The FDA and the fight against Terrorism
Joint Effort to Improve the Health of Older Hispanic Americans
The FDA teams up with the Administration on Aging to help prevent diseases in older Hispanic Americans.

Preventing Listeria Contamination in Foods
To avoid being infected by potentially dangerous Listeria bacteria, pay attention to these special precautions when handling or preparing food.

FDA Cautions Against Ultrasound ‘Keepsake’ Images
The FDA discourages expectant mothers from receiving “casual” ultrasound imaging.

Advisory Committees: Critical to the FDA’s Product Review Process
Find out how the FDA’s advisory committee process helps the agency make regulatory decisions.

Cover Story
The FDA and the Fight Against Terrorism
FDA Commissioner Mark B. McClellan has made counterterrorism an agency priority.

Keeping Pets (and People) Healthy
Here are easy-to-follow steps to keep you and your pet disease-free.

Cervical Cancer Screening
Regular screening tests can help women prevent cervical cancer.

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The Last Word

Inside Cover: Reptiles like this iguana carry bacteria that can infect humans. To find out how to protect your health while enjoying your reptile, dog, cat, or other pet, see page 30.
During the past year, the FDA has taken steps to ensure that better medicines and other products are available to counter potential biological, chemical, and radiological attacks. Besides working with other government agencies to encourage product development and availability, the FDA also is keeping a close watch on bioterrorism-related medical claims being made on the Internet.

In addition, the FDA is working with other government agencies and the private sector to protect the nation’s food supply from attack. About 80 percent of the food Americans eat is regulated by the FDA. The agency is collaborating with the Bureau of Customs and Border Protection to more effectively inspect food imports. Nearly 20 percent of all imports into the United States are food and food products.

A joint effort by the Departments of Health and Human Services and Homeland Security—dubbed Project BioShield—will increase the FDA’s role in the national counterterrorism effort. The bill authorizing the project was approved by the House of Representatives in July 2003. It currently is being considered by the Senate.

For more on the FDA and counterterrorism, see our cover story titled “The FDA and the Fight Against Terrorism,” beginning on page 20.

Ultrasound images are used by health care providers to determine pregnancy and the age or condition of an unborn baby. Increasingly, operators of imaging facilities located in malls and shopping centers nationwide are promoting ultrasound “keepsake videos.” The FDA says that ultrasound is an important diagnostic tool and often used to ensure the health of a fetus. But the agency warns that using the technology to obtain “keepsake” souvenirs is not without risk. For more on the proper use of ultrasound technology during pregnancy, see our feature titled "FDA Cautions Against Ultrasound ‘Keepsake’ Images,” beginning on page 12.

There’s no doubt about it: Americans love their pets. And research indicates that caring for dogs or cats can have health benefits such as lowering blood pressure. However, the animals we share our homes with can also can carry diseases, some of which can be transmitted to humans. To learn more about animal diseases and the risk they pose, see our feature, “Keeping Pets (and People) Healthy,” on page 30.

We also take a look at the role that advisory committees play in FDA regulatory decisions and tell how a new test helps health care providers better screen for cervical cancer in women over 30. Don’t forget to take our quiz on page 38.

The staff of FDA Consumer wishes you a Happy New Year!

Ray Formanek Jr.
Editor

FDA Commissioner, Deputy
Receive IOM Appointments

The Institute of Medicine (IOM), a leading organization that advises the U.S. government on the most critical issues in medicine and public health, has elected FDA Commissioner Mark B. McClellan, M.D., Ph.D., and Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D., as members of the institute. In the past, FDA scientists have been elected to the prestigious IOM, a component of the National Academy of Sciences, but never both the commissioner and the deputy commissioner.

“I applaud Mark and Les for receiving this honor,” says Tommy G. Thompson, Secretary of Health and Human Services. “Every day at the FDA, they show real leadership in developing and implementing creative new ways to better protect and promote the health of Americans. The Institute of Medicine will benefit from their experience and expertise in science and public health.”

New IOM members are chosen worldwide on the basis of their distinguished professional achievement in a field related to medicine and health, and on their involvement in health care, disease prevention, education and research. They contribute to IOM’s reports and research projects without pay.

“Both Les and I are honored to become IOM members, and we will do our part to support the IOM’s unique public health mission,” McClellan said of the IOM appointment, announced in October 2003. “And at FDA, we’re pleased to be part of an organization that is recognized around the world for using the best and latest science to protect and advance the health of the public.”
Antidepressant Use in Children

Following reports of suicidal thoughts and suicide attempts, the FDA issued a public health advisory in October 2003 concerning children with major depressive disorder (MDD) who have taken various antidepressant drugs.

The FDA has completed a preliminary review of reports for eight antidepressant drugs:
- Celexa (citalopram)
- Prozac (fluoxetine)
- Luvox (fluvoxamine)
- Remeron (mirtazapine)
- Serzone (nefazodone)
- Paxil (paroxetine)
- Zoloft (sertraline)
- Effexor (venlafaxine)

Although Luvox was reviewed, the drug is not approved as an antidepressant in the United States.

According to the FDA, the data don’t clearly establish an association between the use of these drugs and increased suicidal thoughts or actions in children. But at this point, it is not possible to rule out an increased risk of these adverse events for these drugs. In June 2003, the FDA recommended that Paxil not be used in children and adolescents for the treatment of MDD.

The FDA recognizes that MDD is a serious condition for which there are few treatment options. In addition to using non-medication treatment approaches, doctors must often make choices among drugs that are available for treating adult MDD. Prozac is the only drug labeled for use in pediatric MDD.

The FDA has scheduled a meeting on Feb. 2, 2004, of its Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee to discuss data and regulatory actions on this topic.

Antidepressants in adults and children should be used with caution, and antidepressants should not be discontinued before consulting with a physician. The public health advisory can be found at www.fda.gov/cder/drug/advisory/mdd.htm.

The FDA Uses New Technology to Improve Food Security

The FDA is using a new electronic registration system for food facilities, developing improved tests to detect food contamination, strengthening security at borders, and pursuing an abundance of research projects to bolster the safety and security of America’s food supply.

An electronic registration system for food facilities went “live” in October 2003, enabling 400,000 facilities worldwide to register online quickly and easily. The system helps facilities comply with an interim final rule that requires all domestic and foreign food facilities to register with the FDA by Dec. 12, 2003. As a result, the FDA will have, for the first time, an official roster of food facilities that will allow timely notification and response in the event of a food safety threat.

The FDA is also developing more rapid, easier, and less costly tests to detect biological, chemical and radiological threat agents in foods. According to a report to Congress issued by the agency in October 2003, the FDA currently has more than 90 different active research projects involving test and sampling methodology development. This agency-wide effort involves many FDA scientific experts and partners in academia, private industry, other government agencies and trade associations.

Another interim final rule, effective Dec. 12, 2003, requires that the FDA be provided prior notice of shipments of human and animal food being imported or offered for import into the United States. The FDA is working closely with the Bureau of Customs and Border Protection (CBP) to ensure that the new regulations and their enforcement promote a coordinated strategy for border protection. CBP employees are serving on the FDA’s behalf at ports where the FDA may not currently have staff and augment FDA staff in the enforcement of the agency’s prior notice regulation.

The FDA’s report to Congress is available on the Web at www.fda.gov/oc/bioterrorism/bioact.html.

First Drug for Moderate-to-Severe Alzheimer’s

The FDA has approved the first drug for the treatment of people with moderate-to-severe Alzheimer’s disease. The new drug, Namenda (memantine), is thought to work by blocking the action of glutamate, a brain chemical that may be overactive in people with Alzheimer’s. Other drugs on the market, approved to treat mild-to-moderate Alzheimer’s, are believed to work by inhibiting cholinesterase, an enzyme that breaks down acetylcholine, a chemical used by nerves to communicate with each other.

Researchers conducted two studies of 250 and 400 people who took Namenda over a six-month period. A third study of 166 people was conducted for three months. In the largest study, patients took Namenda along with Aricept (donepezil), a drug already approved for the treatment of Alzheimer’s disease. In the two other studies, patients were taking Namenda alone. In all three studies, people taking Namenda experienced less deterioration compared with patients treated with an inactive substance (placebo).

Alzheimer’s disease, which affects about 4.5 million Americans, is a degenerative condition affecting memory, judgment and the ability to reason. Although Namenda helps treat the symptoms of Alzheimer’s disease in some people, there is no evidence that it changes the underlying nature of the disease.

The most frequently reported side effects from Namenda in the studies were dizziness, headache, and constipation. These side effects occurred in fewer than 10 percent of those taking the drug.

Namenda is marketed by Forest Laboratories Inc. of Jersey City, N.J.
Third Drug for Impotence

Cialis (tadalafil), approved by the FDA in November 2003, is the third oral medication approved to treat impotence in men. Cialis is different than the other approved products in that it stays in the body longer. It relaxes muscles in the penis and increases blood flow into the penis, which produces an erection.

Cialis was evaluated in clinical trials involving more than 4,000 men with impotence. In two of the trials, men had impotence associated with diabetes or following radical prostatectomy for prostate cancer.

Cialis should not be used by those who are being treated with nitrates such as nitroglycerin tablets or patches. The drug also should not be used with most alpha blockers, medicines used to treat benign prostatic hyperplasia and high blood pressure. The combination of Cialis with alpha blockers may significantly lower blood pressure and lead to fainting or even death.

Men who use Cialis should inform their doctors because some drugs affect the metabolism of Cialis. The drug should not be taken by men for whom sexual activity is inadvisable because of an underlying heart condition. Before taking Cialis, men should tell their doctors about any heart problems they have experienced. Use of the drug is not recommended for those who have suffered a heart attack or stroke within the last six months. Cialis also is not recommended for those who have significantly low blood pressure, uncontrolled high blood pressure, unstable angina, severe liver impairment, or an eye condition called retinitis pigmentosa.

The most common side effects for Cialis include headache, indigestion, back pain, muscle aches, flushing, and stuffy or runny nose. A small number of men also reported abnormal vision.

Before taking Cialis, men are advised to undergo a thorough medical history and physical examination to identify appropriate treatment for their impotence.

Cialis is manufactured for Lilly ICOS LLC by Eli Lilly and Company, Indianapolis.

New Lotion Approved to Treat Hot Flashes

Estrasorb (estradiol topical emulsion) is the latest estrogen therapy product approved by the FDA to treat menopausal hot flashes.

Estrasorb, made by Novavax of Columbia, Md., is absorbed through the skin into the bloodstream after the lotion is applied to the legs, thighs, or calves on a daily basis. Women should not apply sunscreen at the same time as applying Estrasorb because this may affect the amount of estradiol actually absorbed.

In January 2003, the FDA advised women and their doctors that menopausal hormone therapy—estrogen and estrogen with progestins—may be associated with an increased risk of heart disease, heart attacks, strokes, and breast cancer. This was based on the findings of the Women's Health Initiative study conducted by the National Institutes of Health (NIH).

To help women make decisions about whether to take hormone therapy, the FDA and the NIH initiated a nationwide information campaign to raise awareness about the recent findings. As a result, a menopause and hormone therapy fact sheet was developed, as well as a purse guide that women can use to discuss their options with a health professional. These materials can be found on the FDA Web site at www.fda.gov/womens/menopause/default.htm.

Based on the latest evidence, the FDA believes that estrogen and estrogen with progestin products, including Estrasorb, provide valuable therapy for many postmenopausal women, particularly those with hot flashes. The agency reminds women, however, that these treatments also have important risks, and that they should be used in the lowest dose and for the shortest time required to provide relief. Label warnings and cautions for Estrasorb are similar to other menopausal hormone therapy products.

FDA Warning on Unapproved Performance Enhancer

Tetrahydrogestrinone (THG), a substance taken by athletes to improve their performance, is considered to be an unapproved drug by the FDA, and cannot be legally marketed.

The FDA is warning consumers that little is known about the safety of this substance, its structure, and relationship to better-known products. The agency says that its use may pose considerable risks to health. The FDA is concerned about the marketing and use of this unapproved product and is working with other federal law enforcement agencies to aggressively “engage, enforce, and prosecute” those firms or people who manufacture, distribute, or market THG.

While in some cases THG is being represented as a dietary supplement, the FDA says that in fact the substance does not meet the definition of a dietary supplement. Rather, it is a purely synthetic “designer” steroid derived by simple chemical modification from another anabolic steroid that is explicitly banned by the United States Anti-Doping Agency, an independent body that monitors and enforces drug use restrictions in athletic competitions. THG is closely and structurally related to two other synthetic anabolic steroids, gestrinone and trenbolone. Anabolic steroids, which build muscle mass, can have serious long-term health consequences in men, women, and children.

THG cannot be legally marketed without FDA approval under the agency’s rigorous approval standards, meant to ensure that drugs sold to American consumers are safe and effective.
**Guidance on Animal Drugs and Antimicrobial Resistance**

The FDA has released new guidance that outlines a comprehensive approach to preventing the antimicrobial resistance that may result from the use of antimicrobial drugs in animals.

Antimicrobial drugs, such as antibiotics, are medicines often used to treat bacterial infections in both humans and animals. Their use has been one of the great advances in modern medicine—helping to prevent many of the illnesses that were leading causes of death for most of human history. When bacteria develop resistance, human and animal health is at risk because the medicines that we depend on to treat infections become ineffective.

The guidance provides a risk assessment process for animal drug sponsors to determine the likelihood that an antimicrobial drug used to treat an animal may cause an antimicrobial resistance problem in humans who consume meat or other products from that animal. This process can help prevent antimicrobial problems in humans from being improperly used in food-producing animals. Food-producing animals include cows, pigs, chickens, turkeys, sheep, and fish.

If the assessments show that the risks are significant, the FDA could deny the application to market the drug, which would prevent the use of the drug in food-producing animals, or the FDA could approve the drug, but place conditions on its use to ensure it would not pose a human health risk.

For more information, see [www.fda.gov/oc/antimicrobial/questions.html](http://www.fda.gov/oc/antimicrobial/questions.html).

**Green Onions Associated with Hepatitis A Outbreaks**

The FDA says that raw or lightly cooked green onions (shallions) are associated with an outbreak of hepatitis A, a liver disease, in Pennsylvania and three other states. In an attempt to determine the source of the green onions and how they became contaminated, the FDA has been working closely with the CDC and the states so that the problem can be corrected.

Hepatitis A develops within six weeks of an exposure. It is usually mild and characterized by jaundice (yellow skin), fatigue, abdominal pain, loss of appetite, nausea, diarrhea, and fever. Hepatitis A can occasionally be severe, especially in people with liver disease.

The first outbreak of hepatitis A associated with the onions occurred in September 2003 in Pennsylvania, North Carolina and Georgia restaurants. Another outbreak of hepatitis A among patrons of a single restaurant in Pennsylvania occurred during late October and early November.

The FDA is advising consumers to:

- Cook green onions thoroughly. Cook in a casserole or sauté in a skillet.

**New Law to Improve Animal Drug Review**

President Bush has signed legislation that provides user fees to the FDA for animal drug reviews. Known as the Animal Drug User Fee Act (ADUFA), the law, passed in November 2003, establishes a funding system for the new animal drug review process that is similar to that established for the human drug review process more than a decade ago.

The fees collected for these services will be directed toward the FDA’s Center for Veterinary Medicine (CVM) and will be used to provide additional resources for its animal drug review program. The goal is to achieve shorter, more predictable review times by increasing the review staff at CVM and by building better management systems. As a result, the FDA anticipates substantial savings to the industry in regulatory review and developmental expenses without compromising the agency’s high standards for safe and effective products.

The FDA is authorized to collect $5 million in fees in fiscal year 2004, which began Oct. 1, 2003; $8 million in fiscal year 2005; and $10 million in fiscal years 2006 through 2008. The law provides for specific waivers or reductions of fees, including for small businesses and where the fees would present a significant barrier to innovation.

“The resources provided by this law will help CVM scientists keep pace with the rapid advances in science and medicine that drive the quality of health care for our animals,” says CVM Director Stephen Sundlof, D.V.M., Ph.D. “We view this legislation as a vital component in our commitment to promote and protect public and animal health.”

**Check food purchased at restaurants and delicatessens and ask whether menu items contain raw or lightly cooked green onions. Request that raw or lightly cooked green onions not be added to foods.**

The FDA has alerted inspectors at the Mexican border to detain any raw green onions from a small number of implicated firms. Mexican officials have been very responsive during the outbreak investigation and are investigating practices at these firms to determine what might have caused the contamination.

Regulations being developed under the Bioterrorism Act of 2002 give the agency new authority to help improve its ability to contain and prevent outbreaks of foodborne illness. These new regulations and increased presence at the border will help enhance the agency’s food safety and security measures.
Peanut Test Kits Approved

Several test kits to detect peanut proteins in breakfast cereal, cookies, ice cream, and milk chocolate have been designated as "performance tested methods" by the Association of Official Analytical Chemists International (AOAC), working in collaboration with the FDA. The AOAC validates and approves analytical methods used in foods and agriculture. The FDA relies on methods validated by the AOAC in its enforcement programs.

The approved test kits provide quick and reliable methods for the food industry to more readily detect the presence of peanuts in food not labeled as containing peanuts, and can more effectively prevent these products from reaching consumers.

Peanuts can cause severe and, in some cases, fatal allergic reactions in some people.

The approved kits are: Biokits Peanut Assay, developed by Tepnel BioSystems Ltd. of Flintshire, UK; RIDASCREEN FAST Peanut, developed by R-Biopharm AG of Darmstadt, Germany; and Veratox for Peanut Allergen, developed by Neogen Corp. of Lansing, Mich.

The likely users of these kits are organizations that have laboratory facilities, such as research and industrial food operations and regulatory agencies. For example, use of these tests can assist organizations in rapidly determining whether their food processing operations are adequate to prevent the inclusion of peanut products in foods that do not declare peanuts as an ingredient. The tests also can determine whether food processing plant cleanup operations are sufficient to avoid cross-contamination.

Adverse Events and Cypher Stents

The FDA has informed physicians about adverse events associated with the Cordis Corp.'s Cypher Sirolimus-eluting Coronary Stent, a cylindrical metal mesh designed to keep arteries from reclogging after angioplasty procedures. The stent slowly releases the drug sirolimus, which is intended to reduce the rate of re-blockage that occurs with other stents. The FDA approved the Cypher stent in April 2003.

The agency has received more than 360 reports of clotting (thrombosis) occurring after the device was implanted. In more than 70 of these reports, use of the device was associated with death. In the remainder, the device was associated with injury requiring medical or surgical intervention. To date, it appears that the rate of thrombosis is within the expected rate for any stent.

The FDA also has received more than 70 reports—including some deaths—that Cordis considers to be related to hypersensitivity reactions. In most cases, hypersensitivity was minor, but there were some severe reactions. Symptoms in these reports include pain, rash, respiratory changes, hives, itching, fever, and blood pressure changes. Though some of the reported reactions remain unexplained, many are believed to be related to standard drug therapy associated with the procedure.

Hundreds of thousands of patients have been treated successfully with the Cypher stent, and the FDA considers it a safe and effective product when used according to the labeling. The agency will continue to monitor adverse events for the Cypher stent, as it does with all medical devices.

People who have received the Cypher stent should continue to follow their regularly scheduled doctor appointments. People who have experienced an adverse event related to the Cypher stent, and their physicians, are encouraged to report the incident to the FDA. Reports can be made online by following the instructions at www.fda.gov/medwatch/how.htm; by telephone at (800) FDA-1088; by fax at (800) FDA-0178; or by mail at: MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

The information for physicians can be found on the FDA Web site at www.fda.gov/cdrh/safety/cypher.html.

Safety of Food Animal Clones

The FDA has undertaken a process to assess the safety of food products derived from cloned animals and the risks to animals involved in cloning.

The process began two years ago, when the FDA commissioned the National Academy of Sciences (NAS) to consider scientific information on animal biotechnology. The NAS concluded that although food from animal clones posed only a low level of food safety concern, it would be prudent to have more data in order to minimize further safety concerns.

The FDA decided that before it could address any policy issues on animal cloning, it needed to conduct a risk assessment, followed by development of risk management options, in an open and transparent process.

Cloning is a process that allows livestock breeders and others to replicate their best animals, which are then used for breeding stock. Cloning can also be used to expand populations of endangered species.

The FDA previewed a risk assessment on animal cloning in November 2003 at a public Veterinary Medicine Advisory Committee meeting held in Rockville, Md.

The draft risk assessment builds on findings of the NAS and indicates that food products derived from animal clones and their offspring are likely to be as safe to eat as food from their non-clone counterparts, based on all the evidence available. These scientific findings also showed that healthy adult clones are virtually indistinguishable from their conventional counterparts.

Pending a final decision on cloned animals, the agency will continue to request that producers withhold from the market animal clones, their progeny, or products derived from them, with the full expectation that firms will comply with this request as they have willingly done in the past.

Following the close of a public comment period on the risk assessment, the FDA will review the comments in preparing a final risk assessment and draft risk management options.
**UPDATES**

**Genetics and Drugs**

In November 2003, the FDA issued draft guidance that encourages drug and biologic developers to conduct pharmacogenomic tests during drug development. Pharmacogenomics deals with the small genetic differences that help explain why some people respond positively to a drug, while others may not respond or may experience side effects.

Genetic differences also can predict variations in drug metabolism—how quickly or slowly a drug is eliminated from the body. The promise of pharmacogenomics lies in its potential ability to individualize therapy by predicting which people have a greater chance of benefit or risk. This ultimately helps maximize drug safety and effectiveness.

"Using genomic testing to guide drug therapy will constitute a significant shift from the current practice of population-based treatment toward 'fine-tuning' individual therapy," says Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

Scientific understanding of pharmacogenomics is most advanced in the area of drug metabolism. But the FDA anticipates rapid evolution of other uses. For example, experts hope that pharmacogenomic testing will help identify cancers that have a high probability of responding to a particular medication or regimen.


**RESEARCH NOTEBOOK**

**Poor Fitness in Young Adults Associated With Later Cardiovascular Problems**

Poor fitness in young adults is associated with the development of cardiovascular disease risk factors later in life, a new study indicates.

Mercedes R. Carnethon, Ph.D., of Northwestern University's Feinberg School of Medicine in Chicago, and colleagues investigated whether low fitness, estimated by short duration on an exercise treadmill test, was associated with the development of risk factors for cardiovascular diseases (CVDs) and whether improving fitness was associated with risk reduction.

CVDs account for a large proportion of deaths in people over the age of 45. "Numerous risk factors for CVD, including hypertension, diabetes, and hypercholesterolemia [high cholesterol], are suspected to be influenced by fitness, and these factors may mediate the association between low fitness and mortality [death]," the authors said in the study, published in the Dec. 17, 2003, issue of the Journal of the American Medical Association.

The participants, men and women 18 to 30 years of age, were enrolled in the Coronary Artery Risk Development in Young Adults (CARDIA) study. The CARDIA study recruited 5,115 participants from four geographic areas (Birmingham, Ala., Chicago, Minneapolis, and Oakland, Calif.). Participants who completed the treadmill examination at baseline were followed up from 1985-1986 to 2000-2001. A subset of participants (2,478) repeated the exercise test in 1992-1993.

"After adjustment for age, race, sex, smoking, and family history of diabetes, hypertension, or premature myocardial infarction [heart attack], participants with low fitness (less than 20th percentile) were 3- to 6- fold more likely to develop diabetes, hypertension, and the metabolic syndrome than participants with high fitness (at or above 60th percentile)," the authors write. "Improved fitness over seven years was associated with a reduced risk of developing diabetes and the metabolic syndrome, but the strength and significance of these associations was reduced after accounting for changes in weight."

People are said to have "metabolic syndrome" when they have several disorders of the body's metabolism at the same time—such as obesity, high blood pressure, and high cholesterol, according to the American Diabetes Association. The conditions that make up metabolic syndrome, also called "insulin resistance syndrome" or "syndrome X," can lead to hardening of the arteries and an increased risk for cardiovascular and kidney disease.

"Our findings demonstrate the importance of low cardiorespiratory fitness in young adulthood as a risk factor for developing cardiovascular comorbidities [related illnesses] in middle age," the authors say in the study. "Previous work has demonstrated that engaging in a regular exercise program can improve fitness."

Given the current obesity epidemic and observations of a decline in daily energy expenditure in the population, improving cardiorespiratory fitness in young men and women and developing public health policies that encourage physical activity should be important health policy goals, the study's authors conclude.
Study: Distress-Prone People More Likely to Develop Alzheimer's Disease

People who tend to experience psychological distress are more likely to develop Alzheimer’s disease than those who are less prone to experience distress, a new study indicates.

In the study, published in the Dec. 9, 2003, issue of Neurology, people who most often experience negative emotions such as depression and anxiety were twice as likely to develop Alzheimer’s disease as those who were least prone to experience negative emotions. The research is part of a larger study of older Catholic nuns, priests and brothers called the Religious Orders study.

“People differ in their tendency to experience psychological distress, and this is a stable personality trait throughout adulthood,” says study author Robert S. Wilson, Ph.D., of Rush University Medical Center in Chicago. “Since chronic stress has been associated with changes in the hippocampal area of the brain and problems with learning and memory, we wanted to test the theory that psychological distress may affect the risk of developing Alzheimer’s disease.”

Wilson says the findings are important because evidence has shown that many of the adverse effects of stress on the brain can be blocked by drugs, including antidepressants. “But much more research is needed before we can determine whether the use of antidepressants could help reduce the risk of Alzheimer’s disease,” he says.

In the study, 797 people with an average age of 75 were evaluated when they started the study and then on a yearly basis. Participants were evaluated on their level of proneness to stress with a rating scale that has been proven reliable. Participants rate their level of agreement (strongly disagree, disagree, etc.) with statements such as “I am not a worrier,” “I often feel tense and jittery,” and “I often get angry at the way people treat me.”

During an average of 4.9 years of follow-up, 140 people in the study developed Alzheimer’s disease. Those high in proneness to stress—in the 90th percentile—were twice as likely to develop Alzheimer’s disease as those in the 10th percentile.

To investigate whether proneness to distress was an early sign of Alzheimer’s disease rather than a risk factor for the disease, the researchers studied the brains of 141 study participants who died during the course of the study. Of those, 57 met the criteria for probable Alzheimer’s disease. The researchers found that proneness to distress was not related to measures of Alzheimer’s disease pathology, such as plaques and tangles in the brain.

“This result suggests that stress proneness is a co-factor leading to dementia in Alzheimer’s disease, but these results need to be confirmed,” said John C. S. Breitner, M.D., M.P.H., of the VA Puget Sound Health Care System and the University of Washington in Seattle, who wrote an editorial accompanying the study.
Joint Effort to Improve the Health of Older Hispanic Americans

Reducing health disparities among older Hispanic Americans is the focus of a new collaboration between the Food and Drug Administration and the Administration on Aging (AoA), two agencies within the U.S. Department of Health and Human Services (HHS).

“This new effort represents another step toward our goal of closing the health gap affecting racial and ethnic minorities,” says HHS Secretary Tommy G. Thompson. “By focusing the efforts and resources of these two important agencies, we will strengthen our efforts to reach older Hispanic Americans with health messages that can help them stay healthier and live longer.”

As part of the effort, the FDA and the AoA will identify issues that affect the health of older Hispanic Americans and will develop culturally sensitive messages for them. The agencies will also cultivate and expand partnerships with national Hispanic organizations, electronic and print media, and other private organizations to support education and outreach to Hispanic communities.

“We are committed to helping protect and advance the health of all Americans,” says FDA Commissioner Mark B. McClellan, M.D., Ph.D. “Older Hispanic Americans and their families need to have the best health information available and in a language and format they can best understand and use.”

The agencies will work with community partners to develop educational materials and caregiver tool kits on the safe use of medicines, nutrition and healthy eating, drug interactions, reporting side effects, antibiotic overuse, dietary supplements, and health fraud.

To kick off this effort, the agencies hosted a panel on reducing health disparities at a National Hispanic Leadership Roundtable in Washington, D.C., in October 2003. The roundtable was the first of several forums planned by the FDA and the AoA. The two agencies will continue to meet with Hispanic leaders to discuss areas of concern affecting senior Hispanics in America and to share perspectives on approaches for reaching this audience.

“Working together with Hispanic leaders, we hope that we’ll be able to increase the quality and years of healthy life and eliminate health disparities faced by older Hispanics,” says Assistant Secretary for Aging Josefina G. Carbonell.

The older Hispanic population is at high risk for chronic diseases such as heart disease, cancer, HIV infection, stroke, pneumonia, diabetes and influenza. “Many of these conditions are preventable,” Carbonell said at the roundtable. “For example, we know that immunizations effectively prevent influenza.” In 2003, almost one-third of Hispanic seniors did not receive a flu shot. “We need to work on these issues,” said Carbonell.

The Hispanic population over age 65 was 2 million in 2002 and is projected to grow to more than 13 million by 2050. Hispanics made up 5.5 percent of the entire older U.S. population in 2002; by 2050, Hispanics are expected to account for 16 percent of the older U.S. population.

Part of the FDA’s mission is to help the public get the accurate, science-based information it needs to use medicines and foods to improve health.

The AoA’s mission is to promote the dignity and independence of older people, and to help society prepare for an aging population.

For More Information
Food and Drug Administration
www.fda.gov

Administration on Aging
www.aoa.gov
Preventing Listeria Contamination in Foods

By Carol Rados

Keeping ready-to-eat foods cold is key to reducing listeriosis, a serious infection in humans. That’s one of the conclusions of a recent Food and Drug Administration risk assessment on the relationship between foodborne listeriosis and human health.

Listeriosis is an illness caused by eating foods contaminated with Listeria monocytogenes, bacteria found in soil and water. Food-producing animals can carry these bacteria in their intestines. As a result, the disease-causing bacteria may be spread to meat and dairy products. Ready-to-eat foods also can become contaminated within the processing plant, after processing, or along the route from plant to plate.

Listeriosis has been recognized as an important public health problem in the United States. Scientific information from the FDA’s risk assessment outlines measures that industry, retailers and consumers can take to dramatically reduce the risk of this potentially fatal infection.

Listeriosis causes flu-like symptoms, such as fever and chills. Sometimes people have an upset stomach. If the infection spreads to the nervous system, symptoms such as headache, stiff neck, confusion, loss of balance, or convulsions can occur.

Babies can be born with listeriosis if their mothers eat contaminated food during pregnancy. Although healthy people may consume contaminated foods without becoming ill, those at increased risk for infection—people over 60, newborns, and people with weakened immune systems—are more likely to get listeriosis after eating food contaminated with even a few bacteria. People at risk can prevent the infection by avoiding certain high-risk foods and by handling food properly.

Outbreaks of listeriosis are associated with ready-to-eat foods such as hot dogs, luncheon meats, cold cuts, soft cheeses, deli-style meats, and poultry. Although listeria bacteria are killed with thorough cooking or by other heating methods, such as pasteurization, these tough bugs can grow in the refrigerator and survive in the freezer.

The FDA and the Centers for Disease Control and Prevention (CDC) advise that the most important things consumers can do to reduce the risk of illness are:

- Store ready-to-eat foods at 40 degrees Fahrenheit or lower—use a refrigerator thermometer to check the temperature.
- Use perishable and ready-to-eat foods as soon as possible.
- Clean the refrigerator regularly.

Although listeriosis is potentially life-threatening, the CDC’s FoodNet program has recorded over a 40 percent decrease in its incidence during the past five years. The results of the risk assessment reinforce past studies that found that, even though foodborne listeriosis is rare and declining, it remains a public health concern. The CDC estimates that in the United States, 2,500 people become seriously ill with listeriosis each year, and of these, 500 die.
Store ready-to-eat foods, such as luncheon meats, at 40 degrees Fahrenheit or lower to reduce the risk of listeriosis.

The following advice is provided for pregnant women, older adults, and people with weakened immune systems who are at higher risk for listeriosis:

- Do not eat hot dogs and luncheon meats, unless they are reheated until steaming hot.
- Do not eat soft cheese such as feta, brie, and Camembert, blue-veined cheeses, queso blanco, queso fresco, and Panela, unless it is labeled as made with pasteurized milk.
- Do not eat refrigerated pâtés or meat spreads. Canned or shelf-stable pâtés and meat spreads may be eaten.
- Do not eat refrigerated smoked seafood, unless it is contained in a cooked dish, such as a casserole. Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna, or mackerel, is most often labeled as “nova-style,” “lox,” “kippered,” “smoked,” or “jerky.” These fish are found in the refrigerated section or sold at deli counters of grocery stores and delicatessens. Canned or shelf-stable smoked seafood may be eaten.
- Do not drink unpasteurized milk or eat foods that contain unpasteurized milk.

For More Information
Preventing foodborne illness
www.foodsafety.gov

Listeriosis risk assessment
www.cfsan.fda.gov, click on “National Food Safety Programs,” and then “Risk Assessment”
It's risky business taking pictures of unborn babies when there's no medical need to do so. That's the word from the Food and Drug Administration, which is concerned about companies trying to turn an important medical procedure into a prenatal portrait tool. Facilities with captivating names such as Fetal Fotos, Peek-a-Boo, Womb with a View, and Baby Insight are popping up in strip malls and shopping centers all over the country. And they're promoting "keepsake videos" that use the latest ultrasound technology to produce high-resolution three-dimensional and four-dimensional (moving) images showing the surface anatomy of babies developing in the womb. The lure of this burgeoning industry is that...
parents-to-be get to see characteristics like facial features, hair, and even the baby's sex, and often they can count fingers and toes before their baby is born. Some women even have videos made at various stages of their baby's growth. And the videos are often being marketed as a prized addition to collections of childhood memorabilia.

As compelling as these sneak previews may be, the FDA is warning women about the potential hazards of getting keepsake videos. The agency also is warning companies against creating them for entertainment purposes. While ultrasound has been around for many years, expectant women and their families need to know that the long-term effects of repeated ultrasound exposures on the fetus are not fully known. In light of all that remains unknown, having a prenatal ultrasound for non-medical reasons is not a good idea.

What is Ultrasound?

Ultrasound imaging is a common diagnostic medical procedure that uses high-frequency sound waves to produce dynamic images (sonograms) of organs, tissues, or blood flow inside the body. Prenatal ultrasound examinations are performed by trained professionals, such as sonographers, radiologists, and obstetricians. The procedure involves using a transducer, which sends a stream of high-frequency sound waves into the body and detects their echoes as they bounce off internal structures. The sound waves are then converted to electric impulses, which are processed to form an image displayed on a computer monitor. It is from these images that videos and portraits are made.

Obstetricians use ultrasound at a very low power level to check the size, location, number, and age of fetuses, the presence of some types of birth defects, fetal movement, breathing, and heartbeat. When ultrasound is used by a qualified clinician to check for this kind of medical information, the FDA says the medical benefit far outweighs any risk.

At somewhat higher exposure levels, given daily for weeks at a time, ultrasound is used to speed the healing of bone fractures. At even higher levels, the technology produces a heating effect in tissue that is useful in treating sprains and pulled muscles.

Why All the Fuss?

Ultrasoundic fetal scanning, from a medical standpoint, generally is considered safe if properly used when information is needed about a pregnancy. Effects can harm a fetus, the FDA says the fact that these effects exist means that prenatal ultrasounds can't be considered completely innocuous.

As more advanced ultrasound technologies (usually using higher ultrasound intensities) become available, greater numbers of expectant mothers and their families are requesting fetal keepsake videos and portraits for souvenirs. Sometimes these images may be made by people not well trained, or for longer exposure times and at higher levels than are usually used in medical situations. At the same time, the medical community is discouraging the use of ultrasound unless it is medically necessary.

Mel Stratmeyer, Ph.D., in the FDA's Office of Science and Technology, says that most animal studies have not identified any fetal harm with low-dose ultrasound exposure.

"But the issue of keepsake videos has to be that if there's even a possibility of potential risk, why take the chance?" Stratmeyer says. Animal studies have been performed during the last 30 years to investigate the effects of the procedure on a fetus, due to the increased use of obstetrical ultrasound in the 1970s. Human studies, however, are not feasible for the same reason that experts are cautious about casual ultrasound: It's too risky to subject unborn babies to any unknown effects.

"The problem with experimental
Health care providers can check the condition of an unborn child using ultrasound technology to produce images.

research," Stratmeyer says, "is that you really need both animal and human studies to make more predictable outcomes." He adds that as technology advances and becomes more complex, the potential for physical effects to be identified in the future also increases.

However, a few studies, Stratmeyer says, suggest that exposure to diagnostic ultrasound during pregnancy may have an effect on human development, such as delayed speech in children.

Danica Marinac-Dabic, M.D., an epidemiologist in the FDA's Office of Surveillance and Biometrics, says that the most consistent finding in the recent literature is a potential association between prenatal ultrasound exposure and subsequent left-handedness, especially among boys. At least three large follow-up studies involving thousands of school-age children in Sweden and Norway suggested such an association.

"Since ultrasound examinations in these studies took place in the late 1970s and early 1980s," says Marinac-Dabic, "and the fact that modern ultrasound equipment is capable of producing approximately eight times higher intensities than equipment used a decade ago, we continue to study the possible long-term effects of prenatal ultrasound in both animal and human epidemiologic studies."

The History of Fetal Photos

The FDA first learned about keepsake video productions from consumers in Texas in 1994. The Texas Department of Health and the FDA's Dallas district office jointly inspected three firms. The FDA then initiated investigations of similar firms in other parts of the country. Investigators uncovered numerous companies offering a wide variety of ultrasound packages. Among the agency's findings were that ultrasound was being performed by untrained, unlicensed technicians and often without a doctor's supervision.

The FDA wrote about its concerns to 10 health professional organizations and the National Electrical Manufacturers Association, stating that anyone promoting, selling or leasing ultrasound equipment for making keepsake fetal videos could be breaking the law. The agency asked the organizations to have

**Legitimate Uses for Ultrasound Imaging**

- Diagnosing pregnancy
- Determining fetal age
- Diagnosing congenital abnormalities
- Evaluating position of placenta
- Determining multiple pregnancies
their members discourage patients from having ultrasound procedures for non-medical reasons and to notify the FDA of any keepsake video operations in their communities.

Not a Wise Choice

For every reason a mother-to-be wants a keepsake video, there are good reasons she shouldn’t have one. Women cite early bonding with their babies, determining the baby’s sex, and a desire to share their prenatal experiences with friends and families as major reasons in favor of the videos. And the quality of images in commercial videos makes them especially tempting.

Because many obstetricians still use two-dimensional imaging, which is considered standard in prenatal care, women may seek the more advanced three- and four-dimensional images used by some keepsake businesses, in which the features of an unborn infant are more easily recognizable to the non-professional.

But health experts say these are not medical reasons for having an ultrasound. Lawrence D. Platt, M.D., president-elect of the International Society of Ultrasound in Obstetrics and Gynecology and a practicing obstetrician-gynecologist in Los Angeles, adds that while physicians need to be sensitive to expectant mothers’ feelings, “We have to go beyond emotions in this case. We have to do the right thing,” he says. “Ultrasound is a form of energy and it must be respected.”

Besides concern that unskilled technicians could be performing and interpreting such ultrasounds and that the procedure is not always done under the supervision of a qualified physician, some facilities may be using equipment that’s not in good working order.

“No all ultrasounds are created equal,” says Nancy Hueppchen, M.D., a maternal fetal medicine specialist at Johns Hopkins Hospital in Baltimore. “Patients don’t know the level of expertise of the person performing the procedure.” Hueppchen says there’s also the worry about ultrasounds not being conducted in medical settings. “These portrait facilities are not equipped to provide counseling should something go wrong, or proper guidance if a gross abnormality is suspected,” she says.

The FDA also notes that some video companies have been known to use the ultrasound machine on higher energy exposures for as long as an hour to get the pictures. The procedure should always be done at the lowest possible energy output and for the least amount of time. Exposure to ultrasound for longer than the time specified by the FDA for fetal monitoring could pose a potential risk to the health of the mother and her developing fetus.

Some companies make it clear that they are not providing diagnostic ultrasounds, but those that don’t may wrongly give women the impression that their ultrasound examination will identify problems.

The FDA and the American Institute of Ultrasound in Medicine (AIUM), which also strongly discourages the non-medical use of ultrasound, have concerns that women are being wrongly reassured by commercial sonograms. Women may misinterpret the studio ultrasound as a medical examination, thus giving them a false sense of security. And inaccurate findings may cause them to undergo unnecessary follow-up tests.

“Even in the best of hands,” says Hueppchen, “fetal structural problems can be missed due to technical and gestational age limitations, thus falsely reassuring the patient.”

Understanding the Laws

Ultrasound is conducted with a prescription medical device that is regulated by the FDA. The agency sets the standard for the level of energy to be used for various treatments or diagnoses, including fetal ultrasounds. This standard restricts ultrasound exposure to levels that produce few, if any, effects on the fetus, based on epidemiological evidence.

The FDA can take action against the keepsake industry in two ways: for promoting a device for other than its approved use, and for using a prescription device without a prescription from a medical professional. By promoting and advertising keepsake videos, the advertiser is creating a new intended use for the device, and this requires premarket review by the FDA. And many keepsake facilities do not appear to be requiring doctors’ prescriptions from their customers.

Kimber C. Richter, M.D., a deputy...
director in the FDA's Office of Compliance, says that regulation of the commercial ultrasonic imaging of fetuses is complicated because each video company scenario is different.

"In some cases, there may be no prescription and no physician oversight," she says. "In others, there may be a physician involved but no clear doctor-patient relationship." And in still others, "the video might be made through an extra visit to the physician that the patient normally sees." Richter says the regulatory approach in all these cases varies. "FDA regulates devices, but the qualifications and behavior of technicians and physicians would be regulated by the states," Richter says.

The FDA announced in 2002 that anyone administering ultrasound to consumers without a medical prescription is breaking the law. "In the past," says Richter, "the FDA has taken regulatory action, such as a warning letter or even seizure, when these devices were used for entertainment purposes without a prescription."

Margaret T. Tolbert, deputy director of the FDA's Division of Device User Programs and Systems Analysis, says that the agency is updating its current Web statement warning consumers about the unknowns of using ultrasound equipment for entertainment purposes and is developing a set of questions and answers to educate those considering keepsake videos as a business opportunity.

Since a number of advertising examples recently have come to the FDA's attention—suggesting an increase in entertainment ultrasounds—the FDA is currently taking a closer look at these businesses. "We are reviewing these cases and will consider regulatory action as appropriate," says Richter.

The Bottom Line
The prescription status of ultrasound equipment ensures that pregnant women will receive professional care that contributes to their health and to the health of their babies. Performing prenatal ultrasounds without following state and federal guidelines puts a mother and her unborn baby at risk. Therefore, the procedure should only be used to provide medical benefit. Besides being inappropriate and contrary to responsible medical practice, the bottom line is: Why take a chance with your baby's health for the sake of a video?

To report keepsake video operations in your community, write to: Diagnostic Devices Branch, Office of Compliance, Center for Devices and Radiological Health, HFZ-322, 2098 Gaither Road, Rockville, MD 20850.

Official Statements on Ultrasonic Fetal Imaging

Food and Drug Administration:
Persons who promote, sell or lease ultrasound equipment for making "keepsake" fetal videos should know that FDA views this as an unapproved use of a medical device. In addition, those who subject individuals to ultrasound exposure using a diagnostic ultrasound device (a prescription device) without a physician's order may be in violation of state or local laws or regulations regarding use of a prescription medical device.

American Institute of Ultrasound in Medicine (AIUM):
The AIUM advocates the responsible use of diagnostic ultrasound. The AIUM strongly discourages the non-medical use of ultrasound for psychosocial or entertainment purposes. The use of either two-dimensional (2D) or three-dimensional (3D) ultrasound to only view the fetus, obtain a picture of the fetus or determine the fetal gender without a medical indication is inappropriate and contrary to responsible medical practice. Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient.

European Committee for Medical Ultrasound:
The embryonic period is known to be particularly sensitive to any external influences. Until further scientific information is available, investigations should be carried out with careful control of output levels and exposure times. With increasing mineralization of the fetal bone as the fetus develops, the possibility of heating fetal bone increases. The user should prudenty limit exposure of critical structures such as the fetal skull or spine during Doppler studies (a type of ultrasound that detects movement, direction and speed, such as fetal heartbeat).
Advisory Committees: Critical to the FDA's Product Review Process

The FDA uses advisory committees to enhance the agency's regulatory decisions.

By Carol Rados

The Food and Drug Administration regulates more than 150,000 marketed drugs and medical devices. At any time, nearly 3,000 investigational new drugs are being developed. More dietary supplements than ever before are on the market, and Americans today have a much broader range of food choices. Then there are the scores of blood products and veterinary medicines for which the FDA is responsible.
Access to this growing range of products offers opportunities for advancing public health and improving people's lives. But it also creates new vulnerabilities and greater potential risks for people who use the products. To keep up with the challenges that the FDA's full-time experts face when reviewing innovative and rapidly evolving technologies, the agency hires "special government employees" whose opinions complement its goals to provide safe and effective products.

These outside advisers make up the FDA's technical and scientific advisory committees. The primary role of an advisory committee is to provide independent advice that will contribute to the quality of the agency's regulatory decision-making and lend credibility to the product review process. In this way, the FDA can make sound decisions about new medical products and other public health issues. And although advisory committees have a prominent role in the product approval stage, they are sometimes included earlier in the product development cycle and are asked to consider issues relating to products already on the market.

Committees typically are asked to comment on whether adequate data supports approval, clearance, or licensing of a medical product for marketing. Advisory committees also may recommend that the FDA request additional studies or suggest changes to a product's labeling. Their recommendations are just that—advice—and do not bind the agency to any decision. While committee discussions and final votes are very important to the FDA, the final regulatory decision rests with the agency.

Advisory committee meetings often receive considerable media attention, and the agency welcomes such scrutiny because it helps provide public assurance of a responsible process.

Committee Members and Participants

Rapidly expanding technology in food and drugs in the 1960s led to growing opinion among scientists and other public health experts that the FDA could perform its mission of consumer protection more effectively by using public advisory committees. With the passage of the Federal Advisory Committee Act in 1972, Congress prescribed the formal use of advisory committees throughout the federal government.

Membership in advisory committees must be "fairly balanced"—that is, as open and inclusive as possible—according to the law. Committee membership is expected to include ethnic, gender, and geographic diversity, as well as people with recognized expertise and judgment in a specific field, such as clinicians and researchers. Most members of the FDA's drug advisory committees, for example, are physician-scientists whose specialties or research involve the kinds of products being reviewed. Other members might include statisticians, epidemiologists, nutritionists, and toxicologists—experts in preclinical (animal) studies. The FDA also insists on getting industry and public perspectives, and nearly all committees include industry and consumer representation.

"Placing people on committees that have different perspectives and expertise gives balance to the discussions and final recommendations," says Linda Ann Sherman, M.D., M.P.A., director of the FDA's Advisory Committee Oversight and Management Staff. "The agency aims for a lively discussion."

Industry representatives address global concerns for industry. They do not represent their employer; rather, they bring to the table their opinion of an issue, such as whether or not an additional preclinical study is necessary for a new class of drugs. The industry representative may express the opinion that the cost of such a study would be prohibitive and not give enough additional information to be cost-effective and could potentially delay the marketing of a product.

Consumers are represented on committees by technically qualified professionals who have specific links with consumer advocacy groups. In addition, some committees have patient representatives. These individuals present "real world" concerns of the patient who is to be the potential recipient of the new medical product.

For example, scientists and the FDA might be considering a pill form of a drug that's already approved as an injection, but there may be problems with a person's ability to absorb the drug in pill form. The patient representative's role might be to point out that the committee should weigh the seriousness of the absorption problem against the value of patients taking the drug more consistently when it's offered in a more convenient dosage form. In any case, patient representatives, who can be voting or non-voting members, offer their experiences in an effort to provide a realistic look at a new product. It's important for patient representatives to have a general knowledge of the disease and the ability to comprehend the scientific data that is presented.
Most committee members vote at the end of each meeting on questions that are posed to them, while some do not vote. The main impact a member provides, however, is his or her contribution to the discussion, and not the final vote.

Notices requesting nominations to advisory committees are published in the Federal Register (www.gpoaccess.gov/fr/index.html). Typically, potential members are referred by professional, scientific and medical societies, academic institutions, government agencies, consumer and patient groups, and former and current advisory committee members. Self-nominations also are encouraged.

Committees are required to dedicate a minimum of 60 minutes of each meeting to “open public comment.” The public is invited to appear before the committee. Interested people may present information, orally or in writing, relevant to the meeting topic. Those who want to speak are encouraged to register.

Most meetings are supplemented by temporary voting members, or consultants, who are the world’s experts on the topic being discussed. These consultants are also special government employees, but are present only for the specific meeting.

Committee Meetings

Committees, which range in size from 10 to 15 members (and may be supplemented by additional FDA consultants), typically meet twice a year in the Washington, D.C., area. Meetings generally last two days. Members stay at a designated hotel at government expense. Travel expenses, including local transportation, and meal expenses are reimbursed at government rates, and a modest fee is provided for each day of service. An FDA official serves as the administrative executive secretary of each committee. Before an advisory committee meets, members will have already received and reviewed specific questions from the FDA, along with other materials, such as summaries of information on the safety and effectiveness of a new product. Prior to every meeting, each member is evaluated for any potential conflicts of interest. For example, a member may not participate in a meeting if he or she holds a financial interest in the product under consideration, since the action taken could potentially provide the member with a personal financial gain or loss.

So, how does the agency determine which products will undergo advisory committee review in the first place?

“Surprisingly,” Sherman says, “many products do not make it to advisory committees.” Those that do usually represent new technology or some element of controversy.

For example, a recent meeting to discuss the latest data regarding silicone breast implant safety highlighted the mixed opinions about the risks and benefits of the implants. “The meeting provided a valuable forum for discussing the issue from many diverse perspectives and for raising important additional questions,” Linda Kahan, deputy director of the FDA’s Center for Devices and Radiological Health, said after the advisory committee meeting. “That is the point of the FDA’s advisory committee process,” she says, “to air issues that are controversial, complex, and do not have simple answers.”

The decision to involve an advisory committee is usually at the discretion of the division director of one of the FDA’s five product centers.

Sherman says no count can be given to the number of products approved as a result of advisory committee recommendations. “Much of the advice accepted is not whether or not a product should be approved, but about some unique aspect of safety, effectiveness, or clinical development of that product.”

In addition to serving as an important mechanism for outside input for the FDA, advisory committees are a vital public resource for information about new medical products. These meetings often represent the FDA’s first public discussion of a new medical product and can be an invaluable source of information for patients, health care providers, and others who are interested in the product. Transcripts of FDA advisory committee discussions are posted at www.fda.gov/ohrms/dockets/ac/acmenu.htm.

Each FDA committee must be renewed by the agency every two years, or its charter automatically expires. Renewals must be approved by the FDA Commissioner or his designated appointing official. An assessment to renew is made based on the activity of the committee and the agency’s continuing need for expertise in a particular scientific specialty.

“The FDA values the service its advisory committee members provide and the process itself,” adds Sherman. “The system allows for full participation of all of FDA’s stakeholders to assist in the agency’s regulatory decisions.”

For more information on FDA advisory committees, visit www.fda.gov and click on the “Advisory Committees” link.
The FDA and the Fight Against Terrorism

Secretary of Health and Human Services Tommy G. Thompson checks out the department’s command center during a recent practice exercise. The center supports round-the-clock communication between federal and local agencies during public health emergencies.
Minutes after two hijacked airliners crashed into the World Trade Center on the morning of Sept. 11, 2001, the Federal Aviation Administration stopped all flights from U.S. airports. It marked the first time that air traffic came to a halt nationwide. Soon after, a third plane crashed into the Pentagon, and a fourth plane thought to be headed for another target in Washington, D.C., crashed into a field in Somerset County, Pa.

All told, more than 3,000 people died. Experts from the Food and Drug Administration immediately became involved. They ensured that blood could be collected quickly from people living near the disaster sites to help the injured survivors. Other agency experts evaluated burn wound dressings that could be used to treat victims and checked on reserves of drugs and medical supplies.

And while the country was still reeling from these tragedies, terrorists launched more attacks through the mail in October 2001. Letters containing anthrax spores (Bacillus anthracis) were mailed to U.S. senators and members of the media. The Centers for Disease Control and Prevention (CDC) recorded 22 cases of anthrax. There were 11 cases of cutaneous (skin-based) anthrax and 11 cases of inhalational anthrax. Among the inhalational cases, there were five deaths.

A key challenge for public health workers was the fact that early inhalational anthrax symptoms are similar to those of common illnesses such as the flu. Lung infections with anthrax can rapidly become fatal unless appropriate antibiotic treatment is started very soon after symptoms develop.

Two postal workers at the Brentwood mail facility in Washington, D.C., were among those who died from exposure to inhalational anthrax. They initially presented with non-specific symptoms and were diagnosed as having common infections that did not require hospitalization. Their doctors considered the possibility of anthrax only after they became aware of media reports about other postal workers with inhalational anthrax. Experts from the National Institutes of Health, the Johns Hopkins School of Medicine and Public Health, and area hospitals published a report on the two anthrax-related deaths in the Nov. 28, 2001, issue of the Journal of the American Medical Association. The authors concluded that rapid communication of information between public health agencies and health care professionals is needed in the event of a serious infectious disease outbreak.

At the time of the terrorist attacks, the FDA had already approved the drug Cipro (ciprofloxacin) to prevent the progression of anthrax following inhalation of anthrax spores under the FDA's accelerated approval regulations. In November 2001, the agency clarified that two more drugs—doxycycline and procaine penicillin G—also were approved to treat inhalational anthrax. The FDA initiated public education about the treatments, which included providing dosing regimens and answering questions about the use of antibiotics in children and pregnant or nursing women.

The FDA worked closely with blood banks in anthrax-affected areas to determine whether people incubating this disease may have donated. This enabled the removal of potentially unsafe blood from the blood supply.

Later, when operators of some Web sites seeking to capitalize on the threat sold unapproved foreign-made Cipro over the Internet, the FDA issued warnings and reminded consumers that only FDA-approved products can be legally marketed in the United States.

A Comprehensive Approach

"It was always our job to protect the public health," says Jeff Shuren, M.D.,

The FDA has adopted five broad strategies for counterterrorism:

- **Awareness:** Increasing awareness through collecting, analyzing, and spreading information and knowledge.
- **Prevention:** Identifying specific threats or attacks that involve biological, chemical, radiological or nuclear agents.
- **Preparedness:** Developing and making available medical countermeasures such as drugs, devices, and vaccines.
- **Response:** Ensuring rapid and coordinated response to any terrorist attacks.
- **Recovery:** Ensuring rapid and coordinated treatment for any illness that may result from a terrorist attack.
J.D., assistant commissioner for policy at the FDA. “But in an environment of heightened security, we are applying even more resources to counterterrorism in all areas of the agency.”

This means safeguarding all products that the agency regulates, including food, drugs, medical devices, cosmetics, and animal feed. The FDA also works to speed the development of medical countermeasures—human and animal drugs, vaccines and other biologics, blood and blood products, diagnostic tests, and devices that can prevent, diagnose, and treat illnesses related to a terrorist attack. FDA Commissioner Mark B. McClellan, M.D., Ph.D., has identified counterterrorism as one of his strategic priorities.

The FDA’s Office of Regulatory Affairs (ORA) is responsible for ensuring that all FDA-regulated products are in compliance with laws and regulations that the FDA is charged with enforcing. The agency responds rapidly to emergencies and redirects efforts when necessary to respond to incidents of product tampering and other unforeseen events. The FDA’s Office of Criminal Investigations (OCI), part of ORA, maintains relationships with domestic and foreign law enforcement agencies and serves as the FDA’s liaison with the intelligence community.

To bolster the FDA’s counterterrorism efforts, McClellan appointed Margaret Glavin, one of the nation’s foremost food safety experts, to the new position of Assistant Commissioner for Counterterrorism Policy in October 2003. In addition to serving as the Commissioner’s senior adviser on counterterrorism, Glavin oversees the newly established Office of Counterterrorism Policy.

“We’re implementing a comprehensive, integrated counterterrorism program that can only be done by working closely with other agencies and industry,” Glavin says. “Of course, working with the FDA centers to prevent a terrorist attack against food and medical supplies will be a major part of our efforts, but we are also working on other key priorities that the Commissioner has laid out.” Glavin also coordinates with other agencies within the U.S. Department of Health and Human Services (HHS), such as the CDC and the National Institutes of Health (NIH), as well as the U.S. Department of Defense (DoD), the White House Homeland Security Council, and the Department of Homeland Security (DHS).

The FDA is working with the NIH, CDC, DoD, industry, and foreign governments to ensure the availability of drugs and vaccines through the Strategic National Stockpile (SNS), which is intended for deployment in response to national emergencies. The SNS is a stockpile of antibiotics, antitoxins, vaccines, medical supplies, medications and surgical items.

Emergency drug packages known as Push Packs are strategically located in warehouses across the country and can be sent to any destination in the United States within 12 hours of a federal decision to deploy them. In addition, under pending legislation called BioShield, promising new products that have not been approved, licensed, or cleared by the FDA could be used temporarily under new emergency authorization procedures if alternatives are not available to cope with a terrorist attack.

A top priority is relaying information about counterterrorism to the public quickly. The FDA’s Web site (www.fda.gov) is a primary way the agency communicates with consumers. A section of the site is devoted to counterterrorism, along with links to other government agencies and tips on how to avoid bogus counterterrorism products. For more information, visit www.fda.gov/oc/opacom/hottopics/bioterrorism.html.

Food Safety and Security

Food safety and security fall under the jurisdiction of several centers and offices within the FDA, including the Center for Food Safety and Applied Nutrition and the National Center for Toxicological Research, which conducts scientific research to support the agency’s regulatory needs. The FDA’s Center for Veterinary Medicine has authority over food additives and drugs given to animals, including food-producing animals.

In the past, food safety concerns centered on accidental and natural food contamination that could occur. But now, there is concern that biological, chemical, or radiological agents could be intentionally introduced into our food supply.

Several recent incidents in other countries highlight the importance of the FDA’s watchdog role in food security. In 2002, a restaurant owner in China added chemicals to a competitor’s food, killing dozens of people and sending hundreds to the hospital. In another incident in 2002, three people were arrested in Jerusalem for allegedly planning a mass poisoning of patrons at a cafe. And in January 2003, several people were arrested in London for plotting to add a deadly poison called ricin to the food supply on a British military base.
The FDA is responsible for ensuring the safety of about 80 percent of the nation's food supply. FDA oversight includes the safe production, processing, storage and holding of domestic and imported food. The exceptions are meat, poultry and processed egg products, which are under the jurisdiction of the U.S. Department of Agriculture (USDA).

If a terrorist-related outbreak occurred in the United States, the FDA would work closely with federal, state, and local authorities to identify the problem, investigate, and get the contaminated products off the market quickly. Here are some examples of how the FDA works to safeguard the food supply:

Prevention and Surveillance: After Sept. 11, 2001, the FDA conducted food supply vulnerability assessments. The FDA also issued guidance documents on security measures that the food industry can take to minimize the risk that food will be subject to tampering or other criminal actions. The guidances are aimed at food producers, processors, transporters, importers, retailers, food service establishments, and cosmetic processors. The agency has also issued guidance for the milk industry.

The FDA is working with the USDA and other federal and state agencies on the Electronic Laboratory Exchange Network (eLEXNET), the first integrated, Web-based data exchange system for sharing food testing information. It allows multiple agencies engaged in food safety activities to compare and coordinate findings of laboratory analyses.

A critical component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a variety of biological, chemical and radiological agents. The FDA has worked closely with the CDC and the USDA to establish the Food Emergency Response Network (FERN)—a national network of laboratories ready to respond to a food security emergency.

Protecting Imports: The FDA is improving its efforts to ensure the safety of the nearly 6 million food shipments that arrive in the United States each year. With additional funding for counterterrorism, the FDA has hired more than 655 new field inspectors to monitor imports. The addition of these field employees has resulted in increased surveillance of imported foods and enhanced laboratory analysis capacity.

Within the last two years, the number of ports that have an FDA presence has more than doubled from about 40 ports in 2001 to about 90 ports by the end of 2002. In addition, the agency has increased by more than sixfold the number of food import exams conducted at the border, from 12,000 in fiscal year 2001 to more than 78,000 in fiscal year 2003.

The agency has also updated its labs to handle the increased number of food samples that may be contaminated by terrorism. There are more than 90 active FDA research projects on the development of tests and sampling methods to quickly detect contaminated food. A major focus is on developing rapid test kits that can be used to quickly inspect food at ports of entry to the United States.

Four Major Regulations: Under the authority of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, signed by President Bush in June 2002, the FDA developed four new regulations that address provisions of the law.

- Registration of food facilities. This regulation became effective in December 2003. It requires owners and operators of foreign or domestic food facilities that manufacture or process, pack, or hold food for human or animal consumption in the United States to submit information to the agency about the facility and emergency contacts. More than 400,000 facilities are expected to register through the FDA's new electronic registration system, which went online in October 2003.

- Prior notification of imported food shipments. This regulation, which became effective in December 2003, requires the FDA to receive prior notice of imported food shipments before the food arrives at a U.S. port. The FDA expects to receive about 25,000 notifications about incoming shipments every day.

- Establishment and maintenance of records. Manufacturers, processors, packers, importers, and others are required to keep records that identify the source from which they receive food and where they send it.

- Administrative detention. The agency has new authority to detain any food for up to 30 days for which there is credible evidence that the food poses a serious threat to humans or animals.
Medical Countermeasures

Ensuring that safe and effective medical products are available for diagnosing, treating, and preventing illness due to terrorist agents is the responsibility of the FDA’s Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. Biologics are medical products derived from living sources. These products include vaccines, blood and blood derivatives, and cells and tissues for transplantation.

The FDA works with other health agencies and manufacturers to identify promising research and to encourage the development of new products. The FDA supports clinical research to find out whether products approved for one indication could be used for an indication related to counterterrorism. In some cases, the FDA conducts research on its own.

Under a new regulation known as “the animal efficacy rule,” the FDA can approve medical treatments against terrorist agents based on effectiveness data from animal studies when human studies are unethical and not feasible. Studies demonstrating the safety of the new product in humans are still required.

The FDA also publishes guidance for using medical countermeasures in special groups such as the first responders in an emergency, people in the military, people who live near nuclear facilities, pregnant women, children, and people with compromised immune systems.

As part of national policy, the FDA places high priority on Category A agents, a designation the CDC gives to the greatest threats to public health. Category A agents include the organisms that cause anthrax, plague, smallpox, tularemia and viral hemorrhagic fevers, as well as botulinum toxin. Here are some examples of areas in which the FDA works on medical countermeasures:

Anthrax: Anthrax is an infectious disease caused by the spore-forming bacterium Bacillus anthracis. There are three forms of anthrax infection: skin (cutaneous), gastrointestinal, and inhalational.

Cutaneous anthrax can be acquired when spores enter cuts or abrasions in the skin. It is marked by a sore that progresses from a red raised area on the skin to an ulcer with a black center. Gastrointestinal anthrax can result from ingesting food that contains B. anthracis spores. It can cause fever, loss of appetite, nausea, and vomiting, which can progress to vomiting of blood and severe, often bloody, diarrhea and abdominal pain.

Inhalational anthrax, which is associated with the highest death rates, occurs when spores are inhaled and cause infection in the lungs. Initial symptoms are similar to a cold or the flu, but the illness worsens over several days and a high fever typically develops.

The treatment for all types of anthrax is antibiotics. The antibiotics approved by the FDA are Cipro (ciprofloxacin), drugs in the tetracycline class such as doxycycline, and some drugs in the penicillin class such as procaine penicillin G.

The anthrax vaccine is primarily given to people in the military and is only recommended for individuals considered to be at high risk, such as scientists who handle anthrax bacteria in a research lab. During the anthrax attacks in 2001, the FDA made one type of anthrax vaccine, Anthrax Vaccine Adsorbed, available under an investigational new drug application (IND) for people who are not in the military and who had been exposed to inhalational anthrax. An IND allows a treatment to be made available before final FDA approval of the drug. These individuals also received antibiotics.

The FDA is part of an interagency working group, together with NIH, CDC, DoD, and HHS, that is focused on encouraging the development of new generation recombinant anthrax vaccines intended to prevent inhalational anthrax both before and after exposure.

The genetic makeup of anthrax is being studied to help improve vaccines and treatments. FDA scientists are studying a weakened infectious strain of bacteria as a possible carrier to stimu-
Besides Cipro (ciprofloxacin), antibiotics approved by the FDA to treat anthrax include drugs in the tetracycline class such as doxycycline and some drugs in the penicillin class.

Smallpox: The last confirmed case of smallpox in the United States was in 1949, and the last naturally occurring case in the world was recorded in Somalia in 1977. The World Health Organization has declared the illness eradicated, but if one case were intentionally introduced, the result could be a public health emergency. Caused by the variola virus, smallpox is highly contagious and can be spread by close contact with a person who has smallpox symptoms—high fever, fatigue, headaches, backaches, vomiting, rash, and pus-filled blisters. There is no proven treatment. The death rate in the past was about 30 percent, and death rates can be higher for infants and young children.

Smallpox can be prevented through vaccination. Dryvax (smallpox vaccine, dried, calf lymph type), made by Wyeth Laboratories of Marietta, Pa., is the only smallpox vaccine currently licensed by the FDA. In October 2002, the FDA approved a license supplement for a 100-dose kit of Dryvax with a new supply of diluent, which is the liquid that’s mixed with dried vaccine before it’s administered. Before this supplement, Dryvax was only available for use in clinical investigations under an IND.

In December 2002, President Bush announced a voluntary national plan to contain a smallpox outbreak through vaccinating smallpox response teams across the country. These teams are made up mostly of health care workers. Part of the plan involved developing a national stockpile of the vaccine. The FDA’s work with manufacturers and the CDC has boosted the stockpile of investigational smallpox vaccine by hundreds of millions of doses. In addition, under CDC-sponsored INDs, the FDA has approved the use of various investigational smallpox vaccines. The FDA has also approved INDs for Vaccinia Immune Globulin (VIG), which is used to treat some rare but life-threatening complications of the smallpox vaccine. The FDA’s research laboratories have developed two new methods to test and monitor the strength of VIG preparations.

In the spring of 2003, the CDC and DoD reported several types of cardiac problems among some people who had recently received the smallpox vaccine. The FDA is working with other agencies on the ongoing evaluation of these events. Although it’s unknown if smallpox vaccine causes atherosclerotic cardiovascular disease, the Advisory Committee on Immunization Practices recommends that people with underlying heart disease or three or more known cardiac risk factors (hypertension, diabetes, and smoking, for example) not be vaccinated. Also, a link between the smallpox vaccine and inflammatory heart disease appears to be likely.

The FDA made appropriate changes to the Dryvax package insert to reflect these findings. Several smallpox vaccines that are related to the same vaccine strain used in Dryvax but grown in cell culture are being developed. FDA scientists are pursuing studies that may support development of safer smallpox vaccines.

Plague: Plague is caused by the bacterium Yersinia pestis. Bubonic plague is the most common type of naturally occurring plague. It is transmitted through the bite of an infected flea or
exposure through a cut. Symptoms of bubonic plague include swollen, tender lymph nodes, headache, fever, and chills. If untreated, bubonic plague may result in death.

In pneumonic plague, the lungs are infected with the plague bacterium. People with pneumonic plague can transmit plague to other people, whereas bubonic plague cannot be spread from person to person. Antibiotics approved by the FDA to treat plague are streptomycin, doxycycline, and other drugs in the tetracycline class.

The FDA has requested grant applications for clinical trials for plague treatments, and in conjunction with the CDC, the FDA is funding research on evaluating rapid diagnostic test kits for plague. The FDA, along with the NIH and DoD, has funded studies investigating the safety and effectiveness of gentamicin and other antibiotics for plague. There is no plague vaccine available in the United States. The originally licensed whole-cell plague vaccine is no longer being manufactured and there is no vaccine inventory remaining. Given the potential threat, the FDA is accepting applications for newly developed plague vaccines that could be licensed.

Nerve Agents: These chemical agents interfere with nerve function, causing paralysis, suffocation, and seizures. The FDA worked with the U.S. Army to approve pyridostigmine bromide for combat use to protect people in the military from soman, a nerve gas that can kill in 15 minutes. Evidence of pyridostigmine bromide's effectiveness was obtained primarily from studies in monkeys and guinea pigs. It was the first drug approved under the animal efficacy rule.

In January 2002, the FDA also approved ATNAA (atropine/pralidoxime) autoinjector to treat nerve gas intoxication. And in June 2003, the agency approved new dosage forms of AtroPen (atropine) autoinjectors for use in children and adolescents exposed to nerve agents.

Radioactive Contamination: Radioactive material could be introduced into the food or water supply or with explosives that spread radioactive materials.

In 2001, the FDA collaborated with the NIH to issue a final guidance applying to children and adults on the use of potassium iodide (KI) in radiation emergencies. When given in the recommended dose, KI reduces the risk of thyroid cancer in people at risk for inhaling or ingesting radioiodines. KI floods the thyroid with non-radioactive iodine and prevents the thyroid's uptake of radioactive molecules.

In September 2002, the FDA approved ThyroSafe Tablets (potassium iodide) as a thyroid-blocking agent for use in radiation emergencies. This drug underwent fast review, and the dosage form can be used in children because it's half the strength of formulations that were previously approved.

Normally, a drug or device company collects data on a new product and submits it to the agency. But in two instances, the FDA found the data on its own, and then called for manufacturers to submit applications. The first example is Prussian blue, a substance that has been used as a pigment for artists since 1704. The substance can treat people exposed to radioactive cesium or radioactive and non-radioactive thallium. Radioactive cesium could be used in a "dirty bomb" or other terrorist device. Prussian blue traps thallium or cesium in the intestine so that they can be passed out of the body in the stool rather than reabsorbed into the body. This reduces the amount of radiation in the body. In March 2003, the FDA received its first marketing application for Prussian blue in response to the agency's call for applications. On Oct. 2, 2003, this application was approved, giving the nation the first drug that can be used as a medical countermeasure to the threat of radioactive cesium.

The FDA also determined conditions under which pentetate calcium trisodium (Ca-DTPA) and pentetate zinc
# Examples of Medical Countermeasures

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Approved/Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redline Alert Test</td>
<td>Used with other tests to determine whether a person has anthrax disease.</td>
<td>Dec. 9, 2003</td>
</tr>
<tr>
<td>Reactive Skin Decontamination Lotion</td>
<td>Used by the military to remove or neutralize chemical warfare agents and fungal toxin from the skin.</td>
<td>March 29, 2003</td>
</tr>
<tr>
<td>Pyridostigmine Tablets</td>
<td>Treat soman nerve gas poisoning. First drug approved under the animal efficacy rule.</td>
<td>Feb. 5, 2003</td>
</tr>
<tr>
<td>HemCon Bandage</td>
<td>Temporary control of severely bleeding wounds. For military battlefield treatment.</td>
<td>Nov. 4, 2002</td>
</tr>
<tr>
<td>Smallpox Vaccine (Dryvax)</td>
<td>Prevention of smallpox infection. An amendment to the license for a 100-dose kit of Dryvax with a new supply of diluent and needles.</td>
<td>Oct. 25, 2002</td>
</tr>
<tr>
<td>ThyroSafe Tablets, 65 mg (potassium iodide)</td>
<td>Thyroid blocking agent for use in radiation emergencies. For adults and children.</td>
<td>Sept. 10, 2002</td>
</tr>
<tr>
<td>QuickClot</td>
<td>Emergency use as temporary treatment for wounds. For military use.</td>
<td>May 29, 2002</td>
</tr>
<tr>
<td>ATNAA (atropine/pralidoxime)</td>
<td>One injection of the two products, for poisoning by nerve agents.</td>
<td>Jan. 17, 2002</td>
</tr>
<tr>
<td>Nucleic Acid Amplification Assay for Anthrax</td>
<td>An assay that tests for presence of anthrax, made available under an investigational device exemption.</td>
<td>Dec. 21, 2001</td>
</tr>
<tr>
<td>Ciprofloxacin (Cipro)</td>
<td>Inhalational anthrax post-exposure in adults and children.</td>
<td>Aug. 30, 2000</td>
</tr>
<tr>
<td>Skin Exposure Reduction Paste Against Chemical Warfare Agents</td>
<td>Protecting skin from contact with chemical warfare agents (blister and nerve agents).</td>
<td>Feb. 2000</td>
</tr>
</tbody>
</table>

**Source:** FDA

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Sodium (Zn-DTPA) are safe and effective for treating certain kinds of radiation exposure. The agency then encouraged submission of new drug applications for these products. Ca-DTPA and Zn-DTPA are usually given intravenously, and have been used as investigational drugs for 40 years. The FDA determined the drugs can be safe and effective for treating internal contamination with plutonium, americium, or curium, substances that can be found in the fallout from the detonation of nuclear weapons and waste from nuclear power plants. Ca-DTPA and Zn-DTPA work by increasing the rate of elimination of these substances from the body.
Obesity rates have skyrocketed over the last 20 years, and the situation keeps getting worse. More than 60 percent of adults in the United States are overweight or obese, according to the Centers for Disease Control and Prevention (CDC). About 15 percent of children and adolescents are overweight. And the list of related health problems is long. People who are overweight or obese are at increased risk for high blood pressure, high cholesterol, diabetes, heart disease, certain cancers such as breast and colon, depression, and other illnesses.

FDA Commissioner Mark B. McClellan, M.D., Ph.D., says the current policies and advice to the public on obesity haven’t been effective enough. He is calling on researchers, the food industry, consumer groups, and the medical community to work with the FDA to tackle this epidemic. “Helping more Americans achieve a healthy weight is a major priority,” McClellan said at an FDA public meeting held on Oct. 23, 2003, at the National Institutes of Health in Bethesda, Md. "We want people to have good, clear information about the nutritional value of foods, and we want to protect them from false and misleading claims." McClellan noted that too many people are looking to dietary supplements as a quick fix for being overweight or obese. "Dietary supplements may help you lose weight, but they also pose health risks," he said.

The public meeting was sponsored by the FDA’s Obesity Working Group, which McClellan formed in August 2003 to develop strategies to help consumers lead healthier lives through better nutrition. The group is led by FDA Deputy Commissioner Lester Crawford, D.V.M., Ph.D.

The public meeting included FDA presentations and a public participation session, encouraged discussion on six main questions:
- What are the top priorities for nutrition research to reduce obesity in children?
- What is the available evidence that the FDA can use to guide effective efforts to prevent and treat obesity by behavioral and medical interventions?
- What changes to food labeling could result in the food industry developing healthier foods and in consumers selecting healthier foods?
- What research opportunities exist that might best support the development of healthier foods?
- What are the most important things that the FDA could do to make a significant difference in addressing overweight and obesity, based on the scientific evidence available?
- What are the available evidence on the effectiveness of education campaigns to reduce obesity?

The FDA’s Obesity Working Group is scheduled to complete a report that includes an action plan in February 2004. The action plan will set out specific means for developing and implementing new and innovative ways to help consumers make healthier choices. The working group is charged with developing a message and outlining an obesity education program to deliver the message.

The working group may craft approaches that propose improvements to the food label, increase collaborations with the restaurant industry to better inform consumers, facilitate development of more medical products to treat obesity, and identify research needs for producing healthier foods, as well as research to get a better understanding of consumer behavior and motivation.

Several organizations presented comments to the FDA at the meeting, including the American Obesity Association, which would like to see more focus on the treatment of obesity and stressed the importance of enforcement for fraudulent weight-loss products.

The Center for Science in the Public Interest suggested the use of a “healthy food symbol” that could make it easier for consumers to spot nutritious foods. The National Food Processors Association suggested the need for all stakeholders to refocus Americans’ understanding of the role of diet and exercise to achieve and maintain healthy weight.

Other participants included the International Food Information Council, the Girl Scouts of America, the Physicians Committee for Responsible Medicine, Shape Up America, and the Center for Consumer Freedom.

The FDA is reviewing public comments on obesity issues, which were due to the agency on Nov. 21, 2003. For more information, see www.fda.gov/oc/opacom/hottopics/obesity.html.
Pets occupy an esteemed place in many of our households, often being treated as members of the family. They offer a source of amusement, pleasure, and companionship. They provide opportunities for outdoor exercise and socialization. And, according to some studies, they can decrease our blood pressure, cholesterol levels, and triglyceride levels.

But along with the emotional rewards and health benefits of pet ownership also come health risks. Pets—and other animals—can give us diseases.

Regular vaccinations and veterinary care can help keep your pet healthy and keep it from transmitting infections to you.
Animal diseases that can be transmitted to humans are known as zoonotic diseases, or zoonoses. Some people are more likely than others to get zoonoses: the elderly, pregnant women, infants and children less than 5 years old, people undergoing treatments for cancer, people who have received organ transplants, and people with suppressed immune systems, such as those with HIV/AIDS.

If you fit into one of these categories, the Centers for Disease Control and Prevention (CDC) advises avoiding contact with certain animals that are more likely than others to carry diseases: reptiles (turtles, lizards, and snakes), baby chicks, and ducklings.

The list of zoonoses is long and continues to grow as people travel to more remote parts of the world and bring diseases back with them, and as animals that carry diseases are imported. The first human outbreak of monkeypox, a rare smallpox-like disease, occurred in the United States in May 2003. The disease was believed to have been brought into the country in April by a shipment of rodents and other small mammals imported from Africa. These animals infected prairie dogs being sold as pets, which in turn infected humans in close contact with the prairie dogs.

In June 2003, in response to the monkeypox outbreak, the Food and Drug Administration and the CDC banned the import of all African rodents, and the transport, sale, and release into the environment of prairie dogs and six species of African rodents. In November 2003, both agencies issued a new rule that clarifies and extends the import and transport restrictions for these animals. This interim rule, which is open for public comment until Jan. 20, 2004, gives an increased measure of protection to help prevent future outbreaks of monkeypox in the United States.

Even if people never leave the country or acquire a pet from further away than their local animal shelter, they may still be vulnerable to getting certain diseases from pets. Fortunately, the risk of getting a disease from your pet is small, and you can minimize the risk by practicing good personal hygiene, keeping pet areas clean, controlling disease-carrying insects, and getting regular vaccinations and veterinary care for pets.

Parasites, bacteria, fungi, and viruses are the culprits responsible for spreading many diseases from pets to humans.

Parasites, bacteria, fungi, and viruses are the culprits responsible for spreading many diseases from pets to humans. Some are more common and troublesome for pets and pet owners than others.

**Worms**

Worms, such as roundworms and hookworms, can infect dogs, cats, and some other animals. Worms can also infect people if they ingest the organisms or, in the case of hookworms—which can penetrate the skin—if they walk barefoot on infected soil.

Worms live in the intestines of animals and are expelled in animal feces, which can become contaminated from worm eggs that are passed in animal feces and hatch in the soil. If your animal has worms, get it treated and clean up after it promptly, advises Linda Wilmot, D.V.M., a veterinary medical officer in the FDA's Center for Veterinary Medicine (CVM). "Don't give the eggs that are passed in the feces time to hatch."

More than 90 percent of puppies are born with worms, says Wilmot. Mother dogs can pass worms to their puppies before birth and both dogs and cats can pass it to their offspring through their milk after birth.

Touching the stool or contaminated soil and then touching the mouth or handling food are common routes of transmission of worms to humans. Children are at risk for acquiring worms if they walk barefoot or play in the dirt where an infected dog has defecated or on the floor where a dog may have tracked in dirt or feces.

Hookworm larvae can cause painful inflammation in areas where they penetrate a person's skin and crawl just below the skin's surface. The larvae can also travel through the body, eventually reaching the small intestine. There they develop into half-inch-long worms, attach themselves to the intestinal wall, and suck blood.

Roundworms may also cause problems. "Between 5 percent and 20 percent of children have been infected by dog roundworm at some time in their lives," says Larry Glickman, V.M.D., Dr. P.H., a professor of epidemiology and environmental health at the

Parasites, bacteria, fungi, and viruses are the culprits responsible for spreading many diseases from pets to humans.
feces is one possible route of human Toxoplasmosis worms in the future. Help prevent your pet from getting treatments schedule. Your veterinarian can provide dewormers and beginning at two weeks of age. Your vet deworming drugs in dogs and cats be Veterinary Parasitologists advise using CDC and the American Association of cats and people. Guidelines from the able to destroy worms that infect dogs, Wilmot. FDA-approved drugs are avail the best defenses against worms, says Purdue School of Veterinary Medicine. In most cases, it never becomes apparent and doesn't need to be treated, he says. But in some cases, larvae migrate through the body and damage tissues and organs.

Just one roundworm larva has been known to damage the retina of the eye and cause blindness. Glickman developed an eye fluid test, used by some eye doctors and the CDC, to detect the dog roundworm in people's eyes so they can be treated before permanent damage sets in.

Prevention and early treatment are the best defenses against worms, says Wilmot. FDA-approved drugs are available to destroy worms that infect dogs, cats and people. Guidelines from the CDC and the American Association of Veterinary Parasitologists advise using deworming drugs in dogs and cats beginning at two weeks of age. Your veterinarian can provide dewormers and a treatment schedule.

Adult animals should have their stool tested at least annually by a veterinarian, who can also prescribe drugs to help prevent your pet from getting worms in the future.

Toxoplasmosis

Cats may be carriers of Toxoplasma gondii, a parasite causing the disease toxoplasmosis. Direct contact with cat feces is one possible route of human infection, but toxoplasmosis is more likely to spread to people through eating raw or undercooked meat. Food animals may become infected by grazing in fields or eating feed contaminated with cat feces. People can also get toxoplasmosis from gardening and accidentally ingesting soil where an infected cat has defecated. Wearing gloves while gardening and washing hands afterward are recommended.

Cats pick up the toxoplasma parasite by eating rodents, birds or other prey, undercooked meat, the feces of infected cats, or contaminated soil. Most cats infected with Toxoplasma don't show signs and don't need to be treated, but those that do get sick may be diagnosed with laboratory tests and treated with medications. The CDC estimates that more than 60 million people in the United States probably carry the toxoplasma parasite, but few become ill from it. Those who get sick may have flu-like symptoms such as swollen glands and muscle aches.

Pregnant women with cats in the household need to take special precautions because toxoplasmosis can cause miscarriage, premature births and birth defects.

Pregnant women and others with suppressed immune systems should avoid changing a cat’s litter box or, at a minimum, wear disposable gloves and wash their hands thoroughly afterward, says the CDC. Changing the box daily is recommended because it takes the toxoplasma parasite at least 24 hours to become infectious. It’s also possible to become infected by inhaling the dried feces, so seal the waste in a plastic garbage bag for disposal. Cover children's sandboxes when not in use to prevent contamination from cat feces.

Antimicrobial drugs are available to treat people who become infected with toxoplasmosis.

Salmonellosis

Salmonellosis is a disease caused by the bacterium Salmonella. People usually get salmonellosis by eating contaminated food, such as undercooked meats or eggs. But Salmonella can also be transmitted to people through pets, particularly reptiles, baby chicks, and ducklings, which commonly pass the organism in their feces.

Most, if not all, reptiles carry some Salmonella in their intestinal tract, says Scott Stahl, D.V.M., owner of Stahl Exotic Animal Veterinary Services in Vienna, Va., and past president of the Association of Reptilian and Amphibian Veterinarians. Stahl says he and other reptile veterinarians have stopped testing the animals for Salmonella. “They tend to intermittently shed the organism, so a fecal culture may be a false negative,” he says, giving the reptile owner a false sense of security. Once the bacteria are shed in droppings, Salmonella may be found on the reptile’s skin, its cage, the floor, and any other surface the animal touches.

Since Salmonella are part of a reptile’s normal bacteria and cannot be eliminated from its intestinal tract, people need to practice good hygiene around...
Children are enchanted by face-to-face encounters with animals in public settings. But their fascination can fade quickly if the animal gives them a disease.

“In the past few years, we’ve seen numerous outbreaks of disease among persons visiting petting zoos, farms and county fairs,” says John Dunn, D.V.M., Ph.D., an epidemiologist at the Centers for Disease Control and Prevention (CDC).

Infections in people, particularly children, have been linked to venues where they had hands-on contact with animals. One of the largest outbreaks occurred in 2000 among school groups and families that visited a dairy farm in Worcester, Pa. Fifty-one people reported symptoms that included bloody diarrhea, fever, and vomiting within 10 days of their visit. While none of the infected people died, 16 needed to be hospitalized, including one child who required a kidney transplant.

The illnesses, caused by a strain of the bacterium Escherichia coli (E. coli), arose from nail-biting, eating food, or other manners of touching the mouth with hands after petting the animals, according to the CDC. This and similar incidents prompted the CDC to publish federal safety guidelines for operators of events and facilities that offer public contact with farm animals. The guidelines recommend providing hand-washing facilities with soap and disposable towels, posting information about diseases that can be contracted from animals, and prohibiting human food in the interaction area.

“We’re not advocating that people don’t interact with animals,” says Dunn. “We want to emphasize hygiene and education; people should be informed that there is some risk when handling animals, especially when eating afterwards without washing their hands.”

Ringworm

Ringworm is not caused by worms, but by several different types of fungi. People can get this skin and scalp disease just by touching the skin or fur of an infected animal, typically a cat, which holds the fungal spores. Ringworm can also infect dogs, ferrets, horses, rabbits, guinea pigs and other animals.

Signs of the disease can be “virtually invisible” in some cats and dogs, says Wilmot, but they can still transmit the disease to people. Others will lose patches of fur or hair, exposing bare skin with a lesion that is sometimes ring-like and itchy. Ringworm in people may show itself as a ring-shaped, reddish, itchy rash that can be dry and scaly or wet and crusty.

Keeping animal areas clean will help prevent ringworm, since the disease-causing fungi grow in dirt and contaminated bedding. In addition to contracting it from animals, people can also get ringworm from contact with other infected people or their personal items.

Topical and oral medications may be used to treat ringworm in people and pets.

Cat-Scratch Disease

The CDC estimates that more than 20,000 people in the United States get cat-scratch disease (CSD) each year. Most cat scratches don’t develop into CSD, but those that do may cause fever, fatigue, headache and swollen lymph glands.

The bacteria believed to cause CSD may be transmitted by fleas. About 40 percent of cats carry the infectious bacteria at some time in their lives, according to the CDC. Many do not show signs of illness, but some develop fever, lethargy, swollen lymph glands, inflamed eyes and gums, and neurological disease, requiring treatment by a veterinarian. Cat owners should use a good flea control, keep cats’ claws trimmed short, and discourage rough play to prevent scratches and bites. If you are bitten or scratched, wash the area immediately with soap and water. Do not let cats—or any animal—lick open wounds on your body.

Rabies

Rabies, a deadly viral disease that infects the brain and spinal cord in animals and people, is transmitted through the saliva of a rabid animal, usually by a bite. Vaccines to help prevent rabies are available for dogs, cats,
horses, ferrets, and some farm animals. Pet owners should keep their pets' vaccinations, including rabies vaccinations, up to date. Vaccines for animals are licensed by the U.S. Department of Agriculture (USDA) and vaccines for people are approved by the FDA.

The number of rabies cases in domestic animals has steadily declined since animal control and vaccination programs began in the 1940s. Today, domestic animals account for less than 10 percent of the reported animal rabies cases. The number of cases in wild animals, however, has increased. Rabies is frequently found in raccoons, skunks, bats, and foxes.

People and pets should avoid contact with wild or unfamiliar animals. If you are bitten, immediately wash the wound with soap and water; clean the bite by allowing the wound to bleed, and get medical help at once. If a pet is bitten by a wild animal, seek veterinary assistance immediately.

After a person has been exposed to rabies, rabies immune globulin (proteins that function as antibodies) and the first of five doses of vaccine must be given promptly. The remaining four doses are given over a 28-day period. This regimen works by stimulating the immune system to produce antibodies that neutralize the rabies virus before it causes the actual disease. By the time symptoms appear, it is too late for this treatment, and the disease is almost always fatal.

According to the CDC, no one in the United States has developed rabies after being exposed to it when the vaccine was given promptly. Unlike the older rabies vaccines, which were painful injections in the abdomen, today's rabies vaccines are relatively painless and can be given in the arm.

Adults should supervise young children to make sure they wash their hands thoroughly with running water and soap after contact with animals.

Flea- and Tick-borne Diseases

Fleas and ticks are responsible for a number of diseases in pets and people. Some types of ticks, for example, can transmit the bacteria that cause Lyme disease to animals and humans. Fleas can harbor tapeworm larvae, which grow into adult tapeworms in the intestines of pets or people who may swallow the infected fleas.

Owners of pet rodents should avoid exposure to their droppings and should periodically disinfect rodent habitats while wearing gloves and washing hands afterward. Traps should be used to rid the house and property of wild mice and rats. Make sure to tell your doctor if you or your child has flu-like symptoms and has had recent contact with rodents.

Mycobacteria

Fish and the water they live in can harbor bacteria that may cause illness in people. Mycobacterium is one of the main infectious germ families associated with fish and aquarium water. A
BARF and Bacteria

There is a growing trend on the part of pet owners to feed pets a diet that includes raw meat and bones, typical of what animals in the wild would eat. For dogs and cats, these diets are often referred to as BARF—bones and raw food, or biologically appropriate raw food.

"The FDA believes that feeding raw meat diets to pets is not consistent with its goal of protecting the public from significant health risks," says William Burkholder, D.V.M., Ph.D., the Food and Drug Administration's pet food specialist. In addition, he says, raw meat and bones do not have all the required nutrients that a pet, for example, a dog, needs on a daily basis.

But in recognition of owner preferences and the popularity of these diets, the FDA has published draft guidelines to manufacturers of pet foods that contain raw meat or other raw animal tissues for dogs, cats, and other pets as well as captive animals that are not pets (such as zoo animals). The guidelines give recommendations on manufacturing practices and labeling to protect pet owners and pets from risks involving food safety and nutritional deficiency.

Pet owners who feed raw meat and bones should handle these products very carefully to avoid bacterial contamination, says Burkholder. Just as when preparing raw foods for humans, use hot water and soap to wash hands, utensils, containers, and surfaces that come into contact with the food. Don't put your hands near your mouth until you've washed them, and don't allow your pet to lick your face right after it has eaten raw meat.

Pets may also contract an infection from raw meat. "Vomit and diarrhea are potential sources of infection for humans," says Burkholder. "If your animal gets sick, wash your hands after cleaning up."

If owners choose to feed bones to their pets, they should supervise their pet when it is chewing on bones, he adds. "If the pet consumes a big chunk of bone that won't pass through the digestive system, it could perforate the gastrointestinal tract, which is life-threatening for the pet. Owners would need to seek immediate veterinary care."

Psittacosis

The bacterium Chlamydia psittaci is the cause of a common bird disease, psittacosis. The disease is also called parrot fever because of its frequent occurrence in parrot-type birds—especially cockatiels and parakeets. Some birds may get sick from it, while others show no signs of illness. Bacteria from infected birds are found in their droppings and nasal discharges, and people can become infected by inhaling the dried droppings and secretions.

People exposed to birds with psittacosis should see a health care provider if they develop flu-like symptoms such as fever, chills, headaches, muscle aches, or dry cough. Left untreated, psittacosis can develop into pneumonia and other health problems. Antibacterial drugs are used to treat the disease in birds and people.

To help prevent transmission of psittacosis, Victoria Hollifield, D.V.M., of Best Friends Veterinary Hospital in Derwood, Md., recommends that people not allow birds to peck around the mouth area, or to fly around the house, particularly in eating or food preparation areas. Hand washing after contact with birds and wearing a dust mask and gloves when cleaning the cage are also good precautions. "The inhalation of particles is what's so potentially dangerous to us," says Hollifield, "and when you are scrubbing out the cage you tend to push a lot of those particles into the air."

Getting regular veterinary checkups for all pets is important, but it's especially critical for birds, says Hollifield. Being flock animals, birds will hide their signs of illness. "If they show that they're weak, the other birds will push them out," says Hollifield. "By the time you see a bird acting or looking like it's sick, it's probably been sick a long time and it's probably very sick at that point."

Hollifield advises pet owners to get birds and other pets from a reputable source who can produce documentation to show that the animal has been tested for certain diseases. This is particularly important for exotic pets, says Hollifield, who sees hedgehogs, chinchillas, and even tarantulas in her veterinary practice. She advises people to think carefully before getting an exotic pet, and never take in an exotic animal caught in the wild. They are more likely to carry parasites and become sick in captivity.

"I think pets are a wonderful part of our lives, and especially beneficial to children," says Hollifield. "But we know more about domesticated animals and are better equipped with vaccines and knowledge to make these safe pets. It is a safer choice to select a domesticated animal for a pet."

For More Information

CDC Web site for animal/human health risks
www.cdc.gov/healthypets
A Pap smear has long been a part of a woman’s routine health care. The Pap can detect cell changes that may lead to cancer of the cervix, the lower part of the uterus, or womb. Women age 30 and older can now opt to get an additional test along with their Pap smear to increase the odds of detecting abnormal, or precancerous, cells before they turn into cervical cancer. This test checks a sample of cervical cells for the presence of the genetic material (DNA) of human papillomaviruses (HPVs).

“One of the high risk factors for having cervical cancer is a persistent HPV infection,” says Thomas Simms, a Food and Drug Administration biologist who evaluated the HPV DNA test. “Greater than 95 percent of cervical cancers have detectable HPV DNA in them.”

In March 2003, the FDA approved the HPV DNA test to be used simultaneously with the Pap test to screen for cervical cancer in women age 30 and older. The Hybrid Capture 2 High-Risk HPV DNA, made by Digene Corp. of Gaithersburg, Md., was initially approved in 2000, but only as a follow-up test for women who had abnormal or inconclusive Pap tests.

The Tests and What They Mean
A woman who visits her doctor to have a Pap test may be offered the HPV DNA test as well. “A woman 30 years and older has an option to choose to have the HPV testing,” says Noel Del Mundo, M.D., an FDA gynecologist. Women who have both the Pap and the HPV DNA tests performed will not notice any difference in the procedure. The doctor will collect cervical cells for both tests at the same time by gently rubbing the surface of the cervix with a special collection device. The cells will then be sent to a laboratory for analysis.

If both the Pap and the HPV DNA test results are negative, a woman’s doctor may advise her to wait for three years before being retested, according to guidelines from the American College of Obstetricians and Gynecologists (ACOG). But more frequent testing is recommended if other high risk factors are present, such as a weakened immune system or a history of cervical cancer.

If only one of the tests is negative, the doctor may advise the woman to return for retesting in six to 12 months. But if the Pap smear shows a mild cellular abnormality (called atypical squamous cells of undetermined significance, or ASC-US), and the HPV DNA test is positive, the doctor may recommend further tests. "HPV DNA testing for women with mild cellular abnormality will help the physician determine whether the patient should have a colposcopy and biopsy," says Del Mundo.
In a colposcopy, the doctor looks for a lesion on the cervix with a special magnifying instrument called a colposcope. If a lesion is found, the doctor will take a biopsy, in which a sample of the lesion is removed to check it for precancerous cells.

The FDA cautions that, while a positive HPV test can provide useful information for a woman and her doctor, it does not necessarily mean that she will develop cervical cancer. And although negative Pap and HPV test results indicate a very low risk (0.2 percent) for developing cervical cancer, that doesn’t mean that changes won’t occur. Infections or changes in cells may arise in the future, so continued screening is important.

Although the HPV DNA test in conjunction with the Pap test is not advised for women under age 30, these women should still get annual Pap tests, according to ACOG guidelines. The first screening for cervical cancer should occur about three years after a woman has her first sexual intercourse, but no later than age 21.

All women, regardless of negative test results, should still visit their doctors yearly for a pelvic examination, which includes checking the reproductive and other organs for abnormality in shape or size.

**HPVs are Common**

There are more than 100 types of HPV, according to the American Cancer Society (ACS). Some of them cause the noncancerous warts that typically grow on the hands or the bottom of the feet.

Other types of HPVs are sexually transmitted. Some cause wart-like growths on or around the genitals and anus of both men and women, but these visible external warts have not been linked with cancer. Other HPVs cause visible warts in the cervix, but because they rarely develop into cancer, they are often referred to as “low-risk” HPVs. But still other types of HPVs have been linked with cancer. These “high-risk” HPVs aren’t usually found as visible warts. Both high-risk and low-risk types can cause the growth of abnormal cells in the cervix. The HPV DNA test can detect the presence of 13 HPVs that are associated with a high risk of cervical cancer.

Sexually transmitted HPV infections are very common. Fortunately, it is very rare for an HPV infection to lead to cervical cancer. This is especially true for women under 30, who have a relatively high rate of HPV infection but rarely develop cervical cancer, says Simms. The HPV DNA test was approved for women age 30 and older because of the higher risk of cervical cancer in this age group. "Women over 30 have fewer HPV infections, but if they develop a persistent HPV infection, it can eventually lead to precancerous changes in the cervix," says Simms.

According to the ACS, most people will not know that they have HPV because it usually goes away on its own. "Most HPV infections are detected only transiently—the body’s immune system clears signs of the infection," says Laura Koutsky, Ph.D., professor of epidemiology at the University of Washington in Seattle. "Currently, it is not known if the virus clears in most women or only a few women," she says. "Regardless, if the virus is no longer detectable, a woman’s risk for cancer appears to be very low."

Because HPVs can be sexually transmitted, a positive HPV DNA test result may be troubling to women and their partners. But testing positive for HPV does not necessarily mean that the virus was contracted recently, says Koutsky. "You or your husband or partner may have contracted the virus many, many years ago," she says. "Keep in mind that current estimates indicate that more than 50 percent of sexually active adults have been infected with HPV."

**Regular Screening Is Important**

The ACS estimates that in 2003, more than 13,000 new cases of invasive cervical cancer will have occurred in the United States, resulting in 4,100 deaths from the disease. The rates of death from cervical cancer for several racial and ethnic groups, such as Hispanics and American Indians, are higher than the national average. And for blacks, the death rate is more than twice the national average.

The National Cancer Institute reports that regular Pap screening does reduce deaths from cervical cancer. Women who have not been screened face a significantly greater risk of developing the disease. With regular screening and follow-up care, cervical cancer is avoidable, and, if caught early, curable.

**For More Information**

National Cancer Institute
Cervical Cancer Home Page
[www.cancer.gov/cancerinfo/types/cervical](http://www.cancer.gov/cancerinfo/types/cervical) (800) 4-CANCER (800-422-6237)
TTY: (800) 332-8615

American Cancer Society
Cervical cancer page
[www.cancer.org](http://www.cancer.org) (click on "choose a cancer topic," then "cervical cancer") (800) ACS-2345 (800-227-2345)

American Social Health Association
National HPV and Cervical Cancer Resource Center
[www.ashta.org/hpvccrc](http://www.ashta.org/hpvccrc) (877) HPV-5868 (877-478-5868)
Take the FDA Consumer QUIZ

Do you know what the FDA is doing to safeguard the public from terrorist threats? Is it a good idea to get an ultrasound image to add to your baby’s scrapbook? Is it possible to catch an illness from your pet? To find out how much you know about these and other health-related topics, take our quiz.

Hint: The answers to all these questions can be found in the January-February 2004 issue of FDA Consumer (and at the bottom of this page). Good luck!

1. How much of the U.S. food supply comes under FDA regulations?
   a. 20 percent
   b. 50 percent
   c. 80 percent
   d. 100 percent

2. In what year was the last confirmed case of smallpox reported in the United States?
   a. 1932
   b. 1949
   c. 1964
   d. 1972

3. About what percentage of children and adolescents are overweight?
   a. 5 percent
   b. 10 percent
   c. 15 percent
   d. 25 percent
   e. 50 percent

4. Which pets normally carry some Salmonella in their intestinal tract?
   a. Dogs and cats
   b. Ferrets and chinchillas
   c. Lizards and snakes
   d. Horses
   e. Parrots and other birds

5. Ringworm is caused by:
   a. Microscopic worms
   b. Worms visible to the naked eye
   c. Worms that move in a circular motion
   d. Several different types of fungi

6. How many cases of cat-scratch disease occur in the United States each year?
   a. About 5,000
   b. Less than 10,000
   c. More than 20,000
   d. About 40,000

7. A bacterial illness that can be transmitted through the bite or scratch of a rodent or by ingesting food or water contaminated with rodent feces is called:
   a. Rodentia bacillus
   b. Rat-bite fever
   c. Rat-scratch fever
   d. Rodentitis

8. How many deaths in the United States (estimated) could be attributed to cervical cancer in 2003?
   a. Less than 5,000
   b. More than 5,000
   c. More than 10,000
   d. More than 25,000

9. The procedure in which a doctor looks at the cervix for abnormal cells through a special magnifying instrument is called:
   a. Biopsy
   b. Colposcopy
   c. Pelvic exam
   d. Cryotherapy
   e. Endocervical curettage

10. Ultrasound imaging generally is considered safe when:
    a. The expectant mother waits to have it done until she’s six months pregnant
    b. Important medical information is needed about the health of an unborn baby or its mother
    c. Family members are sure there is no risk involved
    d. It is performed in the first trimester of pregnancy

Answers
Clinical Trials Web Site Reaches Landmark

For three years, the National Institutes of Health has operated ClinicalTrials.gov (http://clinicaltrials.gov), an Internet data bank providing reliable information about ongoing studies of drugs and biological products regulated by the FDA. Now the site has posted its 1,000th clinical study sponsored by the private sector, a milestone FDA officials call “significant” because it complements agency goals to make critically important public health information available to patients and improve access to promising new therapies. Clinical trials are conducted to evaluate the safety and effectiveness of new drugs, medical procedures, or other means of treating, diagnosing or preventing diseases.

All told, ClinicalTrials.gov lists about 9,000 federally and privately sponsored trials. Most of these are being conducted in the United States and Canada, but the site includes studies underway in 90 other countries.

Visitors to ClinicalTrials.gov can pinpoint information on the location of clinical trials, trial design and purpose, and how to participate. The site allows browsing by condition or by sponsor, and it functions as a gateway to other clinical trial information. It also contains a short course in clinical trials.

Arthritis, Muscle and Skin Information—En Español

As part of its efforts to serve a growing population of Spanish-speaking consumers, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has launched En Español, a Web site with vital information about research and health education on arthritis, rheumatic diseases and disorders of bone, skin, muscle, and connective tissue.

Many of the conditions covered on the site—lupus, arthritis and osteoporosis, for example—are chronic and can cause lifelong pain and disability. NIAMS considers outreach to the Hispanic/Latino community important because these conditions affect minorities and women disproportionately, both in increased numbers and increased severity of the diseases.

At www.niams.nih.gov/index_espanol.htm, En Español also has links to dozens of helpful publications available either online or by mail and lists of contacts for questions about grants or clinical trials.

Other Spanish-language information related to the federal government is available from FirstGov at www.firstgov.gov/Espanol/index.shtml.

A Checklist for Using Home-Based Medical Devices

People who are ill or have disabilities frequently must use home-care medical devices to help them cope with and treat their disorders. Device examples include wheelchairs, ventilators, blood glucose meters, and blood infusion pumps. Patients using these devices, or their care providers, may need training or other health care-related services to use and maintain their devices safely and effectively in their homes or elsewhere, such as at work or school.

To help patients get the most out of their home-care medical devices, the FDA’s Center for Devices and Radiological Health has created an online brochure containing a checklist covering all aspects of device operation.

For example, the brochure cautions that users should know as much as they can about how the device works. Users then can check off tips such as “read the patient education information,” “keep instructions for use close to your device,” or “pay attention to what the alarms and error messages mean.”

Other topics covered in the brochure include:
• backup plan and supplies
• family and caregiver education
• keeping children and pets away from devices
• reviewing your condition often with your doctor
• reporting any serious injuries, deaths, or close calls.

You can check out the checklist at www.fda.gov/cdrh/cdrhhhc/brochure-checklist.html.

‘Uncle Sam’ Eases Form Frustration

Sure, it’s happened to you before: You need a specific form to submit for a government service and you just can’t lay your hands on it. Well, Uncle Sam, a site maintained by the University of Memphis, aims to end your frustration. It contains a list of the most requested government forms that can be downloaded.

What’s on the list? Here’s a sample of participating agencies and departments:
• Patent and Trademark Office
• U.S. Postal Service
• Social Security Administration
• State tax organizations
• Treasury Department (for savings bonds forms, among others)
• State Department (for passport applications).

The site, at www.lib.memphis.edu/govpubs/forms.htm, also includes a link to the FDA’s “Public Use Forms” catalog, which offers forms for many FDA programs.

John Henkel is a member of the FDA’s Website Management Staff.
Life without animals, either in the wild or as pets, is nearly impossible to imagine. Think of a sky without birds, a forest without bears or deer, a sea without fish, or—for many of us—a home without a dog or cat or bird.

Some of us, such as farmers, veterinarians, or dog breeders, build our working lives around animals. But animals mean so much more than just a job or a business to so many of us. Animals will capture the interest of a small child and make adults feel healthier and more at ease. That could be why so many of us own pets.

Recent surveys have reported that Americans care for about 77 million pet cats. In addition, there are more than 43 million dog owners—and 65 million dogs—in the United States. Birds, fish, rabbits, ferrets, guinea pigs, hamsters, gerbils, and reptiles of various sorts are also popular.

Some studies have indicated what all those pet owners already know intuitively—that people enjoy health benefits from the human-animal bond. It seems that pets can help people lower their blood pressure or cope with AIDS. Senior citizens and children receive enormous comfort from the companionship of pets.

Living with animals has many benefits, but to enjoy those benefits we also have to accept the responsibility for keeping the animals healthy. That’s where the Food and Drug Administration plays a significant role. The focus of the FDA’s Center for Veterinary Medicine is animal health.

CVM reviews animal drugs before they can be marketed and after they are on the market to be sure that the drugs are effective and safe for the intended animal, a task that takes the talents of veterinarians, animal scientists, chemists, biologists, microbiologists, pharmacologists, toxicologists, statisticians, and epidemiologists. The center reviews all drugs that are intended for use in animals, whether a food-producing farm animal or a household pet.

CVM scientists will take that extra step to ensure animal safety. For instance, the center recently approved a drug to sterilize male puppies. It’s a chemical alternative to surgical castration. CVM first determined that the product would work effectively, and that it could be used in a way that was safe for the puppies, but did not stop there. The reviewers realized that in actual use, veterinarians would have to use the proper injection technique to prevent injury to the puppy. Veterinarians would have to be taught the proper technique. To address that concern, the company developed training material for veterinarians, including a videotape that showed correct injection techniques.

The center monitors reports of adverse effects from the use of animal drugs on the market. If problems are discovered, CVM can require companies to send “Dear Doctor” letters to veterinarians to inform them of risks that have been identified, or to provide client information sheets so that pet owners clearly understand the risk and benefits of a product. For example, Pfizer Inc. responded to the center’s request to develop a client information sheet for dog owners who give their dogs Rimadyl, a pain relief medicine. The drug is effective, but veterinarians and owners must be cautious using it. The client information sheet was written so that dog owners know what side effects to look for.

The center also has responsibility for the safety of livestock feed and pet food. If a problem is reported with pet food, the FDA investigates, and the center determines the cause and the seriousness of the problem. CVM also develops guidance on special diets, such as the raw meat diets that some dog specialists are recommending.

The FDA gives this much attention to the health of animals because we owe it to the animals in our care. But also, the health of animals is important for the health of people. As the article in this issue of FDA Consumer points out, sick animals can transmit diseases to humans, so keeping an animal healthy can also help keep humans healthy.

But, perhaps more important, animals and humans often develop strong bonds of affection and companionship. It’s in our nature to protect what’s important to us, so it’s important to protect the health of our animals.

Stephen F. Sundlof, D.V.M., Ph.D., is director of the FDA’s Center for Veterinary Medicine.
STEROIDS
DONT’PUMP
TROUBLE

HEART DISEASE
LIVER CANCER
DEPRESSION
STUNTED HEIGHT
EATING DISORDERS
RISK OF HIV
HOSTILITY AND AGRESSION
ACNE

Department of Health and Human Services
Food and Drug Administration