

MATURITY HEALTH MATTERS

FDA Health News for Older Adults, Their Families and Caregivers

Issue 9

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Preparing for Natural Disasters

FDA wants you to know how to keep food, medicine, medical devices, vaccines, biologics (products derived from living sources such as humans, animals, and microorganisms,), and pets safe during natural disasters.

If there is a power outage, you are encouraged to note the time of the power outage. **Do not open freezers and refrigerators until power is restored.** This will help conserve the cold mass of the products.

Food

Food that has been exposed to flood waters or that has not been properly refrigerated, including due to a power outage, can cause illness. **When in doubt, throw it out.** Do not eat food or drink water or other beverages that may have been exposed to flood water. Boil water to make it safe or, using a medicine dropper, add eight drops of bleach to one gallon of water, and let it stand for 30 minutes before drinking it.

Keep coolers on hand. Coolers can help keep refrigerated food cold if the power will be out for more than four hours. Purchase or make ice cubes, or freeze ice packs, and store in the freezer for use in the refrigerator or for later use in a cooler.

If your freezer **thermometer reads 40 degrees Fahrenheit or below** the food is safe and may be refrozen.

Medicine

Keep your medicine containers in zippered plastic bags. Store them up high or where they are not likely to be reached by flood water. Take the bags and medicines with you if you must evacuate.

Keep a list of your medicines. Be sure to include: the name of your medicine, the dose of the medicine, how frequently you take the medicine, and your doctor's name and phone number. If a medicine container falls into flood water, replace the medicine.

If the container gets wet but it appears that flood water did not touch the medicine, then use the medicine, but only until a replacement can be obtained. Do not use the medicine if any pills were touched by flood water. Save the original containers. Ask your doctor or local public health agency for help.

If there is a natural disaster such as a hurricane, people with diabetes may not be able to refrigerate their insulin. Insulin products may be left unrefrigerated (between 59 and 86 degrees Fahrenheit) for up to 28 days and still maintain their strength. They should be replaced with a new supply as soon as possible.

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- Natural Disasters
- Wrinkle Fillers
- Vaccines
- MedWatch Reporting
- News from the FDA
- Crossword

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Natural Disasters - continued from page 1

Medical Devices

Keep your medical device and supplies clean, dry and up-to-date.

Request evacuation from your local public health authority before bad weather occurs. Seek emergency services, for example - your local power company, **before** a natural disaster occurs if you depend on your device to keep you alive.

Because of the fire risk, use battery powered flashlights or lanterns rather than gas lights or candles when oxygen is in use. This lowers the risk of fire.

Contact your distributor or device manufacturer if your device appears to be damaged or you need a back-up device.

Check all power cords, batteries, and other device supplies to make sure they are not wet or damaged by water. If electrical circuits and electrical equipment have gotten wet, turn off the power at the main breaker.

Vaccines and Other Biologics

To preserve cold storage conditions of refrigerated or frozen biological products during a power outage, individuals responsible for the storage may consider removing them from the freezer after one day (if the power outage continues) and packing them in dry ice. But if the vaccines are not cold to the touch upon removal from the freezer, you should throw them away.

Although certain vaccines are temperature-sensitive, most refrigerated vaccines are relatively stable at room temperature for limited periods of time. In addition, many products will maintain their medical strength (potency) for a few days in the relative cool of a closed refrigerator.

Most biological products, including bacterial and viral vaccines, allergenic extracts, and blood products require specific storage conditions to maintain their safety, purity, and potency. But, check and follow the product labeling for specific tips on handling.

Blood Products and Plasma Derivatives

Blood banks and plasma centers typically have back up generators and emergency procedures in place for storing products in the event of a power outage. For those facilities and in-home users that may not have emergency back up power, the following may be helpful:

There is some evidence that freeze-dried (lyophilized) coagulation products may be stored at room temperature for a fairly long period of time without loss of potency. If you are concerned about the exposure or effectiveness of a particular product, please contact the supplier or the manufacturer **before** a natural disaster occurs.

Many immune globulin products are licensed for storage at 36 to 46 degrees Fahrenheit and some products may be stored at room temperature for all or part of the time before expiration. Because storage temperatures and times are specific to each product, you should follow the package insert recommendations, if you have questions. Products requiring lower temperatures can be stored on wet ice. All of these products should not be frozen. If you have any questions about the storage of these products, you should consult the package inserts.

Within the source below, there are ten additional links with more specific information about foods, medicine, insulin, medical devices, vaccines and other biologics, and taking care of pets.

Source: <http://www.fda.gov/consumer/updates/hurricane052307.html>

Injectable Cosmetic Wrinkle Fillers

Injectable cosmetic wrinkle fillers are soft tissue fillers that help reduce the appearance of wrinkles, restoring a smoother appearance. Most of these injectable wrinkle fillers are temporary, because they are eventually absorbed by the body. The smoothing effect lasts for about six months and sometimes longer.

There are two types of wrinkle fillers:

- **Temporary – FDA approved absorbable fillers include:**
 - **Collagen injections** are made of highly purified cow (bovine), pig (porcine), or human collagen, which is found in skin and other tissues in the body.
 - **Hyaluronic acid** gel is a protective, lubricating gel that is produced naturally by the body and binds with water to plump the skin.
 - **Calcium Hydroxylapatite** is a mineral injected in the form of a gel that is a major component of bone.
 - **Poly-L-lactic acid (PLLA)** is a biodegradable, biocompatible synthetic polymer used for many years in dissolvable stitches and bone screws.
- **Permanent – FDA approved non-absorbable filler**
 - **Polymethylmethacrylate beads (PMMA microspheres)** are tiny round, biocompatible, smooth plastic particles.



Uses

The absorbable injectable cosmetic wrinkle fillers are FDA approved for correcting soft tissue contour defects, such as moderate to severe wrinkles and folds of the face.

The non-absorbable injectable cosmetic wrinkle filler is FDA approved for correcting folds (laugh lines) around the mouth.

Some injectable cosmetic wrinkle fillers are approved only for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (HIV).

Risks

As in any medical procedure, there are risks involved. Possible side effects include:

- Infection
- Bruising
- Redness
- Swelling
- Pain
- Tenderness
- Itching, rash
- Raised bumps of skin (nodules or granulomas that may need to be surgically removed)
- Skin may die if the cosmetic wrinkle filler is injected and blocks a blood vessel. This may cause severe scarring.

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- A sore (abscess) may occur at the injection site
- The injected cosmetic wrinkle filler may break through your skin.
- Open or draining wounds may occur
- Blurred vision and flu-like symptoms may occur
- Increased allergic reaction that may lead to a severe allergic reaction that requires immediate emergency medical assistance (anaphylactic shock)

While the majority of the side effects associated with these fillers occur shortly after injection, in some cases these side effects may emerge weeks, months or years after injection.

Points for Patients to Consider

Before deciding to have injectable cosmetic wrinkle fillers, you should:



- Be aware that the safety of these products is unknown when used during pregnancy, in breastfeeding females or in patients under 18 years of age.
- Understand that the safety is unknown when these products are used with Botox or other wrinkle therapies.
- Be aware that the safety is unknown when these products are used repeatedly over a long period of time.
- Be informed that the safety of these products have been studied only for use in the face.
- Know the product and all its possible side effects.
- Talk with a doctor who can refer you to a dermatologist or cosmetic surgeon.
- Select a doctor who is trained to do the procedure.
- Have realistic expectations and discuss them with your doctor.
- Be aware that insurance does not usually cover elective cosmetic procedures.

You should **NOT** use these products if any of the following applies to you:

- You have severe allergies marked by a history of anaphylaxis (acute allergic reaction)
- You are allergic to collagen (pork or beef) or eggs
- You are allergic to lidocaine
- Your skin is inflamed or infected
- You are prone to form excessive scarring (keloids) and/or thick scarring (hypertrophic scars)
- You have a bleeding disorder
- You have an active inflammatory condition, (cysts, pimples, rashes or hives) or infection. The wrinkle filler injection should be postponed until this inflammatory condition is controlled.

FDA has approved these products **only** as injectable cosmetic wrinkle fillers. They should **not** be used for:

- Plumping the lips (lip augmentation)
- Increasing breast size (breast augmentation)
- Implanting into bone, tendon, ligament, or muscle
- Implantation into blood vessels, because it may obstruct blood flow

Vaccines – Staying Healthy

Serious illnesses and deaths from many infectious diseases have declined because of vaccinations. However, if we stopped being vaccinated, we would see disease epidemics again. Although some people may think that vaccines are only for young children, they are very important, and encouraged, for older adults too. For example, most hospitalizations and deaths from the flu occur in people over 65 years. Older adults should know what vaccines they need to remain protected throughout their lifetime.

Vaccines Recommended for Older Adults		
Disease	Complications of Not Getting Vaccinated	Other Information
Flu (Influenza)	For people over 65, most hospitalizations and deaths from the flu occur in this age group	October or November is the best time to get vaccinated, but you can still get vaccinated in December or later. Flu season can begin as early as October and last as late as May.
Pneumonia (Pneumococcal Disease)	This disease can lead to serious infections of the lungs, blood and covering of the brain	This vaccine is for people over 65
Tetanus (Lockjaw)	Tetanus is a severe, often fatal disease. Approximately 20 percent of reported cases end in death.	All adults should receive a booster every ten years.
Diphtheria	The bacteria produces a poisonous substance (toxin) which frequently causes heart and nerve problems.	Although diphtheria is rare in the U.S., it is common in other parts of the world. (and it's only a plane ride away)
Whooping Cough (Pertussis)	Spasms of severe coughing	Combination vaccines for tetanus, diphtheria, and whooping cough are available for older adults up to 64 years.
Shingles (Herpes Zoster)	Painful skin rash with blister-like lesions usually on one small side of the body. Some adverse effects may not be temporary.	For adults 60 years and older
Measles, Mumps and Rubella (MMR)	These diseases can lead to ear infection, pneumonia, seizures, deafness, meningitis and arthritis.	Anyone born after 1956 should get at least one dose of the MMR vaccine unless they have had the vaccine or each of the three diseases (according to the CDC)
Hepatitis B	Serious disease that affects the liver.	All unvaccinated adults at risk for infection should be vaccinated.

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Talk with Your Doctor

Talking with your doctor is the best way to find out what vaccines you need to protect yourself from preventable diseases. In addition to the commonly known vaccines for flu, there are vaccines for pneumonia, tetanus (lockjaw), diphtheria, and shingles that can be especially serious diseases for older adults. If you do not know which vaccinations you have received, your doctor can help determine your vaccination history. In some cases, a blood test can show whether you have immunity to particular diseases.

Childhood Vaccinations

Some adults incorrectly assume that the vaccines they received as children will protect them for the rest of their lives. However, as we age, we become more susceptible to serious diseases caused by common infections (such as: flu, pneumonia and tetanus). Therefore, re-vaccination should be discussed with your doctor.

Traveling Overseas

If you have plans to travel overseas, talk to your doctor at least four to six weeks before your trip. Most vaccines take time to become effective in your body and some must be given in a series over a period of days or sometimes weeks. For example, transmission of the hepatitis A virus (HAV) occurs by the fecal-oral route, either by direct contact with an HAV-infected person or by eating or drinking HAV contaminated food or water. If you are going to a country where there may be a concern about HAV, the vaccine series should be started at least one month before traveling. The timing of the injections will provide you with the best protection.

The Centers for Disease Control and Prevention (CDC) offers a checklist on what you need to know about vaccinations before traveling. In addition, CDC provides an immunization schedule for adults, as well as vaccine information statements, that provide helpful information about benefits, risk and timing of immunization. See CDC's websites below.

Sources:

FDA Consumer Jan-Feb 2007. For complete information go to:

- http://www.fda.gov/fdac/features/2007/107_vaccines.html

The Centers for Disease Control and Prevention (CDC)

- <http://wwwn.cdc.gov/travel/contentVaccinations.aspx>
- <http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm>
- <http://www.cdc.gov/vaccines/pubs/vis/default.htm#hepa>



CROSSWORD ANSWERS	
DOWN	ACROSS
1 Shingles	3 Throw Out
2 Pneumococcal	6 Medical Devices
4 Vaccines	8 Packaging
5 Report Problems	9 Non-Absorbable
7 Absorbable	10 Wrinkle Fillers



MedWatch Reporting Is Important to FDA and to YOU!

Consumers play an important public health role by reporting to FDA any problems they have when using any products that the FDA regulates. Timely reporting allows the agency to take prompt action. There are a number of ways you can report problems to the agency, depending on the type of problem and product.

The following charts will help you make your report.

<h3>Problems to Report to MedWatch</h3> <p>MedWatch is for reporting four types of problems with human health care products. Examples of each are shown here.</p>			
Serious Adverse Event	Product Quality Problem	Product Use Error	Problem with Different Manufacturer of Same Medicine
<ul style="list-style-type: none"> • death • life-threatening situation • requires admission to hospital or longer-than-expected hospital stay • permanent disability • birth defect, miscarriage, stillbirth, or birth with serious disease • requires medical care to prevent permanent damage 	<ul style="list-style-type: none"> • suspected counterfeit product • potentially contaminated product indicated by suspicious odor or unusual color • inaccurate or unreadable product labeling 	<ul style="list-style-type: none"> • mixing up products with similar drug names or packaging • taking wrong dose of a drug because of confusing dosing instructions on label • error while using a medical device that appears to result from confusing or misleading design, instructions or packaging. • lab test used for another purpose, such as testing children’s samples based on claims for adult testing of samples. 	<ul style="list-style-type: none"> • not getting same results from a generic drug as a brand name

Source: <http://www.fda.gov/consumer/updates/reporting061008.html>

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Quick-Reference Chart for Reporting Problems to FDA		
Type of Problem	Type of Product	Report to
Emergency (serious, life-threatening event)	FDA-regulated products (human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, cosmetics, radiation-emitting electronic products)	<ul style="list-style-type: none"> • FDA's 24-hour emergency line at 301-443-1240 or • FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html) • Also contact your health care professional for medical advice.
<p>Serious or Unexpected Adverse Event (side effect)</p> <p>Product Quality Problem (such as a medicine having a suspicious odor, suspect counterfeit problems, contamination, instability, defective components)</p> <p>Therapeutic Failure (such as generic not working as well as brand name or other generic brand)</p> <p>Product Use Error (such as mixing up products with similar drug names)</p>	<p>Human Health Care Products:</p> <ul style="list-style-type: none"> • human drugs • medical devices • biologics • blood products and other biologics (except vaccines) • dietary supplements • infant formulas • medical foods such as special nutritional supplements 	<ul style="list-style-type: none"> • MedWatch at www.fda.gov/medwatch/report.htm, or call 1-800-332-1088 to request reporting form or to give verbal report • Fax MedWatch Report to 1-800-FDA-0178 (1-800-332-0178) • Mail MedWatch Report to 5600 Fishers Lane, Rockville, MD 20852-9787 • FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html) • Also contact your health care professional for medical advice.
Food-related Non-emergency (such as allergic reaction to a product with no allergens listed in ingredients; a non-life-threatening foodborne illness)	Food Products [except meat, poultry, and frozen, dried and liquid eggs which are regulated by the United States Department of Agriculture (USDA)]	<ul style="list-style-type: none"> • FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html) • If problem involves meat, poultry, or frozen, dried or liquid eggs, call USDA hotline at 1-800-535-4555.

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Quick-Reference Chart for Reporting Problems to FDA Continued		
Type of Problem	Type of Product	Report to
Illness or Injury Related to a Vaccine	Human vaccines	<ul style="list-style-type: none"> Vaccine Adverse Event Reporting System (VAERS) at https://secure.vaers.org/VaersDataEntryintro.htm, or call 1-800-822-7967 to request reporting form. Also contact your health care professional for medical advice.
Blood Transfusion-Related Fatality	Blood products	Go to www.fda.gov/cber/transfusion.htm , call 301-827-6220 or e-mail fatalities2@fda.hhs.gov .
Cosmetic Problem	<ul style="list-style-type: none"> Wrinkle Fillers Decorative Contact Lenses Novelty makeup Face paint Other cosmetics 	<ul style="list-style-type: none"> Report to MedWatch at www.fda.gov/medwatch/report.htm or call 1-800-332-1088 to request reporting form Fax MedWatch Report to 1-800-FDA-0178 (1-800-332-0178) Mail MedWatch Report to 5600 Fishers Lane, Rockville, MD 20852-9787 Consumers can also report adverse events from cosmetics to the CFSAN Adverse Event Reporting System (CAERS) 301-436-2405; fax 201-436-2452; or email CAERS@fda.hhs.gov FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html)
Product Sold Online (such as a prescription product you suspect is being illegally sold or promoted on the Web without a prescription)	FDA-regulated products sold online (human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, cosmetics, radiation-emitting electronic products)	<ul style="list-style-type: none"> Go to www.fda.gov/oc/buyonline/buyonlineform.htm To report e-mail promoting medical products that you think might be illegal, forward email to webcomplaints@ora.fda.gov.
Animal Food Problem	<ul style="list-style-type: none"> pet food animal feed 	<ul style="list-style-type: none"> FDA Consumer Complaint Coordinator in your geographic area. (See list at www.fda.gov/opacom/backgrounders/complain.html)
Animal Drug or Device Problem	Veterinary drugs or devices	<ul style="list-style-type: none"> FDA's Center for Veterinary Medicine (CVM) at 1-888-FDA-VETS (1-888-332-8387) or go to www.fda.gov/cvm/adetoc.htm.

Source: http://www.fda.gov/consumer/updates/reporting_guide061008.html

Recent News from the FDA

FDA Approves Entereg to Help Restore Bowel Function Following Surgery

FDA approved Entereg (alvimopan) to speed up the time it takes to recover normal bowel function in patients 18 years and older who have had partial large or small bowel resection surgery.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01838.html>

Device Identifies Fatty Deposits in Coronary Arteries

In April 2008, the FDA cleared the InfraReDx LipiScan NIR Catheter Imaging System for marketing. It is a new medical device that allows doctors to see inside the coronary arteries and determine the fat content of the plaque buildup on the artery wall.

<http://www.fda.gov/consumer/updates/arteries050108.html>

FDA Advises Patients to Switch to HFA-Propelled Albuterol Inhalers

The FDA issued a public health advisory to alert patients, caregivers and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers. Chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after Dec. 31, 2008 because they are being phased out. CFCs are harmful to the environment because they deplete the ozone layer above the Earth's surface.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01842.html>

Warning for Regranex—Cream for Leg and Foot Ulcers

On June 6, 2008, the FDA announced that a Boxed Warning has been added to the label of Regranex Gel 0.01% (becaplermin).. The warning addresses the increased risk of cancer death in patients who use three or more tubes of the product.

<http://www.fda.gov/consumer/updates/regranexcream061108.html>

FDA Requests Boxed Warnings on Older Class of Antipsychotic Drugs

FDA has required manufacturers of "conventional" antipsychotic drugs to make safety-related changes to prescribing information on labeling. The labeling will warn about an increased risk of death associated with the unapproved or "off-label" use of these drugs to treat behavioral problems in older people with dementia.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01851.html>

FDA Warns Individuals and Firms to Stop Selling Fake Cancer 'Cures'

FDA sent warning letters to U.S. companies and foreign individuals marketing products that make false claims that the products prevent and cure cancer. The FDA also warns North American consumers against using or purchasing the products, which include tablets, teas, tonics, black salves, and creams, and are sold under various names on the Internet.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01852.html>

Maturity Health Matters

Maturity Health Matters is an FDA publication for older adults, their families and caregivers. We provide our readers with current information on FDA-regulated medical products. This publication can be freely reproduced and distributed. Comments about our publication should be sent to the editors. The information published in this issue was current as of the date of publication.

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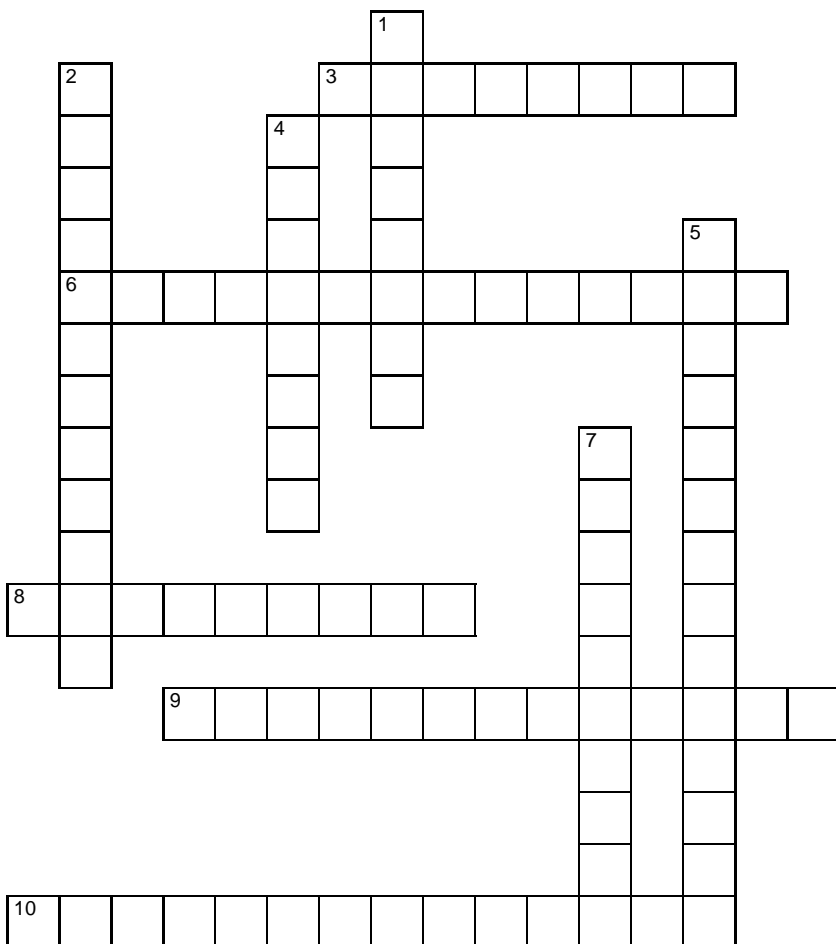
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To receive free email notices of new issues, go to www.fda.gov/cdrh/maturityhealthmatters to sign-up.

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Maturity Health Matters - Crossword*



ACROSS

- 3 After a disaster, do this if you are uncertain if your medicine or foods are safe. (two words)
- 6 Keep these clean and dry after a disaster. (two words)
- 8 Consumers can find important information (codes, numbers, dates) on a problem product here.
- 9 Permanent wrinkle fillers
- 10 If you are allergic to collagen, eggs, or lidocaine, you should avoid these medical devices. (two words)

DOWN

- 1 This vaccine helps avoid a painful rash and blister disease.
- 2 Adults over the age of 65 should ask their doctors for this vaccine.
- 4 These reduce serious illnesses or deaths from many infectious diseases.
- 5 Consumers can do this and play an important role in public health. (two words)
- 7 Temporary wrinkle fillers

***All answers are taken from this issue.**

Crossword answers on page 6