



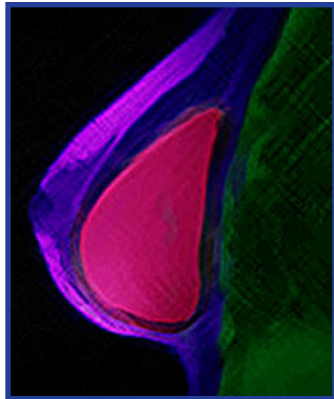
# FDA & YOU

## News for Health Educators and Students

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### Teens and Breast Implants



Breast implant surgery is a growing trend among teenaged women. According to the American Society for Aesthetic Plastic Surgery (ASAPS), women 18 and under accounted for 11,326 breast implant surgeries performed in American women in 2003, compared to 3,872 in 2002.

Despite more than a decade of controversy over their safety, breast implants are more popular than ever among women who want to build upon what nature gave them or who want to restore what disease has taken away. Whatever the reason, opting for breast implants is a personal decision that should be made only after a woman fully understands and accepts the potential risks of the devices and the importance of follow-up evaluations with her doctor. Because it has not been well studied in young people, FDA discourages the use of any breast implant in a patient younger than 18.

Breast implants are designed to change the size and shape of the breast (augmentation), to rebuild the breast (reconstruction), and to replace existing implants (revision). There are two primary types of breast implants: saline-filled and silicone gel-filled. Depending on the type of implant, the shell is either pre-filled with a fixed volume of solution or filled through a valve during the surgery to the desired size. Some allow for adjustments of the filler volume after surgery. Breast implants vary in shape, size, and shell texture.

At this time, there are two manufacturers with approved saline-filled breast implants. No manufacturer has yet received FDA approval to market a silicone gel-filled breast implant for augmentation.

Health officials worry that teens and their parents may not realize the risks associated with breast implants. They also want to be sure that the teen's body has finished developing and that they are psychologically ready to handle the outcome of surgery. While every surgical procedure has potential risks, such as infection, bleeding, and scarring, there are risks that are specific to breast implants. Learning about them is key to being properly informed about the procedure.

"I didn't know my breasts were still growing when I signed up for the surgery," admits Kacey Long, who got saline-filled breast implants in July 2001, when she was 19. Prior to her surgery, the college student from Ennis, Texas, was a 34B, the breast size she thought she would be for life.

Teenagers who are dissatisfied with their bodies see breast implants as harmless and, according to Long, a fun thing to do to improve self-image. Following implantation, Long's breast size increased to a 34D. But complications convinced her to have the implants removed a short time later. Three years later, Long's breast measure 36C - one size larger than before she was implanted - suggesting that her own breasts continued to develop even after the implants were removed.

Many of the changes to the breast that occur with an implant cannot be undone. If a teen chooses to have her implants removed, she may experience dimpling, puckering, wrinkling, or other cosmetic changes. "When you're making a decision that can impact your life at 19," Long advises other young women, "you need to research the subject like you're 50 years old."

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Consumers can get a copy of the "FDA Breast Implant Handbook 2004," which provides in-depth information on both saline and silicone breast implants, by visiting <http://www.fda.gov/cdrh/breast-implants>.

Consider these Breast Implant Facts:

- Breast implants will not last a lifetime. Either because of rupture or other complications, you will likely need to have the implants removed.
- Your breast may not be fully developed and could continue to grow larger, even after implant surgery.
- You are likely to need additional doctor visits and operations because of one or more complications over the course of your life.
- You are likely to have the implants removed, with or without replacement, because of one or more complications over the course of your life.
- Many of the changes to your breast following implantation may be cosmetically undesirable and can't be undone.
- If you choose to have your implants removed, you may experience unacceptable dimpling, puckering, wrinkling, loss of breast tissue, or other undesirable cosmetic changes of the breast.

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## FDA Makes a Change to Tampon Labeling

You may notice a change in the absorbency labeling of tampons in the near future.

FDA has issued a final rule to revise its tampon labeling regulation to change the current term for tampons that absorb 6 grams (g) of fluid or less. A tampon with an absorbency of 6 g or less is currently labeled as "junior". FDA is changing the term "junior" to "light".

FDA believes consumers may think the term "junior" means that the tampon is only for teenaged women, when it may be appropriate for women of any age with light menstrual flow. Women are encouraged to use the lowest absorbency tampon appropriate for their flow to help minimize the risk of Toxic Shock Syndrome (TSS). FDA requires the use of standardized terms for the labeling of tampons to allow women to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles. This final rule is being issued to ensure that labeling of tampons is not misleading.



## The Trouble with Tiny Turtles: A Look at Reptile-Related Salmonella



The case of a 4-year-old Kansas girl who likely got salmonella poisoning (salmonellosis) from three small turtles her mother bought while vacationing in Wisconsin has once again put the spotlight on reptile-related salmonella.

### Exotic Pets

In a 2003/2004 survey, the American Pet Products Manufacturers Association reported that Americans own an estimated 9 million reptiles. Because the

most popular species will not breed if closely confined, most reptiles are captured in the wild or hatched at reptile ranches and imported. The U.S. is a major importer of live reptiles for the pet industry. According to the U.S. Department of Agriculture (USDA) about 2 million live reptiles were imported into the U.S. annually from 1990-1999.

But what many animal lovers don't know is that with these imported pets come exotic forms

of salmonella bacteria that can cause life-threatening illness in humans.

Recently, federal health officials and several states began taking action against the illegal sale of pet turtles with shells less than four inches long.

"Many parents do not know that owning [a reptile] puts their children at risk for salmonella infection," say researchers from the national Centers for Disease Control and Prevention in Atlanta.

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Even in homes where young children and infants are not permitted to touch or come in contact with the animals, they may still become infected, according to a study published in the March 1997 issue of the *Journal of Pediatrics*.

**What Is Salmonella?**

Salmonella is the genus name of a group of bacteria commonly associated with food poisoning from contaminated or undercooked foods, and salmonella poisoning (salmonellosis) is the disease the bacteria can cause. In food-related cases, most people suffer from gastroenteritis, often experiencing vomiting, fever, diarrhea, and cramps. For high-risk individuals, such as those with weakened immune systems, those taking antibiotics, pregnant women, the elderly, and children under 5, salmonellosis may be even more devastating, leading to blood infections, meningitis, abortion, and death.

In a case reported by the New York Health Department in 1995, a pregnant woman with fever and diarrhea went into preterm labor and delivered a baby who died 12 hours later. Follow-up blood samples of mother and child, in conjunction with samples from the family's pet iguana, tested positive for the salmonella strain associated with reptiles.

"Like most other reptiles [including turtles], carry salmonella in their intestinal tracts," says Patrick L. McDonough, Ph.D., assistant director of bacteriology at Cornell University's College of Veterinary Medicine in New York. "The bacteria are 'shed' periodically in the animals' feces, and that's how the bacteria gets on the animals' skin, their cages, and other materials they touch."

An surge of cases at Cornell University since 1993 has prompted officials to warn owners that good hygiene is essential to prevent the spread of salmonella.

"Wash your hands with warm, soapy water immediately after handling [reptiles] or their cage litter, and before touching food or anyone else," McDonough says. He adds that while researchers once believed salmonellosis was transmitted primarily through direct contact with reptiles, it is now known that the bacteria need only be present on surfaces or on the hands of others to infect individuals indirectly.

In one such case, 20 patients were diagnosed with the disease within eight days of visiting a Komodo dragon exhibit at a Colorado zoo. According to Joseph Madden, Ph.D., strategic manager for microbiology at FDA's Center for Food Safety and Applied Nutrition, zoo officials believe that the dragons had, while being moved to their cages, licked several handrails at the zoo, and those areas were then touched by zoo visitors who subsequently ate lunch without washing their hands.

**An Outbreak Revisited**

In the early 1970s, FDA banned the distribution and sale of baby turtles with shells 4 inches in length or less after a quarter million infants and small children were diagnosed with having turtle-associated salmonellosis. The agency believed that turtles larger than 4 inches did not pose the same threat since children would not likely try to fit them into their mouths. CDC estimated that in 1973, pet turtles accounted for 14 percent of the salmonella-caused illnesses in the United States.

But the FDA-imposed ban allows for some exceptions. Turtles can still be exported to other countries and sold to experts for bona fide scientific, educational and exhibition purposes. Selling turtles to pet stores is not considered a bona fide purpose.

Janet McDonald, a public affairs specialist with FDA's San Francisco district office, believes that since the turtle issue is so old, people have forgotten that they are still illegal in the United States.

"We're still seeing sales of baby turtles and iguanas at flea markets and street fairs, and owners need to be aware that these pets can transmit disease, particularly to very young children because of their hand-to-mouth activity," she said. "The sale of reptiles is definitely on the rise."

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*Tiny Turtles - Continued from page 3*

Darrell Lee, an FDA computer expert who works with McDonald, saw firsthand that the sale of baby turtles is "a very brisk business" on a recent visit to Oakland's Chinatown. According to Lee, children were peddling turtles and their cages at a rate of five every 15 minutes.

But some public officials and responsible members of the scientific profession now believe that educating people, rather than regulating reptiles, is more effective in controlling the spread of salmonella infection. According to several state health departments, there has been considerable effort to educate pediatricians, hospitals, clinics, and pet shop owners.

**Be Sensible**

Salmonellosis, from any source, is not a disease to be taken lightly. The bottom line in deciding whether a reptile is right for your family, suggests veterinarian Douglas R. Mader of Long Beach, Calif., in his 1993 report on reptile medicine, is first to consider the ages and overall health of your loved ones. Then, if you decide to go ahead and get a pet reptile, consistently practice meticulous hygiene. Because young children are at increased risk for reptile-associated salmonellosis and severe complications, reptiles may not be appropriate pets in households where family members are younger than 5 years, or are at increased risk for infection.

To put the problem of salmonella infection in perspective, Mader says that if good hygiene is practiced, veterinarians, veterinary staff, and reptile owners are at a greater risk of contracting salmonellosis from uncooked chicken than they are from handling reptiles.

## Reptile Rules

Public health officials, veterinarians, and pet store owners offer the following guidelines to people considering reptiles as pets:

-  Never eat or put anything in your mouth during or after handling your reptile.
-  Never clean cages in the kitchen or anywhere you prepare food for human consumption.
-  Always wash your hands with a disinfectant soap after handling your animals. Washing with water alone is not effective in eliminating salmonella.
-  Do not permit unsupervised handling of reptiles by children under 12.
-  Do not handle reptiles with open cuts or sores unless they are well covered with dressings. Rubber gloves are strongly recommended.
-  Do not use kitchen sinks, bathtubs, or shower stalls for cleaning reptiles or their cages unless you thoroughly disinfect afterwards with a bleach-containing product.
-  Reptiles are not a good choice for day-care centers.
-  Seek the care of a reputable exotic animal veterinarian to obtain regular fecal examinations and diet recommendations for your reptile.

## Focus On: Salmonella Poisoning (Salmonellosis)

**What is Salmonella?**

The Salmonella germ is a group of bacteria that can cause diarrheal illness in people. Salmonella are microscopic living creatures that pass from the feces of people or animals, to other people or other animals. There are many different kinds of Salmonella bacteria. Salmonella serotype Typhimurium and Salmonella serotype Enteritidis are the most common in the United States.



**Symptoms:**

Most people who are infected with Salmonella develop diarrhea, fever, and abdominal cramps 12 to 72 hours after infection. The illness usually lasts 4 to 7 days, and most people recover without treatment.

**How is it transmitted?**

Each year about 40,000 cases of salmonella poisoning (salmonellosis) are reported in the U.S. Salmonella are usually transmitted by eating foods

*Salmonella Poisoning - Continued from page 4*

contaminated with animal feces. Contaminated foods usually look and smell normal. Contaminated foods are often of animal origin, such as poultry, milk, or eggs, but all foods, including vegetables may become contaminated. Many raw foods of animal origin are frequently contaminated, but fortunately, thorough cooking kills Salmonella. Food may also become contaminated by the hands of an infected food handler who forgot to wash his or her hands with soap after using the bathroom.

**Prevention:**

There is no salmonellosis vaccine. Since foods of animal origin may be contaminated with Salmonella, you should avoid eating raw or undercooked eggs, poultry, or meat.

**Treatment:**

Many different kinds of illnesses can cause diarrhea, fever, or abdominal cramps, so lab tests

are required to diagnose salmonellosis. Once Salmonella has been identified, further testing can determine its specific type, and which antibiotics could be used to treat it.

Salmonella infections usually resolve in 5-7 days and often do not require treatment unless the patient becomes severely dehydrated or the infection spreads from the intestines. People with severe diarrhea may require rehydration, often with intravenous fluids. Antibiotics are not usually necessary unless the infection spreads from the intestines.

**What to do if you think you have Salmonella poisoning:**

If you think you have salmonella poisoning, contact your doctor right away. They may want to see you for testing or treatment.

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## Tips for Preventing Salmonella Poisoning

- Cook poultry, ground beef, and eggs thoroughly before eating. Do not eat or drink foods containing raw eggs, or raw unpasteurized milk.
- If you are served undercooked meat, poultry or eggs in a restaurant, send it back to the kitchen for further cooking.
- Wash hands, kitchen work surfaces, and utensils with soap and water immediately after they have been in contact with raw meat or poultry.
- Be particularly careful with foods prepared for infants, the elderly, and people with weak immune systems.
- Wash hands with soap after handling reptiles or birds, or after contact with pet feces.
- Avoid direct or even indirect contact between reptiles (turtles, iguanas, other lizards, snakes) and infants or people with weak immune systems.
- Don't work with raw poultry or meat, and an infant (e.g., feed, change diaper) at the same time.
- Mother's milk is the safest food for young infants. Breast-feeding prevents salmonellosis and many other health problems.

**What else can be done to prevent salmonella poisoning?**

You should report cases of salmonella poisoning to your state health department (<http://www.fda.gov/oca/sthealth.htm>). If many cases occur at the same time, it may mean that a restaurant, food or water supply has a problem which needs correction by the public health department.



## Cleaning up the Flood: Important Food Safety

The U.S. has weathered its share of destructive hurricanes and tropical storms this year. And, even though these weather systems weaken rapidly as they move inland, the remnants of a storm can bring 6 to 12 inches of rain or more to any area it crosses. The resulting water can lead to flooding and lots of damage.

The Partnership for Food Safety Education recommends the following steps be taken in the kitchen when cleaning up after a flood, to avoid foodborne illnesses:

- Wear rubber gloves and other protective clothing
- Clean and sanitize all kitchen surfaces, especially those that may have been contaminated by flood waters
- Wash and sanitize your dishes, utensils and kitchen appliances before using them
- Discard all soft plastic and porous items such as wooden spoons and cutting boards and plastic utensils which may have absorbed contaminants
- Discard all meats, poultry, fish and eggs, fresh produce, jams/jellies sealed with paraffin, home canned foods and any commercial glass jars, foods in cardboard boxes or bags, spices, seasonings and extracts, any foods in canisters and damaged cans
- Undamaged commercially canned goods are safe if paper labels are removed and the cans are sanitized - make sure you write on the lid what is in the can with indelible ink

These simple precautions will keep your family safe from foodborne pathogens. Visit the CDC, American Red Cross or FEMA websites for detailed information on cleaning up after a flood.

\*Sanitizing Solution: 1 teaspoon liquid bleach per quart of water



1. **If you touch raw meat or chicken before you touch anything else you should:**
  - A. Wash your hands with hot soapy water
  - B. Wipe your hands on a paper towel
  - C. Wipe your hands on your pants
2. **Eating raw cookie dough made with raw eggs is OK. True or False**
3. **The best way to defrost frozen meat or chicken is to:**
  - A. Place it on the kitchen counter for a few hours
  - B. Place it in the refrigerator overnight
  - C. Microwave it
4. **At a party, picnic or family meal, it's OK to leave food on the table for:**
  - A. No more than 2 hours
  - B. No more than 6 hours
  - C. No more than 3 hours
5. **When packing food for lunch or a picnic, refrigerated food will be OK for several hours if:**
  - A. The food is in a cooler
  - B. A special ice pack is included
  - C. The food was frozen



## Add Hepatitis B Vaccination to Your Back to School List

Hepatitis B is a disease of the liver caused by the hepatitis B virus (HBV). HBV can affect anyone. Prior to routine use of HBV vaccination in children, more than 200,000 people of all ages became infected with HBV. Some people who become infected never get rid of the virus and are at risk of developing scarring (cirrhosis) of the liver and liver cancer. Each year, about 5,000 people die as a result of this disease.

The good news is that a safe and effective vaccine is available. All children aged 0-18 years should receive the HBV series of three shots. Many states require HBV before school entry. Visit the Immunization Action Coalition website which features a list of hepatitis B vaccination requirement by state (<http://www.immunize.org/laws/hepb.htm>).

Vaccines for Children (VFC), a federal vaccination program, provides routinely recommended vaccines free of charge to children up through 18 years of age. One of the most effective ways to protect your health is to receive the vaccines you need. Find out if you are eligible to use VFC funds (<http://www.cdc.gov/nip/vfc/>).

Children might also need the hepatitis A vaccine.

Hepatitis A vaccine is recommended for children aged 2 years and older in communities where there were consistently increased rates of hepatitis A during the period 1987 to 1997. Check with your health care professional to see if you live in any of these areas.

Remember, vaccination is a very important part of your health care. Be sure to add Hepatitis B vaccination and possibly hepatitis A vaccination to your "Back to School" list!

## FDA Ensures Vaccines are Safe and Effective

Vaccination saves lives - millions of them. In the U.S., vaccination programs have wiped out smallpox and polio and have reduced many diseases like measles, mumps, diphtheria, and whooping cough by 95 percent. Thanks to vaccination, the elderly and chronically ill are less likely to suffer from flu and pneumonia. But vaccines, which contain weakened or killed disease-causing bacteria, viruses, or their components, have to be thoroughly evaluated for safety and effectiveness. This important task is part of the public health mission of the Food and Drug Administration (FDA).

Here's how FDA helps ensure vaccines are safe and effective:

- The designs of studies for testing new vaccines must be approved by the FDA.
- The clinical trials that establish the vaccines' safety and effectiveness are well designed and carefully conducted.
- Following the completion of the studies, FDA scientists review the data, the proposed labeling, and the manufacturing protocols, and conduct their own tests of the product.

- FDA inspectors make certain that the manufacturing facility can properly produce the vaccine before it is licensed and can be used.
- When the vaccine is made, the FDA requires the company to test samples from each lot for safety, potency and purity, and carries out spot-testing of its own.

FDA also cooperates with the Centers for Disease Control and Prevention (CDC) and other institutions in research to develop even safer vaccines. Since 1996, for example, FDA has licensed several whooping cough vaccines that contain only part of the disease-causing bacterium, and have fewer side effects than the whole cell pertussis vaccines

### Monitoring Vaccine Safety

Together FDA and CDC operate the Vaccine Adverse Event Reporting System (VAERS). VAERS receives 800 to 1,000 reports a month of suspected problems associated with the use of vaccines. The FDA reviews and evaluates these reports and monitors overall reporting patterns, as well as trends for individual vaccine lots. The VAERS data make an important contribution to vaccine safety.



## Keep Your Child Healthy: Vaccinate

Recommended Childhood Immunization Schedule United States, 2003

Age Vaccine	Range of recommended ages				Catch-up vaccination				Preadolescent assessment			
	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	24 mos	4-6 yrs	11-12 yrs	13-18 yrs
Hepatitis B	Hep B #1	Hep B #2		Hep B #3		Hep B series						
Diphtheria, Tetanus, Pertussis		DTaP	DTaP	DTaP		DTaP			DTaP		Td	
Haemophilus influenzae Type b		Hib	Hib	Hib		Hib						
Inactivated Polio		IPV	IPV			IPV			IPV			
Measles, Mumps, Rubella						MMR #1			MMR #2		MMR #2	
Varicella						Varicella			Varicella			
Pneumococcal		PCV	PCV	PCV		PCV			PCV	PPV		
Hepatitis A	vaccines below this line are for selected populations										Hepatitis A series	
Influenza											Influenza (yearly)	

Source: The Advisory Committee on Immunization Practices ([www.cdc.gov/nip/acip](http://www.cdc.gov/nip/acip)), the American Academy of Pediatrics ([www.aap.org](http://www.aap.org)) and the American Academy of Family Physicians ([www.aafp.org](http://www.aafp.org)) As of December 1, 2001

This chart shows the U.S. recommended immunization schedule for children. It lists currently licensed vaccines for children 18-years-old and younger, along with the recommended ages for vaccination. Any vaccination not given at the recommended age should be given at a later visit when appropriate. The black bar shows time frames for "catch-up" vaccines for children who fall behind or start their immunizations late. NOTE: Licensed combination vaccines may be used when appropriate and additional vaccines may be licensed and recommended during the year.

For more information or to check if a new schedule has been issued, talk to your pediatrician or visit the National Immunization Program web site at [www.cdc.gov/nip](http://www.cdc.gov/nip). You can also call the National Immunization Hotline at (800) 232-2522 (English) or (800) 232-0233 (Spanish).

## All About Vaccines

### Why do we need vaccines?

Vaccines save lives by protecting us against infectious diseases like measles, mumps and whooping cough.

### How do vaccines work?

When you receive a vaccine it helps your body create antibodies. Antibodies are your body's defensive cells that fight off germs. Sometimes your body can create antibodies on its own. But the diseases you get vaccines for are very dangerous. Most people get very sick and some die before enough antibodies are produced.

### What are some of the infectious diseases vaccines offer protection from?

**Hib:** This vaccine protects us from the Haemophilus Influenza type b bacteria that causes meningitis.

Meningitis is an inflammation of the cover that surrounds the brain and can cause brain damage. Also these bacteria can infect the blood, joints, bones, muscles, throat and the cover surrounding the heart. This is especially dangerous for babies.

**Diphtheria Tetanus Pertussis (DTP):** Diphtheria is an infection that attacks the throat, mouth and nose. This is a very contagious disease, but rare ever since the vaccine was created. Diphtheria can form a gray web that may completely cover the windpipe and can prevent breathing.

If this disease is not treated right away it could cause pneumonia, heart failure or paralysis.

Tetanus is an infection caused by a bacteria found in dirt, gravel and rusty metal. It usually enters the body through a cut. Tetanus bacteria causes the muscles to

move suddenly and sometimes uncontrollably. If tetanus attacks the jaw muscles it causes lockjaw, the inability to open and close your mouth. Tetanus can also cause the breathing muscles to spasm and can be deadly.

You may know pertussis by its more common name, Whooping Cough. Pertussis is a bacteria that clogs the lungs with a thick, slimy mucous. This can cause a severe cough that sounds like a "whoop." The cough can last for 2 months and allows for other bacteria such as pneumonia and bronchitis to attack the body.

**Polio:** Polio can paralyze the legs and chest making walking and breathing difficult or impossible. The first symptoms of polio are fever, sore throat, headache and a stiff neck. Polio is very rare since the vaccine became available.

**MMR:** The first M in MMR stands for Measles. Measles is a highly contagious disease that causes a high fever, cough, and a spotty rash all over. It may also cause ear infections and pneumonia.

The second M in MMR stands for Mumps. Mumps causes painful swollen salivary glands which are under the jaw, as well as a fever and a headache. Mumps also may cause meningitis or hearing loss.

The R in MMR stands for Rubella. Rubella is also called German Measles. It is most dangerous for women who are pregnant. Rubella can cause a mother to have a miscarriage or deliver a baby with heart disease, blindness, hearing loss or learning problems.

Rubella is a mild disease in kids.

**Hepatitis B:** Hepatitis B causes extreme tiredness and jaundice. Jaundice is when all the white parts on



**Vaccines** - Continued from page 8

your body, like your eyes, teeth and nails, turn yellow. Hepatitis B may also cause the liver to stop working.

**Chicken Pox:** Chicken pox is a virus. It causes an itchy rash and a fever. You can catch it from someone who already has it if you touch an open blister on that person's skin or if that person sneezes or coughs around you. Not everyone gets the vaccine, so lots of kids still get chicken pox.

**Hepatitis A:** A serious liver disease caused by the hepatitis A virus (HAV).

**Meningococcal:** Meningococcal disease is an illness caused by bacteria. Meningitis is an infection of the brain and spinal cord coverings that can also cause blood infections.

**Rabies:** Rabies infection is serious, and often fatal, if it isn't prevented. Vaccination induces active

immunity against rabies virus either before (pre-exposure immunization) an exposure occurs or after (post-exposure prophylaxis) an exposure. Rabies shots need to be given as soon as possible after a bite has occurred, before symptoms appear.

**Pneumococcal:** Streptococcus pneumonia bacteria can cause serious illness and death -- approximately 200 deaths each year among children under 5 years old. The pneumococcal vaccine helps prevent pneumococcal disease.

**Influenza:** Influenza is a virus that infects the respiratory tract that can cause severe illness and life-threatening complications in many people. The flu kills an estimated 36,000 people and causes more than 200,000 hospitalizations per year in the United States. Annual flu vaccination is the best way to reduce the chances that you will get the flu.

## Counterfeit Medicines: Filled with Empty Promises

You can avoid counterfeit medicine by purchasing only from U.S. state-licensed pharmacies

While counterfeit medicines are rare in the U.S., you must take an active role in managing your medicines to ensure you're not at risk. Here are some important facts about counterfeit medicine from the FDA.

Counterfeit medicines are fake or copycat medicines. They may:

- be contaminated
- contain the wrong active ingredients (the formula that makes the medicine work)
- be made with the wrong amount of ingredients
- contain no active ingredients at all
- be packaged in phony packaging

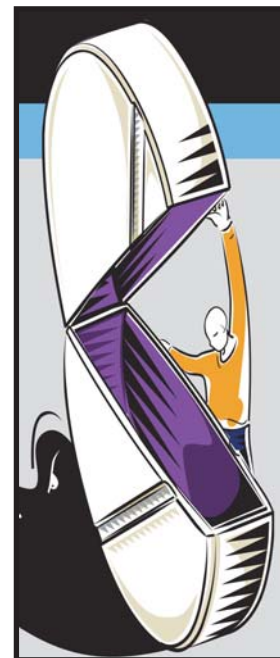
Medicines that are counterfeit may not help the condition the medicine was intended to treat and may lead to dangerous side effects. How can you avoid counterfeits?

- Purchase **ONLY** from state-licensed pharmacies that are located in the United States, where FDA and state authorities can assure the quality of drug manufacturing, packaging, distribution and labeling. This way, you know your medicine is coming from a reputable source, and you can get help if you have any problems with your medicine. If you buy over the Internet:

- Check to see if a pharmacy is licensed, is in good standing, and is located in the United States. Contact your local state board of pharmacy or the National Association of Boards of Pharmacy (NABP) at <http://www.nabp.net> or 1-847-698-6227, or

- Check to see if an Internet pharmacy site has the VIPPS Seal, the seal of the Verified Internet Pharmacy Practice Sites Accreditation Program. This program was established by the NABP to help protect you and guide you through Internet pharmacy shopping. Legitimate pharmacies that carry the VIPPS Seal are listed at <http://www.nabp.net/vipps/consumer/listall.asp>.
- Know your medicine. Any time you get a prescription refilled, check the color, texture, taste and shape of the medicine. Anything different? Talk to your pharmacist.
- Give your doctor and pharmacist a complete list of all medicines (over-the-counter and prescription) that you use. They will also want to know what dietary supplements you use, including vitamins and herbals.

To learn more about counterfeit drugs, visit the FDA Web site at <http://www.fda.gov/counterfeit>.



## Be an Active Member of Your Health Care Team

U.S. Department of Health and Human Services, Food and Drug Administration in cooperation with the Council on Family Health

When it comes to using medicine, it is important to know that no medicine is completely safe. The U.S. Food and Drug Administration (FDA) judges a drug to be safe enough to approve when the benefits of the medicine outweigh the known risks for the labeled use.

Doctors, physician assistants, nurses, pharmacists, and YOU make up your health care team. To reduce the risks from using medicines and to get the most benefit, you need to be an active member of the team.

To make medicine use **SAFER**:

- **S**peak up
- **A**sk questions
- **F**ind the facts
- **E**valuate your choices
- **R**ead the label and follow directions

### SPEAK UP

The more information your health care team knows about you, the better the team can plan the care that's right for you.



The members of your team need to **know your medical history**, such as illnesses, medical conditions (like high blood pressure or diabetes), and operations you have had.

They also need to know **all the medicines and treatments you use**, whether all the time or only some of the time. Before you add something new, talk it



over with your team. Your team can help you with what mixes well, and what doesn't.

It helps to give a **written list** of all your medicines and treatments to all your doctors, pharmacists and other team members. Keep a copy of the list for yourself and give a copy to a loved one.

### Be sure to include:

- prescription medicines, including any samples your doctor may have given you
- over-the-counter (OTC) medicines, or medicines you can buy without a prescription (such as antacids, laxatives, or pain, fever, and cough/cold medicines)
- dietary supplements, including vitamins and herbs
- any other treatments
- any allergies, and any problems you may have had with a medicine
- anything that could have an effect on your use of medicine, such as pregnancy, breast feeding, trouble swallowing, trouble remembering, or cost

### ASK QUESTIONS

Your health care team can help you make the best choices, but you have to ask the right

questions. When you meet with a team member, have your questions written down and take notes on the answers. You also may want to bring along a friend or relative to help you understand and remember.

Use the Question Guide at the end of this pamphlet to help you get the answers you need from your health care team. If you don't understand an answer, ask again.

### FIND THE FACTS

Before you and your team decide on a prescription or OTC medicine, learn and understand as much about it as you can, including:



- brand and generic (chemical) names
- active ingredients—to make sure that you aren't using more than one medicine with the same active ingredient
- inactive ingredients—if you have any problems with ingredients in medicines, such as colors, flavors, starches, sugars
- uses ("indications" and "contraindications")—why you will be using it, and when the medicine should/should not be used
- warnings ("precautions")—safety measures to make sure the medicine is used the right way, and to avoid harm
- possible interactions—substances that should not be used while using the medicine. Find out if other prescript

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- side effects (“adverse reactions”)—unwanted effects that the medicine can cause, and what to do if you get them
- possible tolerance, dependence, or addiction—problems that some medicines can cause, and what you can do to avoid them
- overdose—what to do if you use too much
- directions—usual dose; what to do if you miss a dose; special directions on how to use the medicine, such as whether to take it with or without food
- storage instructions—how and where to keep the medicine
- expiration—date after which the medicine may not work, or may be harmful to use

Your pharmacy, the library, the bookstore, the medicine maker, and the Internet have medicine information made for consumers. If you have questions, ask your health care team.

**EVALUATE YOUR CHOICES—Weigh the Benefits and Risks**



After you have all the information, think carefully about your choices. Think about the helpful effects as well as the possible unwanted effects. Decide which are most important to you. This is how you weigh the benefits and risks. The expert advice from your health care team and the information you give the team can help guide you and your team in making the decision that is right for you.

**READ THE LABEL AND FOLLOW DIRECTIONS**



**Read the label to know what active ingredient(s) is (are) in the medicine.** The active ingredient in a prescription or OTC medicine might be in other medicines you use. *Using too much of any active ingredient may increase your chance of unwanted side effects.*

**Read the label each time you buy an OTC medicine or fill your prescription.** When buying an OTC, read the "Drug Facts" label carefully to make sure it is the right medicine for you. Prescription and OTC medicines don't always mix well with each other. Dietary supplements (like vitamins and herbals) and some foods and drinks can cause problems with your medicines too. Ask the pharmacist if you have questions.

Before you leave the pharmacy with your prescription, be sure you have the right medicine, know the right dose to use, and know how to use it. If you've bought the medicine before, make sure that this medicine has the same shape, color, size, and packaging. Anything different? Ask your pharmacist. If your medicine tastes different when you use it, tell your health care team.

Read and save all the information you get with your medicine.

**Read the label each time before you use the medicine.**

Be sure it's right in 5 ways:

1. the right medicine
2. for the right patient
3. in the right amount
4. at the right time
5. in the right way (for example, swallow instead of chew a pill)

**Follow directions on the label and from your health care team.**

When you are ready to use the medicine, make the most of the benefits and lower the risks by following the directions.

**If you want to stop a medicine your doctor told you to use or to use it in a different way than directed, talk to a team member.**

Some medicines take longer to show that they are working. With some medicines, such as antibiotics, it is important to finish the whole prescription, even if you feel better sooner. When you stop using some medicines, you must reduce the dose little by little to prevent unwanted side effects.

**REPORT BACK TO THE TEAM**



Pay attention to how you feel. If you have an unwanted effect, tell your health care team right away. A change in the dose or a change in medicine may be needed.

**QUESTION GUIDE**

Use this guide with your health care team to find out what you need to know about the



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medicines you use, and about the medicines you are thinking about using. Be sure to find the answers to these questions for any sample medicine your doctor gives you.

- What are the brand and generic (non-brand) names of the medicine?
- What is the active ingredient?
- Could I use a generic form?
- What is the medicine for, and what will it do for me?
- When should I start to feel better?
- When should I report back to the team?
- Will this medicine take the place of any other medicine I have been using?
- Should I avoid any drinks, foods, other substances, or activities while using this medicine?
- Can this medicine be used safely with the other medicines and treatments I already use? Does this include prescription and OTC medicines, vitamins, herbals, or other supplements, and other treatments?
- Should I avoid starting other medicines (prescription or OTC), dietary supplements (like herbals and vitamins) or other treatments while I am using this medicine?
- What are the possible side effects from this medicine? What do I do if I get a side effect?
- Is there any chance that I could become tolerant, dependent or addicted to this medicine? What can I do to avoid this?
- How and when should I use the medicine, in what amount, and for how long? Are there any special directions for using this medicine?
- Will I need any tests (blood tests, x-rays, other tests) to make sure the medicine is working as it should? How will I get the results?
- What should I do if I miss a dose? What should I do if I use too much by mistake?
- How and where should I keep this medicine? (Remember: Always put medicines out of the sight and reach of children and pets.)
- Where and how can I get more information about this medicine?

Remember: To reduce the risks of using medicines and to get the most benefit, you need to be an active member of your health care team.

## Food Safety Quiz - ANSWERS

**1. If you touch raw meat or chicken, before you touch anything else you should:**

Answer: A - Wash your hands with hot soapy water. Raw meat or chicken can have bacteria on it which can get on your hands as well as dishes and utensils. Always wash your hands with warm water and soap for at least 20 seconds before and after you touch raw food. And never put cooked food on the dish that held raw food.

**2. Eating raw cookie dough made with raw eggs is OK.**

Answer: False - Cookie dough contains uncooked eggs and may carry bacteria which causes food poisoning. So, wait until the cookies are done before digging in.

**3. The best way to defrost frozen meat or chicken is to:**

Answer: B & C - Place in refrigerator overnight or microwave. Meat, poultry and seafood need to

stay cold while they thaw. So, the best way to thaw them is in the refrigerator for 1 to 2 days before you cook the food OR in the. When defrosting meat in the microwave be sure to use the "defrost setting" and cook the food right away.

**4. At a party, picnic or family meal, it's OK to leave food on the table for:**

Answer: A - If meat is left out for 2 or more hours, germs can grow. So, put leftovers in the refrigerator or freezer as soon as you finish eating. Put them in shallow dishes so they cool faster. Be sure to eat leftovers in the next few days, before they go bad.

**5. When packing food for lunch or a picnic, refrigerated food will be OK for several hours if:**

Answer: A, B & C - Actually, all three of these answers are correct. As long as the food is kept cold it is fine to take on a picnic even on a hot day.

## Calendar of National Health Events

### SEPTEMBER

**National Food Safety Education Month**

International Food Safety Council  
 National Restaurant Association Education Foundation  
 175 West Jackson, Suite 1500  
 Chicago, IL 60604  
 (312) 715-1010 x712  
<http://www.nraef.org/index.asp>

**National 5 A Day Month**

National Cancer Institute/ Produce for Better Health Foundation  
 6130 Executive Boulevard EPN 4050  
 Bethesda, MD 20892  
 (800) 4-CANCER (301) 496-8520  
 (800) 332-8615 TTY  
<http://www.5aday.gov>

### OCTOBER

**Halloween Safety Month**

Prevent Blindness America  
 500 East Remington Road  
 Schaumburg, IL 60173  
 (800) 331-2020  
 email: [info@preventblindness.org](mailto:info@preventblindness.org)  
<http://www.preventblindness.org>

**"Talk About Prescriptions" Month**

National Council on Patient Information and Education  
 4915 St. Elmo Avenue, Suite 505  
 Bethesda, MD 20814-6082  
 (301) 656-8565  
 email: [ncpie@ncpie.info](mailto:ncpie@ncpie.info)  
<http://www.talkaboutrx.org>

**National Health Education Week  
 (October 17 - 23)**

National Center for Health Education Society for Public Health Education  
 242 W. 30th Street, 10th Floor  
 New York, NY 10001  
 (212) 463-4053  
<http://www.nche.org>

### NOVEMBER

**American Diabetes Month**

American Diabetes Association  
 1701 North Beauregard Street  
 Alexandria, VA 22314  
 (800) 232-3472  
<http://www.diabetes.org>

## Word Find

B L A F E T A N I C C A V  
 Q R W X M S R B L H Z K Y  
 A F E J V I E L I T P E R  
 G S E A R T D S J E B C Z  
 B I W Q S I P A G L N P M  
 G C O U N T E R F E I T H  
 A I D T Y A I U D F G D L  
 F E P W D P A M M R M F C  
 C B N J H E D F P I N I K  
 T I M P D H S H N L A K E  
 P E R T U S S I S D A O G  
 F A L L E N O M L A S N V  
 F O O D S A F E T Y O Y T  
 M X L E B A L N O P M A T

- Breast Implant
- Counterfeit
- DTP
- Food safety
- Hepatitis
- MMR
- Pertussis
- Reptiles
- Salmonella
- Tampon label
- Vaccinate

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<http://www.fda.gov/cdrh/fdaandyou.html>

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 Food and Drug Administration  
 Center for Devices and Radiological Health  
 Rockville, MD 20850

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