for fetuses whose gestational age is between 16 weeks and 26 weeks. The sets consist of a telescopic camera used to view a fetus (fetoscope) and sheaths that are used to pass other surgical instruments and fluid through the entry site.

The HUD program encourages the development of medical devices intended to treat or diagnose a disease or condition affecting fewer than 4,000 people in the United States a year. To receive approval of an HDE application, a sponsor must demonstrate the safety and probable benefit of a device.

First Treatment for Pompe Disease

The FDA has approved a biologics license application (BLA) for Myozyme (algglucosidase alfa, rhGAA), the first treatment approved for people with Pompe disease, a rare but severely debilitating disease that affects between 40,000 and 300,000 Americans.

Pompe disease is inherited and caused by the deficiency or lack of the enzyme acid alpha-glucosidase, which is essential for normal muscle development and function. The disease drastically reduces a person’s muscle and respiratory function, and usually results in death from respiratory failure. Pompe disease is rapidly fatal in newborn babies.

Myozyme had been granted orphan drug designation by the FDA and was approved under a priority review. Orphan products are developed to treat rare diseases or conditions that affect fewer than 200,000 people in the United States. The Orphan Drug Act provides a seven-year period of exclusive marketing to the first sponsor who obtains marketing approval for a designated orphan drug.

The FDA approved Myozyme for administration by intravenous infusion of solution into a vein. The safety and efficacy of Myozyme were assessed in two separate clinical trials in 39 infantile-onset patients with Pompe disease ranging in age from 1 month to 3.5 years at the time of the first infusion.

Patient survival without needing invasive ventilatory support was substantially greater in the Myozyme-treated infants compared with the known high mortality of untreated patients of similar age and disease severity. The drug’s safety and effectiveness in other forms of Pompe disease have not been adequately studied.

A boxed warning is included in the Myozyme label to warn about the possibility of life-threatening allergic reactions. Myozyme is manufactured by Cambridge, Mass.-based Genzyme Corp.
Imaging System Helps Detect Precancerous Cervical Abnormalities

The FDA has approved an imaging system that can help detect an indication of the possible development of cervical cancer.

The LUMA Cervical Imaging System, made by MediSpectra Inc., Lexington, Mass., can help identify sites on the cervix that may contain precancerous cells. It is intended to be used along with colposcopy, a high-magnification evaluation of the cervix, for women who have recently had an abnormal Pap test. The firm’s study of the device showed that it can detect additional cancer precursors missed by colposcopy.

“Cervical cancer is one of the few highly preventable cancers,” says Daniel Schultz, M.D., director of the FDA’s Center for Devices and Radiological Health. “The early detection and removal of pre-cancerous cervical lesions reduces the risk of developing invasive cervical cancer.”

The LUMA system shines a light on the cervix and analyzes how different areas respond to this light. The system then assigns a number, or score, to tiny areas of the cervix, and produces a color map that helps the doctor decide where to take a sample tissue, called a biopsy. The colors and patterns on the map help distinguish between healthy and potentially diseased tissue.

The FDA cautions that use of the LUMA device is not a substitute for a thorough colposcopic exam, which should be performed first to identify areas on the cervix to perform a biopsy.

Another Option for Flu Prevention

In March 2006, the FDA approved the use of Relenza (zanamivir, for inhalation) for the prevention of influenza in adults and children ages 5 years and older. Relenza, an antiviral medication, was previously approved for the treatment of influenza A and B viral infections in adults and children.

The approval of Relenza for prevention gives Americans another option for preventing influenza A and B infections. Tamiflu (oseltamivir phosphate) was previously approved for both prevention and treatment of flu.

The effectiveness of Relenza in preventing seasonal influenza has been demonstrated in four large-scale studies comparing the drug with a pill containing an inactive ingredient (placebo). In two of these trials, the drug substantially reduced the spread of influenza in the participating households in which participants were 5 years or older.

In the other two trials, conducted in communities experiencing a flu outbreak, Relenza reduced the incidence of the disease in both young and older populations. In the first study, with participants ages 18 years and older, the proportion of people who developed symptoms confirmed to be flu was 6.1 percent for the placebo group and 2.0 percent for the Relenza group. The second community study enrolled people ages 12 to 94, with just over half older than 65. In this trial, the percentage of people who developed symp-
Updates

Health Claim for Barley Products

Food processors and manufacturers who market foods that contain a specified amount of barley may include a health claim that their products reduce the risk of coronary heart disease, under a new FDA rule. Specifically, whole grain barley and dry milled barley products such as flakes, grits, flour, and pearled barley, which provide at least 0.75 gram of soluble fiber per serving, may bear the following claim:

“Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [x] grams of the soluble fiber necessary per day to have this effect.”

Coronary heart disease claims the lives of nearly 500,000 Americans each year. High total cholesterol levels and high levels of low density lipoprotein (LDL) cholesterol are known to increase one’s risk for heart disease, so consumers are encouraged to keep these levels as low as possible. Scientific evidence indicates that including barley in a healthy diet can help reduce the risk of coronary heart disease by lowering LDL and total cholesterol levels.

“FDA is pursuing new initiatives to help consumers improve the choices they have for healthy and nutritious diets,” says FDA Deputy Commissioner Scott Gottlieb, M.D. “We firmly believe that one of the best ways to encourage healthier eating habits is to help consumers get truthful, up-to-date, science-based information about food products so that they can make choices that are based on a better understanding of the health consequences of their diets.”

Generic Pravastatin Approved

The FDA has approved the first generic version of Bristol-Myers Squibb’s Pravachol (pravastatin sodium) Tablets, an important step in the agency’s effort to increase the availability of lower-cost generic medications.

Pravastatin is indicated for the treatment of individuals who have high cholesterol levels (hyperlipidemia) or who are at increased risk for atherosclerosis-related cardiac and cardiovascular events, such as heart attack and stroke in which high cholesterol levels are a factor. In 2005, Pravachol was the 22nd highest-selling brand-name drug in the United States, with sales totaling $1.3 billion.

“This approval is another example of our agency’s endeavor to counter rising health care costs by approving safe and effective generic alternatives as soon as the law permits,” says Scott Gottlieb, M.D., deputy commissioner for medical and scientific affairs. “Pravastatin is a widely-used cholesterol-lowering agent, and its generic version can bring significant savings to the millions of Americans with this disease.”

Pravastatin Sodium Tablets (10 mg, 20 mg, and 40 mg) are manufactured by Teva Pharmaceutical Industries Ltd. in Kfar Sava, Israel.

Agencies Create Model Food Emergency Response Plan

The FDA, in cooperation with the National Association of State Departments of Agriculture, the USDA’s Food Safety and Inspection Service, and the U.S. Department of Homeland Security, has announced the availability of a model Food Emergency Response Plan. The goal of the response plan is to enhance the protection of the nation’s agricultural industry and food security through prevention, detection, response, and recovery efforts.

The model plan provides states with a tool to use in developing their own response plan for responding to a food-related emergency.

“FDA remains vigilant in its mission to protect our country’s food supply and continues to maintain collaborative partnerships with our federal and state partners by planning for, monitoring, and reacting to any potential threats,” says Robert E. Brackett, Ph.D., director of the FDA’s Center for Food Safety and Applied Nutrition. “By collaborating more closely with our partners involved in food safety and security, we will better leverage all of the available resources to be better prepared for any food emergency incident.”

A food-related emergency involves the unintentional or deliberate contamination, threatened or actual, of food that may impact human health.

The model plan establishes a uniform structure and content that will result in response plans similar among all states. Plans developed in a similar manner will facilitate seamless regional and national responses to food emergencies.

The response plan was developed through a federal-state cooperative agreement and in consultation with a consortium of stakeholders.
New Treatment for Rare Bone Marrow Condition

The FDA has approved Dacogen (decitabine) injection for treating a condition in which a person's bone marrow does not produce enough mature blood cells.

People with myelodysplastic syndromes (MDS) have a lack of healthy blood cells that can function properly. Dacogen, manufactured by Pharmachemie B.V. Haarlem, The Netherlands, is thought to work by promoting normal development of blood cells.

The drug received orphan drug status for MDS because the condition affects fewer than 200,000 people in the United States.

MDS can develop after treatment with drugs or radiation therapy for other diseases, or it can develop without any known cause. Some forms of MDS can progress to acute myeloid leukemia, a type of cancer in which too many white blood cells are made.

The FDA's approval of Dacogen "offers patients with this rare disease an additional treatment option that may help these patients avoid blood transfusions," says Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research.

The most common side effects reported in clinical studies of Dacogen included low white blood cell count (neutropenia), low platelets in the blood (thrombocytopenia), anemia, fatigue, fever, nausea, cough, bleeding in the skin, constipation, diarrhea, and high blood sugar (hyperglycemia).

Remicade Approved for Children With Crohn's Disease

The FDA has approved Remicade (infliximab) to treat children with active Crohn's disease, a chronic, inflammatory condition of the bowel that can be severely debilitating. Remicade was first approved in 1998 to treat Crohn's disease in adults.

Remicade is a genetically engineered monoclonal antibody that is manufactured using cells containing human and mouse antibody genes. This biotechnology product, which is taken intravenously, blocks the action of a protein called tumor necrosis factor-alpha (TNF-alpha), one of the underlying causes of inflammation in Crohn's disease.

The inflammation often involves the entire wall of the gastrointestinal tract and can result in abdominal pain, gastrointestinal bleeding, diarrhea or loose stools, blockages, and infections.

Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research, notes that there have been no satisfactory treatments for children with moderately to severely active Crohn's disease who have symptoms despite conventional therapies.

"Remicade is not a cure, but it provides a much-needed option for reducing the symptoms and inducing and maintaining disease remission in children who have no other safe and effective therapy," says Galson. "We believe that the potential benefits of this product outweigh the risks that are known and have been carefully evaluated."

The safety profile for Remicade in the children's study was similar to the data that were presented at an FDA Arthritis Advisory Committee meeting in March 2003, and that dealt with the extent to which anti-TNF therapies may increase the risk of serious infections and illnesses, such as sepsis and pneumonia, in certain people.

These risks, which are described in a study in the May 17, 2006, issue of the Journal of the American Medical Association, are included in the current labels for all approved TNF-alpha blocking agents, including Remicade. More recently, the FDA has received rare reports of an aggressive and often fatal type of cancer (hepatosplenic T-cell lymphoma) in adolescents and young adults with Crohn's disease who were treated with Remicade. Most of these people were receiving standard immunosuppressive therapies, such as azathioprine or 6-mercaptopurine, along with Remicade. The FDA is working with the manufacturer, Centocor Inc. of Malvern, Pa., to address this risk by updating the "warnings" sections of the Remicade label.

The FDA continues to monitor the safety of Remicade and similar treatments to maximize their benefits yet limit, to the degree possible, the potential for very serious side effects.
MS Drug Back on Market Under Restricted Program

The FDA has approved an application to resume the marketing of Tysabri (natalizumab) under a special restricted distribution program. Tysabri is a drug used to treat people with relapsing forms of multiple sclerosis (MS) to reduce the frequency of flare-ups.

Tysabri is approved for use as a monotherapy, meaning it should not be used with other drugs that modify the immune system. Tysabri, which is injected directly into a vein (infused), is for people who have not responded to, or cannot tolerate, other treatments for MS.

The FDA initially approved Tysabri in November 2004, but the manufacturer Biogen Idec Inc. withdrew the drug in February 2005 after three patients in clinical trials developed a serious and rare viral infection of the brain. Two of the cases were fatal. On the basis of this information, the FDA put clinical trials of the drug on hold in February 2005. The FDA allowed a clinical trial of Tysabri to resume in February 2006 after reexamining the patients who had participated in previous clinical trials and confirming that there were no additional cases of PML.

To decrease the possibility of people developing PML in the future, while also making Tysabri available to those with MS who could benefit from it, the FDA consulted in March 2006 with its Peripheral and Central Nervous System Drugs Advisory Committee. The committee recommended a risk-minimization program with mandatory patient registration and follow-up to identify as early as possible any cases of PML that may occur and why. In response, Biogen Idec submitted to the FDA a risk management plan, called the TOUCH Prescribing Program, to help ensure safe use of the product.

After a thorough review of the information provided by Biogen Idec, the FDA determined that Tysabri can be made available under the TOUCH Program. Biogen Idec and its distributor for Tysabri, Elan Pharmaceuticals Inc., will manage the program, which includes the following main features:

- The drug will be prescribed, distributed, and infused only by prescribers, infusion centers, and pharmacies registered with the program.
- Tysabri will be administered only to patients who are enrolled in the program.
- Prior to the start of treatment with Tysabri, health care professionals are to obtain the patient's Magnetic Resonance Imaging (MRI) scan to help differentiate potential future MS symptoms from PML.
- Patients on Tysabri are to be evaluated at three and six months after the first infusion and every six months after that, and their status will be reported regularly to Biogen Idec.

New Drug Treatment for Parkinson's Disease

The FDA has approved Azilect (rasagiline), a new drug for the treatment of Parkinson's disease. Azilect is a monoamine oxidase type B (MAO-B) inhibitor that blocks the breakdown of dopamine, a chemical that sends information to the parts of the brain that control movement and coordination.

"This is a welcome development for the more than 50,000 Americans who are each year diagnosed with Parkinson's disease," says Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research. "Parkinson's is a relentless disease with limited treatment options, and each new therapy is an important addition to the physicians' treatment options."

Parkinson's disease is a chronic, progressive neurodegenerative condition caused by the destruction of the brain cells that produce dopamine. As the level of this chemical declines, messages from the brain telling the body how and when to move are delivered more slowly, leaving a person incapable of initiating and controlling movements in a normal way.

Azilect was approved for use as an initial single drug therapy in early Parkinson's disease, and as an addition to a standard Parkinson's disease treatment, levodopa, in people with more advanced disease.

People who take Azilect may have a sudden, large increase in blood pressure (hypertensive crisis) if they also consume tyramine-rich foods or beverages (such as cheese and red wine) or dietary supplements or amines contained in many cough and cold medications. A hypertensive crisis can lead to a stroke and death. People taking Azilect will need to avoid sources of tyramines and amines. Like most other medications for Parkinson's, Azilect has the potential to cause involuntary movements, hallucinations, and lowered blood pressure.

During Azilect's development, melanoma was diagnosed in a small number of people treated with the drug. The manufacturer, Teva Pharmaceutical Industries Ltd., Israel, will perform an after-market study to determine whether or not Azilect increases the risk of this form of skin cancer. The product labeling will recommend that people who take Azilect get periodic dermatologic examinations.
Getting Ready for Another Flu Season

By Linda Bren

Most people probably aren't thinking about flu season in the middle of summer. But government agencies are—in fact, they work year-round to prepare for each influenza season and ensure that enough vaccine is available to protect the American public.

An advisory committee to the Food and Drug Administration has selected the strains of influenza virus that will be included in this year's vaccine, and manufacturers are already in production. And an advisory committee to the Centers for Disease Control and Prevention (CDC) has recommended who should get flu vaccine during the upcoming flu season.

Influenza is a contagious respiratory illness caused by the influenza virus. Flu season in the United States can begin as early as October and can last as late as May, according to the CDC. The season most often peaks in February or later. The past flu season started off with low levels of activity in October and November 2005, with activity picking up considerably in December. The season peaked in early March 2006 and continued at low levels into May.

The CDC reports that each year, 5 percent to 20 percent of the 300 million people in the United States get the flu. Most people recover in a week or two without complications. But more than 200,000 are hospitalized with flu complications, and about 36,000 Americans die each year from the flu.

"Vaccination is still the best protection against influenza and can prevent many illnesses and deaths," says Jesse Goodman, M.D., director of the FDA's Center for Biologics Evaluation and Research. "Ensuring an adequate, safe, and effective supply of influenza vaccine each year is one of the FDA's highest priorities."

Selecting the Strains

New flu vaccine is made each year. "Because the virus mutates, each year's vaccine may be different from the preceding year's," says Goodman. The vaccine is a blend of three different influenza virus strains, and the formulation depends on the virus strains that are predicted to be circulating that particular flu season.

It takes at least six months to produce a flu vaccine, so early in the year, the FDA's Vaccines and Related Biological Products Advisory Committee meets to decide which three strains of the virus should be used. The formulation selected for the 2006–2007 season includes one virus from last year's vaccine and two new viruses.

The FDA has licensed four manufacturers to make flu vaccine for the 2006–2007 season. The vaccine manufacturers estimate that between 100 million and 120 million doses will be produced, at least a 16 percent increase over last season's 86 million doses. The increased production will help accommodate expanding vaccination recommendations as well as reduce the risk of shortages.

Vaccination Recommendations

Each spring, the CDC's Advisory Committee on Immunization Practices (ACIP) recommends who should get influenza vaccines in the upcoming flu season. After considering the ACIP guidance, the CDC issues its recommendations during the summer. According to the CDC, people who should get vaccinated each year include those who are at high risk for complications from the flu, those who are in contact with these high-risk indi-
Centrissa Maines, Ph.D., a microbiologist in the Influenza Branch at the Centers for Disease Control and Prevention, conducts an experiment inside a biological safety cabinet (BSC) within the Biosafety Level 3-enhanced laboratory.

Individuals, and people ages 50 to 64. The upcoming season’s high-risk category includes children ages 6 months to 59 months. The ACIP has recommended vaccinating children in this age group as well as their household contacts. The recommendation expands last season’s recommendation to vaccinate children from ages 6 months to 23 months. The expanded age range means that an additional 5.3 million children and 11.4 million household contacts or caregivers should be vaccinated.

The ACIP also emphasizes the importance of giving two doses of influenza vaccine, at least one month apart, to children between the ages of 6 months and 9 years who have never received influenza vaccine.

Although anyone can come down with the flu, infection rates are highest in children, according to the CDC. Children can spread the virus for twice as long as adults and usually shed more influenza virus, making them flu carriers and sources of infection for others.

The youngest children are at the highest risk of influenza-related illness and death, says Henry Bernstein, D.O., who serves on the American Academy of Pediatrics’ Committee on Infectious Diseases. “Children under 6 months of age are very likely to be hospitalized if they get influenza. They are too young to be immunized, so it’s important to immunize all family members, daycare workers, and other close contacts.”

For More Information
www.fda.gov/oc/opacom/hottopics/flu.html
LASIK is an operation that reshapes the cornea to correct refraction and reduce the need for corrective lenses such as glasses or contact lenses. A specially designed instrument is used to lift a corneal flap in LASIK surgery.
Eye problems, in general, tend to get overlooked in a crowd of broader health issues such as heart disease and cancer. For this reason, the vision health care community has been working hard in recent years to emphasize the importance of proper eye care.

The focus, primarily, has been on increasing the number of people who receive regular vision checks, and addressing diseases, injuries and, according to the National Eye Institute (NEI), the most frequent eye problems in the United States—defects or refractive errors—most often responsible for impairing vision. As a result, vision goals have been added recently to a set of national health objectives, called Healthy People 2010, which are aimed at preventing disease and promoting health.

"These objectives are important because they give vision a prominent place on the public health agenda," says Rosemary Janiszewski, the Healthy People 2010 coordinator for the NEI. "It is an acknowledgment from our country's leading health officials that vision plays a significant role in the nation's overall health."

**How We See**

The "Snellen Eye Chart," a series of letters arranged in lines, is the standard for measuring how well each eye sees. People view the chart at a distance of 20 feet. One eye is covered while the other is tested.

Having 20/20 vision means seeing at 20 feet what a person with normal vision sees at 20 feet. Someone able to read additional lines smaller than the line representing normal vision has 20/15, or even 20/10, vision. A person who has worse-than-normal vision and can only read letters larger than the 20/20 line has 20/40 vision, or higher. As a result, a person who has 20/40 vision can see at 20 feet what the person with normal vision sees at 40 feet. And so on.

The eye does not actually "see" objects. Instead, it sees the light that objects reflect. To see clearly, light striking the eye must be bent or "refracted" through the cornea—the clear window at the front of the eye that provides most of the focusing power. Light travels through the lens, where it is fine-tuned to focus properly on the nerve layer that lines the back of the eye, the retina, and is then sent to the brain through the optic nerve. The retina acts like the film in a camera, and clear vision is achieved only if light from an object is precisely focused on it. If not, the image you see is blurred. This problem is called a refractive error.

**Refractive Errors**

Refractive errors usually occur in otherwise healthy eyes, and are caused mostly by an imperfectly shaped eyeball, cornea, or lens, according to the NEI. Near sightedness (myopia) and farsightedness (hyperopia) are the most common refractive errors. People with myopia see near objects clearly, while distant ones are blurred. People with hyperopia experience just the opposite—they see distant objects clearly, while near ones are blurred. Uneven focus or distorted vision (astigmatism) and aging eye that can't focus close up (presbyopia) are other common refractive errors.

The magnitude of refractive error is measured in units called diopters. Each diopter of refractive error affects a person’s ability to read smaller lines of an eye chart.

Why refractive errors develop is not known. The NEI says that most infants have some degree of hyperopia, but that vision becomes more normal with age, usually leveling off by age 6. However, some children remain farsighted, or become so later in life. While some children may be nearsighted early in life, most myopia occurs later during adolescence. Refractive error can continue to change over a person’s lifetime. According to the NEI, 60 percent of Americans have refractive errors that need correcting for sharper vision.

Glasses, contact lenses, and various eye surgeries and procedures are aimed at reducing refractive errors by focusing light rays properly on the retina. The past 20 years have seen many innovations in vision correction methods, including implantable intraocular lenses and different types of lasers used to reshape parts of the eye, which are regulated as medical devices by the Food and Drug Administration.

The FDA says that it’s important to learn as much as possible about the differences between the available corrective lenses, new and older surgeries, and any other vision correction procedures. It’s also important to know what factors make some a good candidate for certain procedures but a poor candidate for others.

Malvina B. Eydelman, M.D., director of the FDA’s Division of Ophthalmic and Ear, Nose and Throat Devices, adds that it’s important to weigh the benefits and risks of each vision correction option, and to have realistic expectations.
Normal Vision, 20/20 or better

Point of focus is on the retina

Nearsighted or Myopic Vision

Point of focus is in front of the retina

Farsighted or Hyperopic Vision

Point of focus is behind the retina

The cornea and the lens are responsible for focusing light on the retina. The retina acts like the film in a camera, and clear vision is achieved only if light from an object is precisely focused on it. If not, the image you see is blurred. This problem is most often the result of an imperfectly shaped eyeball, cornea, or lens.

Nearsightedness (myopia) affects more than 30.5 million Americans age 40 or older. Hyperopia is less common, affecting 12 million older Americans. Overall, 60 percent of Americans have refractive errors that need correcting for better vision.

Source: National Eye Institute

Corrective Eyewear

The NEI estimates that more than 150 million Americans spend over $15 billion each year on corrective eyewear to compensate for refractive errors. Discussing the latest alternatives to corrective eyewear with an eye care practitioner will help ensure that any risks are minimized.

All contact lenses are regulated by the FDA as medical devices. By law, people need a prescription to buy them, even for "plano" lenses, which are worn solely to change the appearance of the eye.

In addition, because people have many choices in how, where, and from whom to buy contact lenses, the Federal Trade Commission (FTC) enforces the Contact Lens and Eyeglass Rules, which help increase the ability to shop around. In this way, the FTC works to prevent fraudulent, deceptive, and unfair business practices regarding contact lenses.

Contact lens quality continues to improve. Advances in materials have made several types of precision contact lenses available for more people. While different types of plastics offer options for replacement and wear schedules, contact lenses are divided into two main groups: soft and rigid gas-per-
meable (RGP), also called hard contact lenses. From there, the lenses are broken down based on what they're made of, how often they need replacing, and whether they can be worn overnight.

RGP lenses give clearer, crisper vision for some people, according to the NEI. They tend to be less expensive over the life of the lens, but the initial cost often is higher. RGPs last for several years, while soft contacts, depending on the type, are meant to be replaced after short periods. In addition, RGP lenses can be marked to show which lens is for which eye, and they're less likely to tear or rip, making them easier to handle. It may take several weeks, however, to get accustomed to wearing rigid lenses, compared with several days for soft lenses.

Daily-wear soft contacts contain from 25 percent to 79 percent water, are easy to adjust to, and are initially more comfortable than RGPs, due to their ability to conform to the eye and absorb water. Soft lenses aren't as likely to pop out or capture foreign material, such as dust, as hard lenses. There are a variety of soft lens materials available for some people with very sensitive eyes.

The development of hyper-oxygen-transmissible lens materials, for both rigid and soft lenses, has created a new generation of extended-wear contacts that are intended to decrease the incidence of, and the risks for, lens-related eye infections. Silicone hydrogel contact lenses, which, according to the NEI, allow physiological levels of oxygen to reach the ocular surface, have improved the safety of extended- or continuous-wear contacts. Extended-wear lenses are available for overnight, and extended-wear disposables are soft lenses worn from one to six days and then discarded.

In October 2002, the FDA approved a new type of soft contact lens, safe enough to wear continuously for up to 30 nights. These lenses allow six times more oxygen to reach the eye than previously approved lenses. All extended-wear contact lenses, however, carry a greater risk of serious eye infections than lenses that are removed before the wearer retires for the day.

The replacement schedule of contact lenses refers to the length they can safely be worn. RGPs generally are replaced every couple of years because they are made of a durable material, although a prescription change would mean new lenses. Soft contacts come in a wider variety of replacement schedules.

Some special features of many contact lenses, both soft and hard, include

---

**Types of Contact Lenses**

<table>
<thead>
<tr>
<th>Types of Lenses</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid gas-permeable (RGP)</td>
<td>Made of slightly flexible plastics that allow oxygen to pass through to the eyes.</td>
<td>Require consistent wear to maintain adaptation; can slip off center of eye more easily than other types; debris can easily get under the lenses; require office visits for follow-up care.</td>
</tr>
<tr>
<td>Daily-wear soft</td>
<td>Made of soft, flexible plastics that allow oxygen to pass through to the eyes.</td>
<td>Very short adaptation period; more comfortable and more difficult to dislodge than RGP lenses; available in tints and bifocals; great for active lifestyles.</td>
</tr>
<tr>
<td>Extended-wear</td>
<td>Available for overnight wear in soft or RGP lenses.</td>
<td>Can usually be worn up to seven days without removal.</td>
</tr>
<tr>
<td>Extended-wear disposable</td>
<td>Soft and worn for an extended period of time, from one to six days, and then discarded.</td>
<td>Require little or no cleaning; minimal risk of eye infection if wearing instructions are followed; available in tints and bifocals; spare lenses available.</td>
</tr>
<tr>
<td>Planned replacement</td>
<td>Soft, made for daily wear, and are replaced on a planned schedule, most often either every two weeks, monthly, or quarterly.</td>
<td>Require simplified cleaning and disinfection; good for eye health; available in most prescriptions.</td>
</tr>
</tbody>
</table>

Source: American Optometric Association
bifocals, colored contacts, plano lenses, torics for astigmatism, and UV-blocking contacts.

The rule of thumb for contact lens wearers, says James Saviola, O.D., chief of the FDA’s Vitreoretinal and Extraocular Devices Branch, “is to practice good hygiene and follow manufacturers’ instructions for proper use, cleaning, and storage of the lenses.” Report any signs of infection to your doctor, he adds. People should not wear contact lenses longer than the time prescribed by their eye care practitioner. But whatever is prescribed, Saviola says, be sure to ask for written instructions and follow them carefully. Patient package inserts usually accompany contact lenses, and people who are not offered this information by their doctors should ask for it.

Saviola says that a doctor must be certified to fit Ortho-K lenses.

**Plano Lenses—Wearer Beware**

Also known as zero-powered, decorative, or noncorrective lenses, plano lenses at one time were considered cosmetic devices. Their purpose is to temporarily change, for example, a brown-eyed person’s eye color to blue, or to make a person’s eyes look “weird” by portraying Halloween themes or the logos of a favorite sport team. But because these lenses carry the same infection risks to the eye as corrective contact lenses, in 2005, they became medical devices by law.

“FDA strongly believes that eye care providers are needed to fit decorative lenses,” Saviola says, because of concerns about the potential for eye problems, such as pink eye (conjunctivitis) and corneal ulcers. He says that the agency also informed health care professionals of the risk of blindness and other eye injuries “if noncorrective, decorative, or cosmetic lenses are distributed without an eye care professional’s involvement.”

The FDA further advises people to never buy such decorative lenses at any store that doesn’t ask for a valid prescription from an eye care professional. “The FDA has never cleared an over-the-counter novelty lens,” says Saviola. Such sales are illegal in the United States, and for good reason: wearing contact lenses that don’t fit properly is dangerous and can cause serious vision problems, abrasions, and infections.

Maria Higgins, O.D., F.A.A.O., an optometrist who practices in Pittsburgh, was part of the National Contact Lens Enforcement Petition in 2003 that strongly encouraged the FDA to amend the medical device laws to include regulation of all contact lenses.

“I have had numerous experiences where a patient who was new to my office had purchased lenses at an establishment that was less than optimal,” she says. Two girls, in particular, came in with flaring, red eyes. Higgins recalls. They were diagnosed with corneal ulcers as the result of overwearing colored, nonprescription contact lenses purchased from a Dollar Store. Both women had worn two-week, disposable lenses for over four months.

“I am not against patients being able to purchase lenses in places other than my office,” Higgins says, “but I want my patients to be safe.” Fortunately, she adds, since the new law requiring all contact lenses be dispensed by prescription only, “I’ve found that patients do realize the importance of being fitted by a professional.”

---

**The FDA has never cleared an over-the-counter novelty lens.**

The most serious safety concerns with any contact lens deal with overnight use, or extended wear. Rigid or soft, wearing these types of contact lenses overnight increases the risk of corneal ulcers—infection of the cornea that can lead to blindness. Symptoms include vision changes, eye redness, eye discomfort, and excessive tearing. Saviola advises that keeping lenses clean, replacing them often, and wearing them as prescribed by your doctor minimize the risks of wearing contacts.

Orthokeratology (Ortho-K) is a nonsurgical procedure that uses RGP contact lenses to change the curvature of the cornea to improve its ability to refract light and successfully focus on objects.

The Ortho-K system was initially approved for daily wear. But in 2002, the FDA approved the lenses for overnight use. A person takes them out in the morning to enjoy the day free of contacts. This method, however, does not produce a permanent result, and
rect myopia, or to steepen it to correct hyperopia. PRK can also be used to correct astigmatism. The layer of cells covering the cornea, the epithelium, is removed, and the laser sculpts the cornea to correct the refractive error. A bandage contact lens is placed over the eye after the procedure to speed the epithelial healing process.

PRK gained popularity in the mid-1990s, but also was met with limitations. It worked best in patients with low-to-moderate myopia, because with higher levels, there was a risk of corneal haze. The procedure also was associated with some physical discomfort after surgery, since the cornea needed several days to heal. In some cases, it could take several months to reach the best level of vision.

By far the most popular vision correction procedure has been LASIK. Surgeons use a surgical knife, called a microkeratome, to create a hinged flap on the surface, fold it over to sculpt the underlying cornea into a new shape, and fold it back onto the cornea.

To encourage her daughter to consider LASIK, Becky Ricketts, 51, of Mt. Airy, Md., underwent the procedure for severe astigmatism in both of her eyes two years ago.

"I decided to be the guinea pig," she says. "My daughter's eyes were so bad, I just believed she would be better off having LASIK, based on results of the people I knew who'd had it done."

Ricketts's eyesight, though not as poor as her daughter's, was such that she wore glasses every day for most of her life, but not so bad that she was legally required to wear them to drive. "I've always passed my driving tests without glasses," she says. She does admit, however, that she squinted in front of the computer screen, and claims that without glasses, "everything had a fuzzy look." She was not able to wear contact lenses because the astigmatisms were so severe that "if I blinked, the contacts moved and I couldn't see." In fact, any movement of the head, Ricketts says, caused her contact lenses to move.

The advantages of LASIK include a quicker visual rehabilitation, reduced pain and discomfort, and the surgeon's ability to treat higher levels of refractive error without the limitations associated with PRK.

Three years after LASIK, Ricketts says, "My vision couldn't be better. I'm happy I had the surgery," she says, "but I didn't spend my life wanting to have it done."

Although she still wears glasses to correct presbyopia, Ricketts is currently considering a relatively new procedure that would reduce her need for reading glasses.

Doctors say that one of the keys to a successful LASIK procedure is the measurement that an ophthalmologist takes to determine refractive error. Small imperfections in the eye may cause some light to travel through the eye at different angles, making light strike the retina in different places. Collectively, these imperfections are called optical aberrations.

Traditional laser technology allows for correction of the refractive errors myopia, hyperopia, and astigmatism, also known as "lower order" aberrations. A new excimer laser procedure called wavefront-guided LASIK treats lower order and "higher order" aberrations, which are subtle focusing imperfections in an eye's optical system that can result in less-than-optimal clarity.

Wavefront, or custom LASIK, uses a measuring device to create a "map" of how a person's eye focuses light to precisely assess the unique irregularities and variations of the eye. These variations, experts claim, can be as unique as a person's fingerprints.

The FDA approved the excimer laser for use in wavefront-guided LASIK in 2005. Ricketts's 28-year-old daughter, Lindsey Hocker, of Frederick, Md., underwent the procedure for severe astigmatism in both of her eyes.

To encourage her daughter to consider LASIK, Becky Ricketts, 51, of Mt. Airy, Md., underwent the procedure for severe astigmatism in both of her eyes.

Ricketts's 28-year-old daughter, Lindsey Hocker, of Frederick, Md., underwent wavefront-guided LASIK in 2005. It first became available.

"Regular LASIK came highly recommended to me by several people, and seeing the success that Mom had with LASIK convinced me to do it," Hocker says. "But because of the problems I had, I decided to go with my doctor's recommendation for the custom cornea."

The wavefront map is very detailed: Instead of simply creating a general description of the eye's focusing power, for example, nearsightedness, farsightedness, or astigmatism, it records every subtle distortion in the pathway of light moving through the eye.

"Immediately after the surgery," Hocker says, "I could see the clock on the wall for the first time since the fourth grade." The only side effect she has experienced in two years was dry eyes after surgery.
Although it’s natural for people to want to hear the success stories of others who have undergone a type of surgery, the FDA recommends that people avoid being influenced by others encouraging them to have such procedures. Not everyone is a candidate for every procedure.

Laser Epithelial Keratomileusis, or LASEK, is a variation of LASIK, and corrects myopia, hyperopia, and astigmatism. The epithelium, or outer surface of the cornea, is loosened with alcohol, not with the microkeratome used in LASIK. It is then peeled back to expose the cornea. The same excimer laser used in LASIK is applied to the cornea, but only to the surface. The epithelium is placed back into position, and a bandage contact lens is placed on the eye to promote healing. Like LASIK, the recovery time is rapid. Discomfort is somewhat increased, compared with LASIK.

LASEK is similar to PRK. The difference is that with LASEK, the epithelium is replaced after surgery. In PRK, the epithelium is discarded. Both PRK and LASEK are similar to LASIK in that they use the excimer laser to shape the cornea.

While the FDA regulates excimer lasers, the agency doesn’t have the authority to regulate a doctor’s practice of medicine or the off-label use of medical products. Therefore, the FDA does not tell doctors what to do when running their businesses or what they can or cannot tell their patients. Consequently, people considering laser surgery should ask questions and fully understand any procedure they might be considering.

The idea of a person walking into a doctor’s office and an hour later walking out with perfect vision is a very attractive one, but the reality is that these are surgical procedures with potential complications, and perfect results are not guaranteed, experts say. Everette Beers, Ph.D., chief of the FDA’s Diagnostic and Surgical Devices Branch, reminds people that refractive surgeries are elective procedures, some of which can’t be undone.

"People need to remember that you can change glasses or contacts, but not implants or surgery,” he says. Be sure to consult with a refractive surgeon to determine your eligibility for surgery. Beers also warns that surgical procedures are not without some risk, and that "the long-term effects of many procedures are still unknown.”

According to the American Academy of Ophthalmology (AAO), more than 90 percent of people who have refractive surgery for myopia and astigmatism end up with 20/40 vision or better without glasses, a correction sufficient enough to allow them to drive legally without glasses. Sixty percent to 70 percent of patients achieve 20/20 vision or better.

**Implant Procedures**

Corrective artificial lens implants give people who don’t want to bother with eyeglasses or manual insertion of contact lenses another option to consider.

Intrastromal corneal ring segments are semicircular pieces of plastic that are implanted within the cornea to treat mild forms of myopia. They also are sometimes used for other conditions affecting the cornea. The inserts are designed to change the shape of the cornea by adjusting the focusing power of the eyes so that light is focused onto the retina. A small incision is made near the upper edge of the cornea, in which the ring segments are inserted. The incision is closed with two small sutures that are usually removed two to four weeks after surgery.

While tissue removed during laser eye surgeries cannot be replaced, the intrastromal corneal ring segments are removable.

Phakic Intraocular Lenses (phakic IOLs) are new devices made of plastic or silicone, approved by the FDA for correcting nearsightedness. These thin lenses are implanted into the eye to help reduce the need for glasses or contact lenses. A small incision is made in the front of the eye, in which the phakic lens is inserted. Phakic refers to the lens being implanted into the eye without removing the eye’s natural lens. Since phakic IOLs involve entering the eye, unlike LASIK and PRK, the risk of complications is higher.

Phakic lenses are intended to be permanent. If a cataract develops, however, the natural and phakic lenses would be removed and replaced with artificial lenses, says Kesia Alexander, Ph.D., chief of the FDA’s Intraocular and Corneal Implants Branch. But, she adds, “there’s no guarantee that the
eye will return to its previous level of vision," Alexander also says that while phakic lenses are a good alternative for people who are very myopic and can’t be corrected with LASIK, “there’s no guarantee that you won’t always be able to go without glasses.”

**Thermal Procedures**

Conductive keratoplasty (CK) uses radio frequency energy, instead of a laser, to bend the cornea. Also known as “blended vision,” CK corrects for hyperopia. By overcorrecting the cornea, CK causes the eye to become nearsighted. "CK achieves its correction of presbyopia," says Beers, "by inducing monovision with one nearsighted eye."

CK does not involve making an incision, but instead, a tiny probe releases controlled amounts of very low heat from radio frequency energy, causing the outside area of the cornea to tighten like a belt, making the central cornea steeper. CK causes little or no discomfort or irritation, and vision improvement is almost instantaneous. Unlike other types of refractive surgery, such as LASIK, however, correction from CK may be temporary and re-treatment may be necessary.

**Other Refractive Surgery Procedures**

Accommodative and multifocal IOLs are used to treat nearsightedness, farsightedness, and the inability to focus up close because of age. These artificial lenses are surgically implanted in the eye. Unlike the phakic IOLs, which are implanted in front of the eye’s natural lens, accommodative and multifocal IOLs actually replace the eye’s natural lens once a cataract has developed. These lenses enable the eye to regain its focusing and refractive ability.

Monovision is a corrective technique used to treat people with presbyopia. The intent is for the person to use one eye for distance viewing and one eye for near viewing. Having each eye configured for different focusing distances can reduce or eliminate the need for eyeglasses or contact lenses.

The practice was first applied to contact lenses, and more recently to LASIK and other surgeries. In refractive surgery, the technique treats one eye to focus at close proximity, while the other eye is left untreated or, if needed, treated to be able to focus at a distance. This method may be difficult to adjust to at first but, according to the International Society of Refractive Surgery, about six to eight weeks after the monovision procedure, most people's brains are able to adjust to the different focusing ability of the eyes.

The FDA recommends that anyone considering monovision try the contact lens procedure first, as a trial run, before having the surgery, which is permanent. Also, it’s important to check state drivers’ license requirements with monovision.

**Eyglasses—The Reliable Standby**

In some cases, modern technology can provide the best vision correction option. In those cases in which it can’t, eyeglasses may be the way to go. Glasses correct refractive errors by adding or subtracting focusing power to the cornea and lens. The power needed to focus images directly on the retina is measured in diopters. This measurement is also your eyeglass prescription.

Like contact lenses, glasses come in all shapes and sizes, offering an array of choices for both function and fashion. Eyeglass frames, for example, are more durable and tout materials such as titanium and new “memory metals.” Manufacturers are making lenses that are thinner, stronger, and lighter. And lens options include antireflective coating, light-changing tints, line-free (progressive) bifocal, and polycarbonate—the most impact-resistant lens material available.

Regular eye exams are important because they can detect early signs of disease and refractive error long before either leads to vision impairment. Doctors recommend that everyone have an eye exam shortly after birth, and at least every few years until age 40. After that, the eyes should be routinely checked every two or three years. People with diseases such as diabetes and hypertension should have their eyes checked more frequently.

**Who Does What?**

Eye care professionals have different educations, and the services they can provide, described below, are determined by varying regulations:

- **Opticians** grind and dispense eyeglasses, and in some states, fit contact lenses, following prescriptions written by optometrists or ophthalmologists.

- **Optometrists** (O.D.) examine eyes, diagnose and treat vision problems and abnormalities, and prescribe eyeglasses and contact lenses. The medications they are licensed to prescribe to treat eye conditions vary by state.

- **Ophthalmologists** (M.D. or D.O.) are physicians who specialize in treating eye diseases. They are trained to perform eye surgery.

---

**For More Information**

Food and Drug Administration

[www.fda.gov/cdrh/contactlenses/](http://www.fda.gov/cdrh/contactlenses/)

[www.fda.gov/cdrh/lasik/](http://www.fda.gov/cdrh/lasik/)

[www.fda.gov/cdrh/phakic/](http://www.fda.gov/cdrh/phakic/)

National Eye Institute


American Academy of Ophthalmology

[www.aoa.org](http://www.aoa.org)

American Optometric Association

[www.aoanet.org](http://www.aoanet.org)

Federal Trade Commission

[www.ftc.gov](http://www.ftc.gov)

Association of Regulatory Boards of Optometry

[www.arbo.org](http://www.arbo.org)
Some Cold Medicines Move Behind Counter

By Linda Bren

Some over-the-counter (OTC) cold and allergy medicines are being moved behind the counter at pharmacies nationwide as part of the fight against illegal drug production.

Under the Patriot Act signed by President Bush on March 9, 2006, all drug products that contain the ingredient pseudoephedrine must be kept behind the pharmacy counter and must be sold in limited quantities to consumers after they show identification and sign a logbook.

Pseudoephedrine is a drug found in both OTC and prescription products used to relieve nasal or sinus congestion caused by the common cold, sinusitis, hay fever, and other respiratory allergies. The drug is also a key ingredient in making methamphetamine—a powerful, highly addictive stimulant often produced illegally by “meth cooks” in home laboratories.

The new legal provisions for selling and purchasing pseudoephedrine-containing products are part of the Combat Methamphetamine Epidemic Act of 2005, which was incorporated into the Patriot Act. These “anti-meth” provisions introduce safeguards to make certain ingredients used in methamphetamine manufacturing more difficult to obtain in bulk and easier for law enforcement to track.

According to the National Institute on Drug Abuse, methamphetamine use and abuse is associated with serious health conditions including memory loss, aggression, violence, paranoia, hallucinations, and potential heart and brain damage. The Drug Enforcement Administration says there is a direct relationship between methamphetamine abuse and increased incidents of domestic violence and child abuse.

Meth users ingest the substance by swallowing, inhaling, injecting, or smoking it. There are currently no safe and tested medications for treating methamphetamine addiction.

The new law affects several hundred OTC products for children and adults, such as Sudafed Nasal Decongestant Tablets, Advil Allergy Sinus Caplets, TheraFlu Daytime Severe Cold SoftGels, Tylenol Flu NightTime Gels, and Children’s Vicks NyQuil Cold/Cough Relief. “There are very few decongestants on the market that don’t contain pseudoephedrine,” says Charles Ganley, M.D., director of the Food and Drug Administration’s Office of Nonprescription Products.

Ganley says that products containing pseudoephedrine are still available without a prescription and that they are packaged the same way as any OTC drug. “The only difference is that people will have to go to the pharmacist to buy them,” he says. “They just need to ask for them and show ID, and know that there’s a limit to the amount they can purchase.”

Buyers must show a government-issued photo ID, such as a driver’s license, and sign a logbook. Stores are required to keep a record about purchases, which includes the product name, quantity sold, name and address of purchaser, and date and time of the sale, for at least two years. Single-dose packages containing 60 milligrams or less of pseudoephedrine are excluded from the recordkeeping requirement, but must still be stored behind the counter.

The federal law limits the amount of pseudoephedrine an individual can purchase to 3.6 grams in a single day and 9 grams in a month at a retail store. For example, a person may buy Advil Allergy Sinus Caplets, which contain pseudoephedrine and other ingredients, in quantities of up to 146 tablets in one day and 366 tablets in one month. The number of pills or amount of liquid medicine allowable will vary depending on the type of product and its strength.

The limits on the amount an individual can purchase became effective April 8, 2006. The requirements to place products behind the counter and to keep a logbook take effect Sept. 30, 2006. Many drug stores are already complying voluntarily or because some state laws require similar controls.

Drug companies are reformulating some of their products to eliminate pseudoephedrine. Pfizer, for example, while still offering Sudafed nasal decongestants, which contain pseudoephedrine, also markets a line called
Associated Press

A warning display appearing on a cash register when more than three boxes of Sudafed are purchased is shown at a Wal-Mart Store in Troy, Mich.

Sudafed PE as an “on the shelf” alternative. Sudafed PE contains the active ingredient phenylephrine, which is not used to make methamphetamine, and so is not under the same restrictions as pseudoephedrine.

“Drugs that contain phenylephrine are also safe and effective,” says Ganley. “The dosing is a little different—you have to take them a little more frequently than the pseudoephedrine-containing drugs because their effects are not as long-lasting.”

The anti-meth provisions of the Patriot Act restrict the sale of two other drug ingredients, ephedrine and phenylpropanolamine, because of their potential to be used illegally to make methamphetamine. Like pseudoephedrine, drugs containing these ingredients must be placed behind the counter, and buyers must show identification to purchase a limited quantity.

Synthetic ephedrine is used in some topical drugs, such as nose drops, to temporarily relieve congestion due to colds, hay fever, sinusitis, or other upper respiratory allergies. It is also used orally for temporary relief of asthma symptoms.

Phenylpropanolamine was commonly used in OTC decongestants and weight-loss drugs. Today, it is unlikely that consumers will find phenylpropanolamine in their drug stores, says Ganley. In 2000, the FDA asked drug manufacturers to discontinue marketing products containing phenylpropanolamine because of an increased risk of bleeding in the brain (hemorrhagic stroke) associated with the ingredient. The FDA has taken regulatory actions to remove phenylpropanolamine from all drug products.

For More Information
www.fda.gov/cder/news/methamphetamine.htm
Medication Use
A brown paper bag may hold the key to safer use of medications, according to health experts.

"A 'brown bag checkup' is the single best thing that patients can do to avoid medication mistakes and cut down on unnecessary medications," says Douglas Paauw, M.D., professor of medicine at the University of Washington in Seattle. "But I would estimate that only about 10 percent of people actually do it."

The checkup involves putting all of your medications and over-the-counter products in a brown paper bag and bringing them into your doctor's office. The bag should include any over-the-counter or prescription drugs, herbs, vitamins, dietary supplements, and topical treatments such as ointments and creams. "This kind of checkup is a good idea for anyone who takes medication, but particularly for older people who are the most likely to be taking several medications," Paauw says. The average 75-year-old has three chronic conditions and uses five prescription drugs, according to a report from the Merck Institute of Aging & Health.

John Lowery, 87, of Delphi, Ind., goes through his daily medications with his physician, Lisa McTavish, M.D. Lowery carries his medication list in his wallet, keeps it on his computer at home, and gives a copy of it to his doctor every time he sees her.
Researchers at Pennsylvania State University found that when adults ages 65 to 91 were asked to bring in the brown paper bag containing their medicines, the list of medications in the bag was more complete than their official pharmacy records. And people with worse health consistently had poorer matches between the brown bags and the paperwork.

"If not a paper bag, then write out a list and bring that in," Paauw says. You could also share the information with your pharmacist, who can check for drug duplications, interaction problems, inappropriate dosing, and whether each drug is being given for the right indication.

The idea is to have at least one health care professional informed about everything that you take. "This should be done at least every year and preferably more often," Paauw says. "Some of my patients do it at every visit."

When the bottles and tubes are spread out on the table, the picture becomes clear. "When someone pulls out 10 bottles, then something might not be right and we can make adjustments," Paauw says. The doctor can also see that your multivitamin with iron is the reason your thyroid treatment isn't working. "Both iron and calcium supplements can interfere with the absorption of thyroid medicine," says Paauw, who gave a talk on common drug errors at the annual meeting of the American College of Physicians in April 2006.

Stephen Setter, Pharm.D., associate professor of pharmacotherapy at Washington State University in Spokane, says doubling up on therapy is another common problem. "Someone may be taking two products containing acetaminophen," which raises the risk of liver damage. Other common problems include expired medications and medications that are no longer needed, but were never reevaluated.

After you and your doctor settle on what you should be taking, then the next thing is for you to know the name of your medication and what it's for, says Karen Gunning, Pharm.D., associate professor of pharmacy practice at the University of Utah in Salt Lake City. "If an older person has memory problems or difficulty with comprehension, a family member or caregiver could help," Gunning says.

Setter cites an example in which one of his older patients mistakenly thought her glaucoma medication was for treating headaches. "So she was taking her eye medication only when she had a headache, but she should have been taking it every day to treat her eye disease," Setter says. Experts say that it's important to understand your medications because you are more likely to take the medicine correctly, more likely to know what to expect from the medication, and better able to report what you are taking to your doctors and pharmacist.

"Keep the list of medications in your wallet and let a family member know that you have it," Gunning suggests. "Patients should be able to take that list out at the dentist's office, an appointment with a specialist, or in an emergency," she says. "But it's not uncommon for an older patient to come to the hospital and say that their doctor gave them a white pill and that's all they know."

John Lowery, 87, Delphi, Ind., carries his medication list in his wallet, keeps it on his computer at home, and gives a copy of it to his primary care doctor every time he sees her. His oldest son, 65, lives nearby and also knows about the list.

Robert Ferguson, M.D., chief of internal medicine at Union Memorial Hospital in Baltimore, says that intentional noncompliance with the regimen typically occurs because the patient can't afford the medicine or is worried about side effects. "When noncompliance is unintentional," Ferguson says, "it's usually because complying with the regimen became too difficult. It's so complex that it's too hard to keep it up."

Ferguson says he teaches medical residents that the regimen should be
A friend or a relative can accompany an older person to a doctor appointment to help ensure that instructions for medicines are understood and remembered.

as simple as possible and effective, and should result in minimal side effects. “Sometimes, we can reduce the number of medications by treating two problems with one medication,” Ferguson says. There also are ways to make the schedule simpler such as switching from a medicine that’s given three times a day to another medicine that can be given once a day.

You can make sticking to a schedule easier by attaching the medications to meals or other daily activities. Lowery says this works for him. “The three medications that I need to take in the morning go on top of the refrigerator and I have them with breakfast,” he says. “I take the others at night before bedtime.”

For more complicated regimens, pill boxes with compartments can help. Pill boxes are also useful for people who have trouble opening pill bottles. Setter says, “You can ask for pre-filled pill boxes or request bottles without child-proof caps if no children live in or visit the home.” Pharmacies usually charge a nominal fee for pre-filled pill boxes.

Everything from gadgets that beep to simple medication charts posted on the refrigerator can serve as reminders. “For some people, we color code the medication bottles or use a big picture of the sun to signal morning medications,” Setter says.

Setter says he talks with many older people who are confused about the purpose of the drug and the instructions. “The typical scenario is that a patient has three new prescriptions and had to wait in the pharmacy for 30 minutes, so they just want to get the prescriptions filled and go,” he says. “Health providers need to speak more slowly and take the time to explain, which can be a challenge,” Setter says. “And patients should ask questions. But people get intimidated and don’t have time to ask questions.” Writing questions down is always a good idea, Setter says. “Family members and caregivers can help with this.”

Examples of questions to ask about a new medication: What should I do if I forget a dose? Should I take the medicine before, during, or after meals? What should the timing be between each dose?

With some diseases, people may stop taking medication because they don’t understand why they are taking it or don’t feel that it helps. “But we don’t want people to stop taking an osteoporosis drug and then have a fracture a year later,” Setter says. “And with a diabetes drug, we are hoping to prevent blindness, amputation, and kidney disease.”

Lowery, who has survived a heart attack and kidney failure, says he is diligent about managing his medications because he feels they improve his quality of life. From the pills that ease
Most medication side effects are mild and may lessen over time. But if they are bothersome, you should discuss them with your doctor.

Managing Side Effects
Most medication side effects are mild and may lessen over time. But if they are bothersome, you should discuss them with your doctor. The doctor may switch to a different drug or change the dose. "Neither patients nor physicians should shrug off side effects by chalk-ing them up to old age," Setter says. "And side effects shouldn’t be treated with more drugs."

Compared with younger people, older people can be more likely to experience some side effects, Ferguson says. Side effects may also be more troublesome than they would be for someone younger. There are no absolutes here. Some robust 85-year-olds can handle a medication better than a 50-year-old who has a lot of health problems. But generally, older people have a decline in liver and kidney function, which affects the way a drug is broken down and removed from the body. "The kidneys decline about 1 percent each year starting at age 40," Ferguson says. "Medication stays in the body longer and side effects can have bigger consequences in older people."

Examples of side effects that may affect older people more than younger people are dizziness, dry mouth, drowsiness, falls, depression, insomnia, nausea, and diarrhea. David Greeley, M.D., a neurologist at Northwest Neurological Institute in Spokane, says the effects of sedating antihistamines such as diphenhydramine can be disastrous in older people.

Diphenhydramine is commonly found in over-the-counter sleep aids such as Unisom Sleep Gels, Tylenol PM, and cold and allergy medicines such as Benadryl. Greeley says, "Whereas

At about age 40, kidney function begins to decline. As a result, medications remain in the body longer, which can have serious consequences.
Tips for Seniors on Safe Medicine Use

1. Learn about your medicines. Read medicine labels and package inserts and follow the directions. If you have questions, ask your doctor or other health care professionals.

2. Talk to your team of health care professionals about your medical conditions, health concerns, and all the medicines you take (prescription and OTC medicines), as well as dietary supplements, vitamins, and herbals. The more they know, the more they can help. Don’t be afraid to ask questions.

3. Keep track of side effects or possible drug interactions and let your doctor know right away about any unexpected symptoms or changes in the way you feel.

4. Make sure to go to all doctor appointments and to any appointments for monitoring tests done by your doctor or at a laboratory.

5. Use a calendar, pill box, or other things to help you remember what you need to take and when. Write down information your doctor gives you about your medicines or your health condition.

6. Take along a friend or relative to your doctor’s appointments if you think you might need help to understand or to remember what the doctor tells you.

7. Have a “Medicine Check-Up” at least once a year. Go through your medicine cabinet to get rid of old or expired medicines and also ask your doctor or pharmacist to go over all the medicines you now take. Don’t forget to tell them about all the OTC medicines or any vitamins, dietary supplements, and herbals you take.

8. Keep all medicines out of the sight and reach of children.

Source: FDA/Center for Drug Evaluation and Research

A younger person can take it at night and feel back to normal by morning, the medication can linger in the system of someone older, which may result in falls and confusion.”

Pauuw says diphenhydramine can also affect a man’s prostate gland. “An older person who already has trouble urinating can end up in the emergency room with urinary retention,” he says.

Another example is the drug Mirapex (pramipexole), a treatment for Parkinson’s disease, for which there is an increased risk of hallucinations in people older than 65 compared with people younger than 65. “Quinolone antibiotics may also cause hallucinations,” Pauuw says. Examples of quinolone antibiotics include Cipro (ciprofloxacin), Levaquin (levofloxacin), and Floxin (ofloxacin).

In 2005, the Food and Drug Administration warned the public about the use of certain drugs called atypical antipsychotic drugs. The drugs are approved to treat schizophrenia and mania, but clinical studies of the drugs to treat behavioral disorders in older patients with dementia showed a higher death rate associated with their use when compared with patients receiving an inactive pill (placebo). The advisory applies to these antipsychotic drugs: Abilify (aripiprazole), Risperdal (risperidone), Zyprexa (olanzapine), Geodon (ziprasidone), Seroquel (quetiapine), and Clozaril (clozapine). Symbyax (olanzapine and fluoxetine), which is approved to treat depressive episodes associated with bipolar disorders, was also part of the advisory. The causes of death in older patients were varied, but most appeared to be related to the heart or pneumonia.

Reducing Errors

Setter says that older adults sometimes inadvertently receive an initial dose of medication that’s too high. “The dose may be totally appropriate for a younger adult,” Setter says, “but with the aging process, an older adult is less able to tolerate the typical starting dose.”

Health care providers try to find a balance that gives older people appropriate medications and appropriate doses. Experts say the philosophy has always been “start low and go slow”...
Testing Drugs in Older People

Since 1999, drug manufacturers have been required to analyze data on older patients, says Robert Temple, M.D., director of the FDA’s Office of Medical Policy. Most drugs submitted to the agency have been examined for effects in people older than 65, and most prescription drugs have a section in the labeling that addresses geriatric use. “There is a need for more inclusion of older adults in clinical trials, especially in the very old—people 75 and up,” Temple says.

In a study published in the Nov. 15, 2004, issue of the Journal of Clinical Oncology, FDA experts analyzed age-related enrollment of cancer patients into trials of drugs approved by the FDA from 1995 to 2002. They looked at data from close to 30,000 people with cancer from 55 trials. Significant underrepresentation of older people was noted in registration for all cancer treatments except for breast cancer hormonal therapies. People ages 70 and older were the most underrepresented group.

Experts say that certain diseases primarily affecting older people, such as Alzheimer’s and Parkinson’s, are well studied in older adults. But most other diseases are not. Barriers to inclusion of older people in clinical trials include logistic challenges that prevent them from getting to clinics. Or there may be criteria that exclude people who take multiple medications and have multiple diseases.

with dosing for older people because there are not enough clinical trial data in this age group for many drugs, especially in people ages 75 and older.

And because of the use of multiple medications, drug interactions are of concern. “Some interactions aren’t necessarily harmful and can be easily managed,” Setter says. “We want to prevent drug interactions that are dangerous.”

Improving the knowledge base about how drugs work together is helpful, Setter says. “We have clinical guidelines that address individual diseases like Alzheimer’s disease, Parkinson’s, or diabetes. But there is a need for clinical guidelines with a geriatric slant—guidelines that can apply to a person who may have five co-existing diseases.”

Drug–drug interactions occur when a drug may increase the effect of another drug or render it ineffective. Paauw says interactions involving warfarin (Coumadin) are the most common ones that result in hospitalization. Warfarin, a medication that thins the blood and helps prevent clots, is commonly prescribed to older people with an irregular heartbeat (atrial fibrillation) who are at risk of blood clots that can cause strokes.

Warfarin should not be taken with aspirin, ibuprofen, or other nonsteroidal anti-inflammatory drugs because of the increased risk of gastrointestinal bleeding. Warfarin also interacts with the antibiotic Bactrim (sulfamethoxazole), which is commonly used in older people. This combination can result in severe increased bleeding. The supplements Ginkgo biloba, garlic, ginger, and ginseng can also interact with warfarin.

Many interactions can be prevented with more communication between doctors and patients, as well as better coordination between all the health care professionals who see a particular patient, says Nicole Brandt, Pharm.D., director of clinical and educational programs at the Peter Lamy Center for Drug Therapy and Aging in Baltimore. She and her colleagues are partnering with a managed care system to study medication management in older patients who have been discharged from five hospitals. As part of the study, a pharmacist visits newly discharged patients to conduct a medication evaluation.

“The goal is to create a more integrated social and health care support system to improve adherence and reduce errors,” Brandt says. “Ultimately, we want to decrease readmissions to the hospital.”

Sarah Ray, Pharm.D., ambulatory clinical coordinator of pharmaceutical services at Aurora Health Care in Milwaukee, says that technology is increasingly playing a role in improving patient safety. “We’ll notice if patients are discharged from the hospital on a different dose than what they were on when they were in the hospital or before entering the hospital,” Ray says. “I then have to clarify with the doctor, and the prescription may have been written incorrectly.” Ray says she’s able to catch that kind of error because she works in an integrated health care system and has access to computerized information about what the patient was taking in the hospital. But that kind of error might not be caught at an independent pharmacy that does not have access to hospital records.

Ray says she thinks electronic prescribing will make a big difference in reducing medication errors. Electronic prescribing allows doctors to transmit prescriptions to pharmacies electronically. This method decreases errors caused by hard-to-read handwriting and automates the process of checking for drug interactions and allergies. The Medicare Prescription Drug Improvement and Modernization Act of 2003 established standards for electronic prescribing. Final standards will be set by the U.S. Department of Health and Human Services no later than April 2008.

For More Information

“As You Age … A Guide to Aging, Medicines, and Alcohol”
www.fda.gov/cder/consumerinfo/as_you_age_text.htm

“Medicines and You: A Guide for Older Adults”
www.fda.gov/cder/consumerinfo/medAndYouEng.htm

National Institute on Aging
www.nia.nih.gov/

“Saving Money On Prescription Drugs”
www.fda.gov/fdasc/features/2005/505_save.html

“Preventing Serious Drug Interactions”
www.fda.gov/fdasc/features/2004/404_drug.html
Artificial Sweeteners: No Calories...Sweet!

Artificial sweeteners can help consumers cut down on calories and control weight, help to manage chronic conditions such as diabetes, and potentially prevent cavities, according to the American Dietetic Association (ADA).

To date, five artificial sweeteners are approved by the Food and Drug Administration: aspartame, saccharin, acesulfame-K, neotame, and sucralose. The agency regulates artificial sweeteners as food additives, which must be approved as safe before they can be marketed.

“The FDA evaluates a sweetener’s composition and properties, how much of the substance is likely to be consumed, and various types of safety studies,” says Laura Tarantino, Ph.D., director of the Office of Food Additive Safety in the FDA’s Center for Food Safety and Applied Nutrition.

For each of the approved sweeteners, the typical amount used by U.S. consumers is well within designated “acceptable daily intake levels (ADI),” or levels that can be consumed safely every day over a lifetime. Here’s a detailed look at each of the sweeteners.

**Aspartame**

Aspartame is 200 times sweeter than sugar. It has a caloric value similar to sugar (4 kcal/g), but the amounts used are small enough to consider aspartame essentially free of calories. Brand names include NutraSweet and Equal. Aspartame was first approved by the FDA in 1981 as a tabletop sweetener, and for use in gum, breakfast cereal, and other dry products. The use of aspartame was expanded to sodas in 1983, and then to use as a general-purpose sweetener in all foods and drinks in 1996.

Before approval, the FDA reviewed numerous studies showing that aspartame did not cause cancer or other adverse effects in laboratory animals. “This included three studies in which rats were fed aspartame in proportions more than 100 times higher than humans would likely consume,” Tarantino says.

In the mid-1990s, a researcher raised concerns that a rise in brain cancer incidence in the United States was linked to aspartame use. According to FDA experts, there is no scientific evidence supporting a link between aspartame and any type of cancer. The National Toxicology Program, part of the U.S. Department of Health and Human Services, also conducted aspartame studies in mice and found no cancer link.

In 2005, the European Ramazzini Foundation (ERF) published new findings of a long-term feeding study on aspartame in rats. ERF scientists concluded that aspartame causes leukemia and lymphoma and that current uses of aspartame should be reevaluated. After reviewing the study data, however, the European Food Safety Authority (EFSA)
Saccharin was discovered in 1879 and is considered generally recognized as safe (GRAS) by the FDA.

referred a statement in May 2006 that said the ERF’s conclusion was not supported by the data. After learning of the ERF study results, the FDA requested the study data and received a portion of the data in February 2006. The FDA will announce its conclusions after completing its review.

“At this time, our position that aspartame is safe is based on the large body of information previously reviewed,” Tarantino says. “Our conclusions are based on a detailed review of more than 100 toxicological and clinical studies on safety.”

When ingested, aspartame is converted in the body to methanol and two amino acids—aspartic acid and phenylalanine. Tarantino says, “These substances are produced in much greater amounts in other common foods.”

Because of the phenylalanine component, aspartame does carry a risk for people with the rare genetic disorder phenylketonuria. People who have this disorder should avoid or restrict aspartame use because of their body’s difficulty in metabolizing phenylalanine. Its use can cause phenylalanine to build up in the blood at higher levels than normal. The aspartame regulation requires that a statement be placed on the label of all products containing aspartame specifically to alert phenylketonurics of the presence of phenylalanine.

Saccharin

Saccharin is 200 to 700 times sweeter than sugar and has no calories. Brand names include Sweet’N Low, Sweet Twin, and Necta Sweet. Saccharin is used in tabletop sweeteners, baked goods, soft drinks, jams, and chewing gum.

Saccharin was discovered in 1879 and is considered generally recognized as safe (GRAS) by the FDA. By definition in the law, a GRAS substance has a long history of safe use in foods, or is determined to be safe based on proven science. But if new evidence suggests that a GRAS substance may no longer be safe, the FDA can prohibit its use or require further safety studies.

In 1977, the FDA proposed a ban on saccharin because of concerns about rats that developed bladder cancer after receiving high doses of saccharin. In response, Congress passed the Saccharin Study and Labeling Act. This legislation put a moratorium on the ban while more safety studies were underway. Also, foods containing saccharin were required to carry a label warning that the sweetener could be a health hazard and that it was found to cause cancer in laboratory animals. Saccharin has been the subject of more than 30 studies in humans.

According to the National Cancer Institute, further studies showed that saccharin did not cause cancer in humans, and that the bladder tumors in rats were related to a mechanism that isn’t relevant for humans.

In 2000, the National Toxicology Program determined that saccharin should no longer be listed as a potential cancer-causing agent. Federal legislation followed in 2001, removing the requirement for the saccharin warning label.

Acesulfame-K (potassium)

Acesulfame-K is 200 times sweeter than sugar, with zero calories. Brand names include Sunett and Sweet One. Acesulfame-K was first approved by the FDA in 1988 for specific uses, including as a tabletop sweetener. The FDA approved the sweetener in 1998 for use in beverages. In December 2003, it was approved for general use in foods, but not in meat or poultry. Acesulfame-K can be found in baked goods, frozen desserts, candies, beverages, cough drops, and breath mints.

The FDA and the Food and Agriculture Organization/World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives have evaluated the sweetener’s safety. “More than 90 studies support the safety of acesulfame-K,” Tarantino says.

Neotame

Neotame is 7,000 to 13,000 times sweeter than sugar, depending on how it’s used in food, and has no calories. The FDA approved neotame in 2002 as a general-purpose sweetener in a wide variety of food products other than meat or poultry. It has been approved for use in baked goods, soft drinks, chewing gum, frosting, frozen desserts, jams, jellies, gelatin, puddings, processed fruit and fruit juices, toppings, and syrups.

Tarantino says that neotame is structurally similar to aspartame. “The potential release of phenylalanine from neotame is so limited that a warning for phenylketonuric-type individuals isn’t warranted,” she says.

The FDA reviewed data from more than 100 animal and human studies on neotame. These studies evaluated cancer-causing, reproductive, and neurological effects. “Based on a thorough evaluation of the data, there are no adverse effects anticipated when neotame is ingested at levels that are used in foods,” Tarantino says.

Sucralose

Sucralose is 600 times sweeter than sugar on average and has no calories. Although sucralose is made from table sugar, it adds no calories because it isn’t digested in the body. The brand name is Splenda. After reviewing more than 110 animal and human studies, the FDA approved sucralose in 1998 for use in 15 food categories, including as a tabletop sweetener and for use in products such as beverages, chewing gum, frozen desserts, fruit juices, and gelatin. In 1999, the FDA allowed sucralose as a general-purpose sweetener in all foods.
The FDA Approves New Drug for Smoking Cessation

In May 2006, the Food and Drug Administration approved Chantix (varenicline tartrate) tablets to help cigarette smokers ages 18 and older stop smoking.

The drug received a priority review because of its significant potential benefit to public health. Chantix was reviewed in six months rather than the regular review time of 10 months, says Curt Rosebraugh, M.D., M.P.H., M.D., the FDA's deputy commissioner for the Office of Drug Evaluation II. "Chantix underwent priority review," Rosebraugh says, "because at the time the application was filed, a preliminary review of the efficacy studies indicated that smokers treated with Chantix may have a superior rate of smoking cessation compared to Zyban (bupropion), another currently approved product for smoking cessation."

Chantix acts at sites in the brain affected by nicotine and may help those who wish to give up smoking in two ways: by providing some nicotine effects to ease the withdrawal symptoms and by blocking the effects of nicotine from cigarettes if they resume smoking. Rosebraugh says, "If someone slips up, they would probably not have the reinforcement that they would normally get from smoking a cigarette."

According to the Centers for Disease Control and Prevention (CDC), an estimated 45 million adults in the United States smoke cigarettes, and more than 8 million of them have at least one serious illness caused by smoking.

"Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States and is responsible for a growing list of cancers as well as chronic diseases including those of the lung and heart," says Scott Gottlieb, M.D., the FDA's deputy commissioner for medical and scientific affairs. "The agency is committed to helping facilitate the development of products to help people quit smoking and improve their overall quality of life."

The effectiveness of Chantix in smoking cessation was demonstrated in six clinical trials, which included a total of 3,659 chronic cigarette smokers who were treated with varenicline. Five of the six studies were randomized, controlled clinical trials in which Chantix was shown to be superior to placebo in helping people quit smoking. These smokers had previously averaged 21 cigarettes a day for about 25 years.

In two of the five placebo-controlled studies, Chantix-treated patients were also more successful in giving up smoking than patients treated with Zyban. "Both studies had very similar results with approximately 44 percent of people taking Chantix having stopped smoking at the end of 12 weeks, compared with 17 percent of people who were taking placebo and 30 percent of people taking bupropion," Rosebraugh says. "Researchers followed study participants in both studies for a year and found that approximately 22 percent of people taking Chantix, 16 percent of people taking bupropion, and 10 percent of people taking placebo were still smoke-free at the end of the year."

The approved course of Chantix treatment is 12 weeks. Rosebraugh says that for the first three days, patients take 0.5 milligram (mg) once a day, followed by 0.5 mg twice a day for the next four days, and then 1 mg twice a day for the remainder of the treatment period. Patients who successfully quit smoking during Chantix treatment may continue with an additional 12 weeks of treatment that further increases the likelihood of long-term smoking cessation.

"Cigarette smoking is a very difficult habit to break due in large part to nicotine dependence or addiction," says Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research. "Chantix therapy has proven to be effective in smokers motivated to quit and will provide another tool for physicians to use for the millions of smokers who want to quit."

In clinical trials, the most common adverse effects of Chantix were nausea, followed by changes in dreaming, constipation, gas, and vomiting. Chantix is manufactured and distributed by New York-based Pfizer Inc.
Protecting the Public Health:

More Than a Full-Time Job for Many at the FDA

By Linda Bren

Each workday, about 10,000 employees of the Food and Drug Administration—scientists, engineers, physicians, investigators, educators, administrators, attorneys, and others—help make a difference in the health and well-being of Americans.

When their workday ends, many FDA employees volunteer at jobs that promote public health in their local communities, other parts of the United States, or around the world. “The people at the FDA are committed and dedicated to serving the public,” says Janet Woodcock, M.D., deputy FDA commissioner for operations. “They are passionate about making a difference, even beyond their work at the FDA.”

Woodcock says the agency encourages volunteerism. “Our people enrich others’ lives and they are also enriched personally and professionally through volunteer work. In addition to providing a valuable service to a community, many of them bring back knowledge and new experiences that help them in their jobs at the agency.”

FDA employees dedicate their time to a variety of public health services ranging from promoting AIDS awareness in an urban California community to treating malaria in the poorest country in the Western Hemisphere.

Here are some of their stories …
For two weeks each summer, Susan Runner, D.D.S., chief of the FDA's Dental Devices Branch, leaves behind her air-conditioned office in Maryland to do dental work in 90-degree heat in El Salvador. Each year since 2003, Runner has taken a dental delegation of several people to help her, along with 10 suitcases full of donated dental care materials.

“The first year, I found two volunteers who agreed to be my dental assistants: a retired lawyer and a retired special ed teacher, both fluent in Spanish. Some years, I’ve had teen-agers who were fluent in Spanish acting as my assistants. “We usually stay in a village called Aguaje Escondido. I set up my clinic in a little building called the dispensary. Villagers come there to see the promotoras, health workers who have been educated in basic health and first aid. There is no access to regular medical care or dental care. “We eat with the families and live with the families. They’re incredible people to be able to open their homes to us. They don’t have very much, but they share with us what they do have. “Often the homes have dirt floors and are made from cinder block or clay. It’s like the inside is outside. There’s no glass on the windows, and the roof doesn’t meet the ceiling. Some are only two-room homes. It’s not private. Sometimes, bathing is a communal activity in the pilas, a big wash basin outside where you wash clothes, dishes, and yourself. You wear a bathing suit, and dip water and throw it over your head. “We work from about 7:30 in the morning till about 5:00 at night, seeing about 25 patients a day. Most of the villagers have never seen a dentist before. We do a lot of extractions of badly
decayed teeth, but we also do many restorations. The people have a very high carbohydrate-based diet, a lot of sugar, a lot of sucking on sugar cane, so there's a high rate of tooth decay.

"You could probably spend a whole week restoring some of the mouths that we see. We want to see as many patients as we can, so we have to treat just the most troublesome or painful conditions. The people are incredibly grateful for anything that we do, or that somebody would care enough about them to be there at all. We give them toothbrushes and toothpaste and basic oral hygiene instructions. They love having a brand new toothbrush.

"The kids are really quite brave. All the work is done under local anesthesia, so they're totally awake. When you have an extraction, it's not sharp pain but it's a lot of pressure, which can be scary for many children and adults. It's sometimes even scary for my assistants because they are not formally trained dental assistants. They have a hard time with the blood at first, but they get used to it. By the time our two weeks are up, I have all my assistants doing cleanings and giving oral hygiene instructions themselves.

"There was one young woman who was one of the most beautiful women I've ever seen. But when she opened her mouth, I saw that her entire upper set of teeth were riddled with decay—just the most horrible thing. I was able to restore all of her six front teeth with tooth-colored resin material. When we finished and she looked at herself in the mirror, she said, 'I had never thought I would ever have a beautiful smile again. Thank you so much for providing this.'

"The people are desperately poor, but have joy in their lives, which they share with us. They also have plans for their future, which is why they are so happy that we can help provide oral health care.

"People ask me, 'Is it a vacation?' It's not a vacation. It's very hard living there. The running water and electricity don't work consistently. It's very hot and humid. I don't have a dental chair, X-rays, or good lighting. If I'm working on somebody's upper teeth, their head has to be in my lap because I'm sitting on a card table chair and my assistants have a flashlight to shine in their mouth and a little syringe to irrigate with.

"But you're basically doing what you love to do, you get appreciation for it, and you feel like you're helping other humans on earth. We're all part of humanity. There's very little you can do to change the whole world, but on a one-on-one basis, you can develop relationships that I think make things a little better for humanity."
Ian Irony, M.D., is an endocrinologist in the FDA’s Division of Metabolism and Endocrinology Products. His main focus is diabetes, which affects nearly 21 million Americans and is the sixth leading cause of death in the United States. Since 1999, Irony has contributed his time educating people who have been newly diagnosed with diabetes. He teaches part of a two-day class on diabetes management offered throughout the year at Suburban Hospital in Bethesda, Md.

“I teach the first portion of the course, an introduction to diabetes. I talk about the physiology involved, normal and abnormal insulin metabolism and glucose metabolism, types of diabetes, treatments, and complications. You can talk for years on diabetes, but even though it’s just a two-day course, it’s a good overview for patients to help them understand how to care for themselves. It covers many topics and includes a lecture and hands-on cooking demonstration from a dietitian, foot care information from a podiatrist, blood glucose monitoring, and more.

“Each class has about 30 patients. Often, their families come with them. We are starting to see more teenagers—about one-fifth of the patients are teen-agers.

“There are lots of questions. People want to know, ‘Do I have the right diagnosis? Do I really have diabetes? Do I have the right medication?’ At the point that they come to the class, the diagnosis is still relatively fresh and it’s hard for them to accept and comprehend. They don’t usually have a very good idea of what diabetes is, or that they can still lead a normal life and have a normal life span if they comply with the treatment and the associated lifestyle changes.

“I try to reassure them. I tell them that coming to the class is a step in the right direction, but everything that they hear is not going to be valid five or 10 years from now. They’ll want to keep themselves updated and educated on the progress of diabetes research because the knowledge is evolving and we’ll probably have more efficient treatments and safer treatments in the coming years.

“The class benefits both the patients and the presenters. Because I work in the field, I have a general feel of what’s on the horizon in terms of treatments for diabetes. I can’t discuss specific products in development, but I can give them a broad view of where the science is going. There is a lot of hope for new treatments and diagnostic and monitoring methods.

“The class gives me a real appreciation for what patients go through—the psychological aspects as they accept their diabetes as a disease. I can take that back to my work at the FDA as a drug reviewer and put those thoughts into protocols for testing and development of products.
"The other doctors in practice who teach parts of the course also benefit. It gives them an opportunity to listen to patients to find out exactly what their concerns are. As doctors, we tend to think about measures of glycosylated hemoglobin and other parameters for diabetes that affect the outlook for health. But patients' concerns are more about: 'How is it going to limit my life? What type of diet will I be on? How can I fit an exercise program into my daily activities with my already stressful life?' It gives a different perspective to both the patients and the doctors.

"For anyone who wants to gain a better understanding and control of their diabetes, I would suggest that they look for classes offered by their local hospital or the American Diabetes Association. The cost may be covered by insurance."

---

**Search and Rescue From the Saddle**

As a biologist in the FDA's Center for Veterinary Medicine (CVM), Michele McGuinness, Ph.D., spends much of her workweek evaluating new production drugs for poultry. But the weekends are spent with her horses, training to track down missing people.

McGuinness serves as assistant commander and team training officer for TROTSAR, a volunteer equine search and rescue (SAR) team that works with the Maryland State Police. McGuinness the lost person cannot be evacuated using your SAR horse and you can't get a vehicle in or land a helicopter, you may have to help carry somebody out on a stretcher. They say in Maryland, you’re never more than five miles from a road. But five miles is a long way to carry somebody!

"Our team is called out between three and six times a year. We're supposed to be ready to deploy within an hour at any time of the day or night with our horses. We've already had three SAR missions this year. On the most recent one, a missing plane search, we worked with the Maryland State Police, Civil Air Patrol, and ground teams. The plane and deceased pilot were located by a ground team. Our TROTSAR mounted teams were working up the mountain toward the suspected crash site when we heard the find over the radio. We were happy to be part of a successful mission, although sad for the pilot's family.

"Horses provide us with a tremendous field of vision. If you're on the ground, you can't see anywhere near what we can see from the top of a horse. We can cover large distances without tiring because the horse is doing the walking. Having the horse doing the walking frees us up to look for clues or look for people. We don't have to watch where our feet are going—the horse is doing that. And they can carry a lot more gear than people can on their backs.

"When I met Tom, he was wild, sometimes dangerously ill-behaved, and nobody was willing to ride him. I heard Tom called 'useless,' but he was all I had to ride. It was an adventure, Tom and I working things out, but we did.

"Tom and I were out riding with my friend and his inexperienced horse when the accident happened. At one point, one of the reins got caught around the horse's right hind leg. He suddenly exploded into a fury of panicked bucking. I've never heard anything hit the ground so hard as my friend's body smashing onto that trail.

"My friend wasn't breathing. He looked pretty much dead, all crumpled up and with a bloodless white face."

---

Credits her 21-year-old equine partner, Tom, with saving a person's life. And she credits FDA-approved animal drugs with keeping her partner healthy enough to perform the rescue.

"We ride and train year-round, in all kinds of weather. We have to learn incident management standards, in addition to search and rescue skills, as part of the Department of Homeland Security mandate for search teams. We are trained in wilderness first aid and search techniques like clue awareness, crime scene preservation, and map and compass reading. If you're not properly skilled and trained, you become a liability on a search and rescue mission.

"You're supposed to be in good physical condition and so is your horse. If
was lapsing in and out of consciousness and stopped breathing again. I had no choice but to load him onto Tom and take him with me.

“It took us nearly an hour to walk out of the forest. I then had cell phone service and called 911. Tom was fabulous, remained calm even when the LifeFlight helicopter landed in the field nearby. “Tom is handicapped. He has arthritis and a heart murmur and when he pushes too hard, I can feel his heart doing the ‘hokeypokey.’ A CVM veterinarian was able to give Tom some mitigating drugs that help him keep going. Those equine drugs restored my partner’s ability to perform, and that ability saved a person’s life. It is ironic that an old, ‘useless,’ disabled horse is my furry hero.”
Connecting With the AIDS Community

When Lila Kraai is not working as a consumer safety technician in the FDA’s San Jose, Calif., office, she is often visiting with people who have HIV or AIDS, coordinating AIDS awareness events in the community, or packing donated food for delivery to people with AIDS and their families. She also served on San Jose’s Disability Advisory Commission for three years. Once a week, after finishing her FDA workday, Kraai volunteers at The Neil A. Christie Living Center, an educational, social, and emotional support facility for people living with HIV or AIDS.

“I used to live in a house right down the block from a funeral parlor. A good friend of mine kept going to funerals for his friends with AIDS. I decided I wanted to find out more about the disease, so that’s how I got into this work. I’ve been working to help people with HIV and AIDS for about 10 years now.

“At The Neil A. Christie Living Center, we visit with newly diagnosed people to educate them about resources available in the community. We organize classes in English and Spanish that deal with life issues facing those living with HIV or AIDS.

“We get doctors who work in the HIV field to come in and talk with our clients about the latest treatments. And we provide a meal once a week so people can meet each other, talk among themselves, and don’t feel as isolated.

“Their biggest concern is that they don’t think anybody wants to help them. They’re afraid that people are going to shun them or not accept them. We want to reassure them that they are not alone and there are many others going through exactly the same thing. The center is a welcoming, safe place where nobody judges them, everyone is supportive, and names are not released to the outside. The atmosphere is comfortable and a coffee pot and Crock-Pot of soup are on all the time. We encourage the clients to share experiences and we help them figure out how they can carry on a productive life, and enjoy life.

“We have more men at the center than women. The men strike me as being pretty strong-willed people, with a positive attitude. They say the disease is not going to beat them—they’re going to win. But sometimes they don’t. It’s sad when we lose somebody. We have a wake at the center when someone passes away.

“I feel a connection with anyone living with a disease or disability. I suffered a stroke when I was five years old that affected the left side of my body. I’m blind on the left side of both eyes so I cannot drive. On nice days, I bicycle to work, then bicycle to the center.

“Sometimes it’s hard to go after work. I keep putting off chores that I need to do at home. But when I get there, I’m glad I went. The people are so nice and appreciative. It makes me feel good, whole, and fortunate.”
Tan Nguyen, M.D., is a U.S. Public Health Service pathologist in the FDA’s Office of Orphan Products Development in Rockville, Md. For each of the past eight years, Nguyen has spent a week’s “vacation” with a team of 10 volunteers giving medical care to people in a rural area of Haiti. The Department of State describes Haiti as the least-developed country in the Western Hemisphere and one of the poorest in the world. Nguyen concurs and describes his firsthand experience.

“Our baggage allowance on the plane is 140 pounds per person, and everyone is carrying most of this weight in medications. We go to Leon, a village way up in the mountains. We set up a small, dilapidated clinic, and we stay in a little rectory up the street. The parish father supports us, and we sleep outside on the veranda under mosquito netting. I bring my own sleeping bag and pillow. They feed us mostly rice and beans. Sometimes they throw in a little meat and we try not to guess what it is.

“We walk to the clinic, start at 8 a.m., and work till dark when the last patient of the day is seen. We have some solar lights and running water now, but for years, we didn’t have either. We just used a flashlight when we ran out of daylight and a water bucket for hand-washing.

“We treat anything from malaria to machete wounds. We see about 1,000 people in five days. I usually see about 60 or more people per day, for a precious few minutes each. There are no lab tests, no X-rays, nothing but medications and stethoscopes. We make the best diagnosis possible by doing a physical exam and using our clinical skills.

“The people don’t have transportation. Some of the villagers walk 15 miles over treacherous mountain trails to see us. By the time they get to us, it’s night. They sleep outside the clinic, the next day we see them, and they spend another two days to go back up the mountains to their home. They spend five days to see us for five minutes! I don’t complain anymore back home when I have to stand in line at the pharmacy for 15 minutes.

“I see children who are severely malnourished. I see kids eating dirt, they are so hungry. They are real skinny and have a big belly full of worms. I took my microscope with me one time. I wanted to see what parasitic diseases they have. I looked at about 30 stool samples from little kids in the village. Every one of them had multiple parasites. We treat all the children and adults in the village with antiparasitic medications so they don’t get anemia. That’s probably the biggest health impact we make. The teachers come to tell us they’ve noticed a difference in the kids—they look healthier.

“We saw a child who fell into boiling water over the cooking fire. His arm was black from the forearm down. It was ulcerated and pus-filled. His grandmother said it had been like that for three weeks. I asked, ‘Why didn’t you take him to the hospital?’ The grandmother said she was too weak to carry him all the way to the hospital. His arm had to be amputated, but he lived.

“Haiti is an hour and 15 minutes by airplane from Miami, but the country is forgotten. We all realize that we touch the very top surface of the misery, suffering, and pain. But if I can take care of even a few people, it gives me a sense of peace and happiness. They thank me profusely. You hear that and can’t help coming back. You impact the lives of these people—not in a big way that you make them rich, but you make them healthier.” —
As a chemist in the FDA's Kansas City District laboratory, David Foran analyzes food samples to help ensure that the public is not exposed to unhealthy levels of metals in food. After work, the chemist becomes a caseworker for the Red Cross year-round, and in the winter, an Outdoor Emergency Care (OEC) technician on the slopes of the local ski area.

As a caseworker, Foran is called upon to provide emergency relief after national disasters. He was on the first commercial flight into New York City after the terrorist attack on Sept. 11, 2001, and was part of the relief crew in Florida after Hurricane Katrina hit in 2005. Foran also works cases closer to home, helping families deal with tragedies, such as house fires, in the Kansas City area.

“We may get a phone call any time of the night. By the time we’re called and arrive, the fire department has already been there, the fire’s out, and the family is wondering what to do next. That’s where we come in. We assess the damage, in general, and their immediate emergency needs.

“Sometimes people are in shock. We help them think through the process of what they need to do, and help them make the phone calls. Some are upset because ‘my TV’s ruined,’ but we don’t deal with that. We’re concerned with whether they have the basic emergency needs of food, clothing, and shelter. If they don’t have a place to stay, we find a hotel for them. If they need food or clothing, we give them vouchers to use at certain participating vendors. Then we go home and get a few hours’ sleep before getting up to go to work the next day.

“From about mid-December to mid-March, I’m on the ski patrol at a small ski resort north of Kansas City. I do about one shift every other weekend. What happens on a shift is totally unpredictable. I could be on the slopes a whole day with nothing at all happening, or there could be five or six injuries in an hour. The majority are pretty minor.

“Rarely there’s a serious injury where you need to get someone Life-Flighted out. But when bad accidents happen, it’s usually because they violated the Skier Responsibility Code; for example, they weren’t skiing under control. I saw a kid after a 360-degree flip who landed and hit the back of his neck. He was in a clearly marked area for advanced skiers only, and he was not skiing in control. I understand he ended up partially paralyzed.

“In the skiing off-season, I’m one of the instructors in advanced first aid. We are essentially non-urban EMTs—emergency medical technicians. Our medical training puts more emphasis on cold and outdoor environments. Teaching it is a good way for me to refresh. The medical text is over 700 pages. We cover everything from how the circulatory system works, to how to apply a splint to a femur fracture, and much more. Some of it is lecture, but a lot is hands-on training, such as lift evacuation. We practice how to get people out of ski lifts if the lifts fail. You have to manually take them down with ropes and lines.

“I volunteer because I get a certain enjoyment and satisfaction out of it. You’re doing something to help people, they can’t pay you back, and you don’t want the payback. It’s frustrating at times, but most of the time it’s very satisfying.”

For More Information
www.volunteer.gov/gov/
www.firstgov.gov/Citizen/Topics/PublicService.shtml
www.hud.gov/volunteering/

David Foran, a chemist in the FDA’s Kansas City District laboratory, does volunteer work as a Red Cross caseworker and as an outdoor emergency care technician at a ski resort.
Executives Convicted in Device Scheme

Two executives of a Mundelein, Ill., company were convicted on April 13, 2006, of fraudulently selling uncleared surgical sterilizing devices that led to eye damage and to the loss of sight in one eye for 18 patients.

Ross A. Caputo was the president and CEO of AbTox, and Robert M. Riley, the vice president of regulatory affairs of AbTox, when the company received permission to market a small gas plasma sterilizer only for use in sterilizing flat stainless-steel surgical instruments without tubes or hinges. The defendants instead marketed a larger, unauthorized version of the sterilizer and promoted its use for a wide array of non-stainless-steel instruments.

AbTox showed the hospitals that purchased the larger, unauthorized units the clearance letter for the smaller, authorized unit. Because of the way AbTox marketed them, these larger units were used in an unauthorized manner to sterilize complex instruments, including cataract instruments which have small tubes that are used to put solution into a patient’s eye. One unauthorized use was to sterilize ophthalmic instruments that had brass joints which reacted to the sterilizing agent and created a toxic residue. AbTox knew of the reaction, but did not advise users or seek proper corrective action. The blindness was caused by a harmful copper acetate residue that remained in the tube of the instrument after it was sterilized in the machine.

One hundred sixty-eight of the unauthorized units were sold to hospitals nationwide, including U.S. Department of Veterans Affairs hospitals and other government agencies, with sales totaling more than $18 million. Hospitals in Chicago, Columbia, Mo., and St. Louis, reported to AbTox that their sterilizer was suspected of causing injuries to several patients. The company failed to notify the Food and Drug Administration about these reports as required.

“These convictions are evidence of FDA’s resolve to ensure the safety and efficacy of human medical devices,'” says FDA Associate Commissioner for Regulatory Affairs Margaret O’K. Glavin.

The defendants face significant penalties including incarceration, fines, and restitution. Sentencing will be at a later date. Two other defendants, Mark E. Schmitt, former director of marketing of AbTox, and Marilyn M. Lynch, former director of clinical services of AbTox, previously pleaded guilty in the case.

The defendants were found guilty after a nine-week trial in the Northern District of Illinois as the result of a successful prosecution under the direction of U.S. Attorney Patrick J. Fitzgerald for the Northern District of Illinois, in conjunction with the Veterans Affairs Office of Inspector General, the Naval Criminal Investigative Service, the Air Force Office of Special Investigations, and the FDA.
Take the FDA Consumer Quiz

Which artificial sweetener approved by the FDA is 7,000 to 13,000 times sweeter than sugar? Which federal law now requires some cold medicines available without a prescription to be kept behind the counter? What is the Snellen Eye Chart? To find out how much you know about these and other health-related topics, take our quiz.

Hint: The answers to all of these questions can be found in the July-August 2006 issue of FDA Consumer (and at the bottom of this page).

1. Although anyone can get seasonal flu, infection rates are highest in what population?
   a. people older than 65
   b. people ages 50 to 65
   c. women older than 60
   d. men older than 60
   e. children

2. Warfarin is a blood-thinning drug commonly prescribed to older people. Which of the following could interact with warfarin?
   a. the antibiotic Bactrim (sulfamethoxazole)
   b. aspirin
   c. ibuprofen
   d. ginseng
   e. all of the above

3. Which country is the least-developed in the Western Hemisphere, according to the Department of State?
   a. Nicaragua
   b. Haiti
   c. Dominican Republic
   d. Paraguay
   e. Mexico

4. Over-the-counter cold remedies containing pseudoephedrine are now being kept behind the pharmacy counter because of what law?
   a. Federal Food, Drug, and Cosmetic Act
   b. Food and Drug Administration Modernization Act
   c. Dietary Supplement Health and Education Act
   d. Patriot Act
   e. Federal Anti-Tampering Act

5. Pseudoephedrine is a common ingredient in what types of medications?
   a. pain relievers and anti-inflammatories
   b. cold, sinusitis, and hay fever medications
   c. anti-depressants and anti-seizure medications
   d. blood pressure medications
   e. cholesterol-lowering medications

6. What is the Snellen Eye Chart?
   a. a series of numbers arranged in columns
   b. a series of letters arranged in lines
   c. a series of dots arranged in patterns
   d. a series of circles arranged in rows

7. Refractive error is measured in units called:
   a. digitals
   b. digits
   c. diopters
   d. dilators

8. How many artificial sweeteners are currently approved by the FDA?
   a. 2
   b. 5
   c. 8
   d. 10

9. Which artificial sweetener is 7,000 to 13,000 times sweeter than sugar?
   a. aspartame
   b. sucralose
   c. neotame
   d. saccharin

10. Which artificial sweetener carries a risk for people with the genetic disorder phenylketonuria?
    a. aspartame
    b. saccharin
    c. acesulfame-K
    d. sucralose

11. How many adults in the United States smoke cigarettes, according to CDC estimates?
    a. 2 million
    b. 16 million
    c. 45 million
    d. 100 million

Answers:
Recent studies show you can prevent or delay diabetes.

**It's about small steps:** losing a small amount of weight, by walking or biking for 30 minutes 5 days a week and making healthy food choices, can prevent or delay type 2 diabetes. In fact, these small steps worked even better for people over 60 who were at risk for diabetes than for any other age group.

**It's about big rewards:** take your first step today to live a longer and healthier life. Talk to your health care provider about your risk for type 2 diabetes and the small steps you can take to prevent it. It's not too late!

For more information about diabetes prevention, call 1-800-438-5383 and ask for “It's Not Too Late to Prevent Diabetes” www.ndep.nih.gov
An eye care professional applies eyedrops to dilate a patient's pupils.