PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR APRIL 2002 ◆ VOL. 18, NO. 4

Saving Your Sight—Early Detection Is Critical

The following article is excerpted from FDA Consumer *magazine, March-April 2002. We have omitted discussion of some of the new treatments which we are currently evaluating and have added a brief section on drug treatment for glaucoma from the 1999 edition* of Worst Pills, Best Pills.

Sometimes eye diseases occur with the natural aging process. Other times, they run in families, in the same way that cancer or heart disease might. Diseases and conditions such as diabetes and high blood pressure also increase the risk for eye problems. The leading causes of irreversible blindness—glaucoma, macular degeneration and diabetic retinopathy—tend to come on silently, without pain or other symptoms in the earliest stages. The later an eye problem is diagnosed, the harder it becomes to treat. In some cases, any vision that has slipped away may be gone forever.

Experts say that skipping regular and thorough eye exams is chief among the barriers to early detection. It's important to have your eyes regularly checked through dilated pupils so doctors can get a good three-dimensional view of the optic nerve and retina. For a dilated exam, an eye specialist places drops in the eye to enlarge the pupils. "Without dilating the eye, it's like looking inside a room through a keyhole instead of an open door," according to George Blankenship, M.D., immediate past president of the American Academy of Ophthalmology (AAO).

Also problematic is the tendency to ignore symptoms when they do present themselves, says Lee R. Duffner, M.D., an ophthalmologist in Hollywood, Florida. "It's not uncommon to see patients who say they've been having eye problems for a whole year before coming in to get checked—usually because of a spouse or other relative who encouraged them to come in."

Here's a look at four eye diseases you can't afford to miss.

Glaucoma

The Problem

It's not known why, but people with glaucoma typically experience an imbalance in eye fluid production and drainage. Fluid that normally flows in and out of the eye drains too slowly. As that fluid builds up, pressure in the eyeball increases and becomes abnormally high, a condition that can damage the optic nerve, the retina, or other parts of the eye.

It's important to note that there are also patients with glaucoma who actually have what would be considered normal eye pressure, says Sheryl Berman, M.D., a medical officer in the Food and Drug Administration's division of ophthalmic and ear, nose, and throat devices. "This is why it is so critical to have dilated examinations, since routine pressure screening would miss the diagnosis of glaucoma in these eyes." For these people, there are other factors at play

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that may lead to optic nerve damage.

If glaucoma is left untreated, blindness is likely. The most common form of glaucoma is primary open-angle glaucoma, also known as chronic glaucoma. Nearly 3 million Americans have glaucoma, according to the National Eye Institute (NEI), and about half do not know it. That's because glaucoma is a silent stealer of sight; there are usually no symptoms in the early stages. As the disease progresses, people with glaucoma may notice their side (peripheral) vision failing. But by this time, the disease is usually quite advanced and the damage is irreversible. Once vision is lost, it can't be restored. Glaucoma usually affects both eyes, one shortly after the other.

Ida Miggins, 52, a computer specialist from Takoma Park, Maryland, says she learned she had glaucoma three years ago by chance. She hadn't had an eye exam since childhood and hadn't noticed any vision problems. "I was actually taking my mother to her eye appointment, and the doctor suggested that I be checked too," says Miggins. The doctor diagnosed glaucoma in both eyes.

Risk Factors

Early detection is the best way to control glaucoma and prevent major vision loss. Elevated pressure in the eye is the major risk factor for glaucoma. Other risk factors associated with the disease include having high blood pressure, diabetes, and certain diseases that affect blood vessels. A family history of the disease, aging, and African ancestry also increase your risk for glaucoma.

Studies have shown that for unknown reasons, glaucoma presents at an earlier age in blacks, is five times more likely to occur in blacks than in whites, and is about four times more likely to cause blindness in blacks than in whites.

Miggins, who is black, says she had heard of glaucoma. "But I didn't have a clue what it was, nor did I think I was at risk for it because it doesn't run in my family."

If you are in any of the high risk groups for glaucoma—everyone over age 60, those with a family history of the disease, and blacks over age 40—you should get a complete eye exam at least every two years.

Treatment

Though glaucoma is not curable, there are treatments that successfully lower pressure in the eye. The first line of treatment is drugs, and whether you're prescribed eye drops or pills, taking your drugs as prescribed is critical.

The development of several classes of medications to reduce pressure in the eye has allowed for more effective treatment over time, says Wiley Chambers, M.D., deputy director of the FDA's division of anti-inflammatory, analgesic and ophthalmic drug products. For now, glaucoma medications only tackle eye pressure, says Chambers. "We're looking for treatments that can also protect the optic nerve."

Miggins says the first medication she took caused bleeding gums and eye pain. Some side effects may lessen over time, but be sure to report them to your doctor because it could be that the drug or dose needs to be changed.

Elevated pressure inside the eye can be treated in two ways: increasing the amount of aqueous humor that leaves the eye through the canal of Schlemm; or decreasing the amount of aqueous humor that is produced.

Drugs such as dipivefrin (PROPINE), pilocarpine, and physostigmine (ESERINE) increase aqueous humor outflow from the anterior chamber, whereas acetazolamide (DIAMOX), dorzolamide (TRUSOPT) and beta-blockers such as timolol (TIMOPTIC) decrease aqueous humor production. In either case, the total amount of aqueous humor is reduced and the pressure decreased. Timolol is often used for mild glaucoma, except in older adults who have congestive heart failure, abnormal heart rhythms, asthma, or emphysema. In these patients, pilocarpine or carbonic anhydrase inhibitors like dorzolamide or acetazolamide can be an alternative choice. A combination of drugs may be necessary for more severe forms. Surgery is reserved for those people who continue to have optic nerve destruction and visual loss, in spite of multiple drug therapy.

When glaucoma can't be controlled with medication, doctors may turn to laser surgery in which a focused beam of light creates openings in the part of the eye where fluid drains to make draining easier. The next line of treatment is a surgical procedure called trabeculectomy, in which a small opening is made in the front chamber of the eye to make a new pathway from which fluid can drain. Even with surgery, many

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Editor ..... *Sidney M. Wolfe*
Managing Editor ..... *Phyllis McCarthy*
Staff Researcher ..... *Benita Marcus Adler*
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patients who have glaucoma still need medication.

Age-Related Macular Degeneration (AMD)

The Problem

The cause is unknown, but AMD occurs when light-sensing cells in the macula break down. The macula is the central part of the retina and is responsible for clear, sharp vision.

About 90 percent of people with AMD have what's known as the "dry" type, and the remaining 10 percent have the "wet" type. The wet type of AMD is more severe and causes the most vision loss. In the dry type, the light-sensitive vision cells deteriorate but there is no bleeding. In the wet type of AMD, new blood vessels grow and leak blood and fluid under the macula. For some people with the disease, vision is affected very slowly. But for others, the disease progresses rapidly over the course of weeks to months.

"Macular degeneration rarely leads to complete blindness, but often causes severe and irreversible loss of central vision," says Stuart L. Fine, M.D., chairman of the department of ophthalmology at the University of Pennsylvania. Side vision remains, but the center of vision, which is needed for daily tasks like reading and driving, is destroyed.

About 1.7 million Americans have some form of AMD, according to the NEI. It's the leading cause of vision loss among Americans ages 65 and over. The disease is painless, and common symptoms include blurry vision, distorted vision, such as seeing straight lines as crooked or wavy, or a dark, empty area appearing in the center of vision.

Dorothy Borne, 66, a retired food technician from Hahnville, Louisiana, was diagnosed with wet AMD and experienced blurriness in her left eye about three years ago. It presented abruptly because a large quantity of fluid leaked into the macula from abnormal blood vessels.

"When I got to work that morning, I noticed that everything looked blurry," she says. "I didn't know what was wrong."

Risk Factors

Age and a family history of AMD are the biggest risk factors. People over age 60 are at the highest risk, and should get an eye exam at least every two years.

Fine says, "Other risk factors may include smoking, low lifetime intake of dark green leafy vegetables, high blood pressure, and cardiovascular disease. Some epidemiological studies have identified farsightedness and light eye color as risk factors."

According to NEI, women tend to be at greater risk for AMD than men, and whites are much more likely to lose vision from AMD than blacks.

Those at risk should get in the habit of checking their central vision in each eye separately by covering one eye while evaluating the other eye, Fine suggests. It is recommended that some patients keep an Amsler Grid on their refrigerator as a reminder to check their eyes at home. You look at the dot in the center of the grid to see if lines around it appear wavy or distorted, which could be a sign of AMD. Once you have AMD in one eye, there is a roughly 50 percent chance that it could occur in the other eye, so it's important to report any vision changes to your doctor and routinely test the other eye.

Studies have suggested that a diet rich in dark green, leafy vegetables such as spinach and collard or mustard greens lowers the risk of AMD. These foods are a source of nutrients such as vitamin A, vitamin C, and vitamin E. But experts say it's important to recognize that a balanced diet is generally important for eye health, the same way it is for the rest of the body.

Recent NEI research has shown that nutritional supplements—vitamin E, vitamin C, beta carotene, and zinc—*may benefit some people who have advanced AMD.* [Emphasis added] The American Academy of Ophthalmology recommends that if you have intermediate or advanced AMD in one eye only, you should talk with your physician about whether nutritional supplements may help you and how to take them safely. Not everybody needs supplements. For example, in large quantities, zinc can be toxic. Beta-carotene can increase the risk of lung cancer in smokers. High dose nutrients can also interfere with medications and decrease the absorption of other nutrients into the body. [Public Citizen emphasizes that there is no evidence these antioxidants *prevent* macular degeneration.]

Treatment

"For the dry form of AMD there is no specific treatment other than low vision rehabilitation, which shouldn't be underestimated," says Fine (see "Low-Vision Resources" on page 5).

Some cases of wet AMD can be treated with laser surgery. Again, lost vision usually can't be restored, but the laser aims a light beam onto new blood vessels to destroy them to preserve what central vision remains. Borne had laser surgery immediately and ended up having several more surgeries in the span of a few months, which left her with some scarring in the eye. "She needed the surgeries because some of the blood vessels around the macula continued to bleed," says Doctor Monica, Borne's doctor and an ophthalmologist in New Orleans.

In the end, the laser surgeries stopped the bleeding. "If the hemorrhage isn't stopped, there could be even more extensive loss of vision than just central vision," Monica says.

Borne has lost central vision in her left eye, but still has side vision in that eye and can grossly see large objects like cars. Borne, who can still see clearly out of her right eye, says, "I can read, just not for very long. After a while, words start jumbling together." She knows that if her right eye bothers her, day or night, she should call her doctor right away. "I just hope my right eye will stay OK," she says.

Cataracts

The Problem

Cataracts are areas that distort light as it passes through the lens of the eye (opacities). The most common type of cataract is age-related. As we get older, protein in the lens of our eyes can clump together and cloud the lens, which is located behind the iris and the pupil. The lens is responsible for focusing light and producing sharp images.

Cataracts form slowly and typically cause no pain. In late 2000, David Guillot, 65, a retired aerospace engineer from Covington, Louisiana, noticed blurry vision. "I couldn't make out road signs even with my glasses on," he says. Shortly after, he was diagnosed with cataracts in both eyes. In addition to blurriness, common symptoms of cataracts are reduced night vision, problems with glare, frequent eyeglass prescription changes, impaired depth perception, and color distortion. Cataracts usually occur in both eyes.

Risk Factors

Anyone can get cataracts, but it's for those over 60 that cataracts are most likely to interfere with vision. Cataracts can result from natural aging of the lens, but also can occur as a result of eye injury. An eye exam at least every two years is recommended for those over 60.

Some studies suggest that exposure to bright sunlight over several years may lead to cataracts, while other studies refute this, says Walter J. Stark, M.D., professor of ophthalmology at The Johns Hopkins University School of Medicine in Baltimore and director of the corneal and cataract services at the Wilmer Eye Institute. "The recommendation is that if one is outside a lot, say because of occupation, it may help to wear sunglasses that block ultraviolet rays," Stark says. "It won't hurt." Your sunglasses should offer 100 percent or nearly total UV protection. Wide-brimmed hats can also help block sunlight.

People with diabetes are at higher risk for cataracts, and smoking is a suspected risk factor. "It appears that smoking generally makes things worse when it comes to the eyes," Stark says. Taking corticosteroids for other medical conditions also can cause cataracts.

It had been believed that certain vitamins, such as vitamin C, might affect cataracts, but recent research has shown that nutritional supplements do not appear to prevent cataracts or keep them from getting worse.

Treatment

For some people with cataracts, a stronger eyeglass prescription may be all that's needed. Keep up with regular eye appointments and talk with your doctor about how the cataracts affect your ability to work, read, and take part in other routine activities.

When cataracts interfere with daily activities, surgery may be recommended to remove the clouded lens and replace it with a new, artificial one. Monica says it's probably the most satisfying operation for an eye doctor and patient. Cataract surgery has an overall success rate of about 98 percent. According to NEI, it's the most frequently performed surgery in the United States, with over 1.5 million cataract surgeries performed each year.

Like any eye surgery, there are risks such as eye infection and swelling. "Cystoid macular edema is an uncommon complication of cataract surgery that causes swelling and blurry vision," says FDA's Berman.

The most common complication is formation of a secondary opacification (known as posterior capsular opacification) behind the new lens implant, Berman says. "This is treated with a laser that creates an opening through which clear vision is regained."

Just 10 years ago, cataract surgery required a hospital stay of several days. Now, the surgery can sometimes be done in less than 30 minutes on an outpatient basis. Guillot says his surgery took about 20 minutes and he went home that day. He had a cataract removed from one eye in June 2001, and had eye surgery on the second eye about three weeks later. His doctor broke up his cataracts with a high-frequency ultrasound. "I can see much better," Guillot says. "I can read the newspaper, watch TV, and I notice a big difference when I'm on the Internet. Sometimes I don't even need my glasses."

Advances in lens technology have improved cataract surgery over the last several years. "New lens materials, such as soft silicone, acrylic, and hydrogels, are more flexible and foldable," Berman says. "They permit surgery through smaller incisions and some appear to have lower rates of secondary opacification formation." And multi focal lens designs have been approved that provide both distance and near vision, so that reading glasses may not always be necessary. "Future advances might come," Berman says, "as a result of research on lens materials able to form a new lens within the eye itself."

Diabetic Retinopathy

The Problem

When diabetes is uncontrolled, chronic high blood sugar levels can damage the blood vessels that feed the retina of the eye. In nonproliferative diabetic retinopathy (NPDR), an early stage of diabetic eye disease, the blood vessels may leak fluid. This may cause the retina to swell and vision to blur, a condition called diabetic macular edema. In what's known as advanced or proliferative diabetic retinopathy (PDR), abnormal new blood vessels grow on the surface of the retina. The abnormal blood vessels don't supply the retina with normal blood flow, and in addition may eventually pull on the retina and cause detachment.

Diabetic retinopathy is the leading cause of new cases of blindness, accounting for about 8,000 cases each year. It's the most common and serious threat to vision that people with diabetes face. Nearly half of all people with diabetes eventually develop some degree of diabetic retinopathy. It usually occurs in both eyes. There may be no early signs of the disease. More advanced cases may be signaled by floaters, blurred vision, eye pain, or gradual vision loss.

Experts say the rate of diabetic retinopathy is likely to get worse because the number of people with diabetes is increasing. About 16 million people have diabetes and many don't know it. In one recent National Institutes of Health study of Mexican-Americans over age 40, 23 percent of those who didn't know they had diabetes also had early to moderate diabetic retinopathy.

Risk Factors

Uncontrolled diabetes is the prime risk factor for retinopathy. Diabetic retinopathy can usually be managed with a combination of tight blood sugar control, appropriate exercise and diet, and early detection. People who are diagnosed with diabetes before age 30 should begin having dilated exams every year beginning five years after diagnosis. All others with diabetes should

have an eye exam every year. A recent study in the AAO's journal *Ophthalmology* showed that more than one-third of Americans with diabetes don't get a yearly dilated exam as recommended, putting them at risk for vision loss.

Treatment

Some cases of diabetic retinopathy can be treated with laser surgery that aims a strong beam of light onto the retina to shrink or seal leaking or abnormal vessels. But it can't restore vision already lost, which is why early detection is important. In some advanced cases of PDR, a vitrectomy is recommended, in which the surgeon removes the vitreous portion of the eye and replaces it with a clear solution.

Josephine Grant, 54, a former cafeteria worker from Gaithersburg, Maryland., says she had diabetes for several years and then experienced major vision loss seven years ago because of diabetic retinopathy. She is blind in her right eye, and can see a little bit with the left eye. Unfortunately, Grant came to treatment with an advanced form of the disease, which made her prognosis poor, says T. S. Melki, M.D., the Maryland ophthalmologist who performed Grant's surgeries.

If laser surgery is done in time, he says, the disease can be stopped or slowed. Melki says hundreds of patients with diabetes come to see him regularly, sometimes as frequently as every four to five months, so that the level of diabetic retinopathy can be followed closely. "If a patient has minimal disease then the follow-up is less frequent," Melki says. "There are some patients we refer to as 'The Golden Club,' who have had diabetes for over 20 years with no effect on the eye," he says. "So it can be done."

Free and Low-Cost Eye Screenings

EyeCare America-National Eye Care Project, a program of the American Academy of Ophthalmology to provide free or low-cost eye exams. Those who are eligible are people who are 65 or older, U.S. citizens, not in a health maintenance organization, not receiving care through the armed forces or Department of Veterans Affairs, and who haven't seen an ophthalmologist in the last three years. 1-800-222-EYES (1-800-222-3937) *www.aao.org/aaoweb1/Foundation/281.cfm*

Volunteers in Service in Our Nation (VISION) USA, a program to give free eye care to uninsured, low-income workers and their families, sponsored by the American Optometric Association. Eligibility requirements may vary by state. But generally, participants must have a job or live in a household where there is one working member, have no vision insurance, have income below an established level, and have not had an eye exam in the last two years. The deadline to enroll for free services in 2002 just passed. To learn more about the program, visit *www.aoa.org/commcenter/events-vision.asp*.

In January 2003, you can call 1-800-766-4466. The toll-free line is only operational during January of each year.

Recommended Guidelines for Eye Care

Exams before age 5: Toddlers should be screened for common childhood problems such as crossed eye, lazy eye, nearsightedness and farsightedness. *Puberty to age 39*: Should be checked if you experience any eye problems or visual changes such as pain, floaters, flashes of light, blurry vision, or eye injury. *Ages 40 to 65*: Should be examined every two to four years. *Everyone over 65*: Should be examined every one to two years. People at higher risk for eye diseases need to be examined more often. For example, adults with diabetes should have yearly eye exams. Other people at higher risk include blacks over age 40, people with a family history of eye disease, or those with a history of eye injury. *Source: American Academy of Ophthalmology*

Low-Vision Resources

There are many aids and devices that can help in low-vision situations. Among them are magnifying lenses you can mount on your glasses or on a headband, miniature telescopes to help see a television across the room, and talking wristwatches. Here are some organizations that can point you in the right direction for more on resources that help people with vision problems maintain their quality of life.

American Optometric Association
243 North Lindbergh Blvd.
St. Louis, MO 63141
www.aoa.org

Lighthouse International
111 E. 59th St.
New York, NY 10022
1-800-829-0500
TTY: 212-821-9713
www.lighthouse.org

National Association for Visually Handicapped
22 W. 21st St., 6th Floor
New York, NY 10010
212-889-3141
and
3201 Balboa St.
San Francisco, CA 94121
415-221-3201
www.navh.org

National Eye Institute, National Institutes of Health
2020 Vision Place
Bethesda, MD 20892
301-496-5248
www.nei.nih.gov

National Federation of the Blind
1800 Johnson St.
Baltimore, MD 21230
410-659-9314
www.nfb.org

Prevent Blindness America
500 E. Remington Rd.
Schaumburg, IL 60173
1-800-331-2020
www.preventblindness.org

Retinal Detachment

The retina is the light-sensitive layer of tissue that lines the inside of the back of the eye and sends visual messages to the brain. If the retina detaches from its normal position, permanent vision loss can result.

While anyone can experience retinal detachment, head or eye injuries and certain eye conditions increase the risk.

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Nursing Homes
More Can Be Done to Protect Residents from Abuse

The following is excerpted from a GAO report March 2002, #GAO-02-312.

The 1.5 million elderly and disabled individuals residing in nursing homes are a highly vulnerable population. They often have multiple physical and cognitive impairments that require extensive assistance in the basic activities of daily living, such as dressing, feeding, and bathing. Many require skilled nursing or rehabilitative care. In recent years, increased attention has been focused on the quality of care afforded nursing home residents. Concerns with inadequate care involving malnutrition, dehydration, and other forms of neglect have contributed to mounting scrutiny from state and federal authorities. There is also growing concern that some residents are abused—pushed, slapped, beaten, and otherwise assaulted—by the individuals to whom their care has been entrusted. Accordingly, the ability to both apprehend those who have abused nursing home residents and prevent further abuse has generated considerable interest.

While nursing homes are expected to keep residents safe from harm, there are a variety of federal, state, and local agencies—including law enforcement entities—that typically play a part in investigating instances of resident abuse. The federal government and the states share responsibility for the almost 17,000 nursing homes in the nation. The recently renamed Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA)—within the Department of Health and Human Services (HHS)—is responsible for establishing standards that nursing homes must meet to participate in the Medicare and Medicaid programs. CMS contracts with state agencies, such as departments of health, to conduct annual inspections—called surveys—of nursing homes to certify that they are eligible for Medicare and Medicaid payments. These state survey agencies are also responsible for investigating complaints they receive about the care nursing homes provide. In some instances, state survey agencies may notify state or local law enforcement agencies to conduct criminal investigations involving resident abuse. Depending on the policy of the survey agency, it may opt to involve the state's Medicaid Fraud Control Unit (MFCU), typically an investigative component within the state's Office of the Attorney General, or the appropriate local police department in investigating abuse allegations.

We have previously reported on deficiencies in the oversight of the quality of care provided to nursing home residents, noting weaknesses in states' complaint investigations, annual surveys, and enforcement actions. For example, in March 1999, we reported that inadequate state procedures and limited HCFA guidance and oversight resulted in, among other things, extensive delays in investigating serious complaints alleging harmful situations. Also in March 1999, we reported that state surveys identified deficiencies that harmed residents or placed them at risk of death or serious injury in more than one-fourth of nursing homes nationwide. Moreover, sanctions that HCFA initiated against a majority of these homes for noncompliance with federal standards were often not implemented and generally did not ensure that homes maintained compliance with standards. More recently, in September 2000, we reported that, although HCFA had begun requiring states to investigate complaints alleging harm within 10 working days of their receipt, states were not consistently meeting this time frame.

In response to your concerns with the adequacy of protections afforded nursing home residents and the responsiveness of federal, state, and local agencies to allegations of resident abuse, we (1) determined whether allegations of abuse are reported promptly to local law enforcement and state survey agencies, (2) assessed the extent to which abusers are prosecuted and the impediments to successful prosecutions, and (3) evaluated whether sufficient safeguards exist to protect residents from abusive individuals.

To address these questions we limited our work to acts of alleged physical and sexual abuse committed by nursing home employees against nursing home residents. We did not address other forms of abuse such as neglect or verbal abuse nor did we examine instances of nursing home residents abusing other residents. We interviewed CMS officials and reviewed agency policies and pro-

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These include myopia, commonly known as nearsightedness, and posterior vitreous detachment, which occurs when the vitreous (the jelly-like fluid in the eye) breaks away from the back of the eye. The most common symptom of a posterior vitreous detachment is a condition called floaters, specks or strands that appear to float in the field of vision. Sometimes when the vitreous breaks away it can tear the retina, which can lead to retinal detachment.

Symptoms of retinal detachment include seeing floaters, flashes of light, or the appearance of a curtain over the field of vision. It's important to see an eye care professional immediately if you experience these symptoms because early treatment is critical for restoring vision.

Small holes and tears in the retina may be treated in a doctor's office with laser surgery, which uses tiny burns to seal the retina back into place. Another treatment, cryopexy, freezes the area around the hole in the retina. Retinal detachments may require surgical treatment to reattach the retina and a hospital stay.

Product Recalls

February 12—March 10, 2002

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS & DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is *www.fda.gov*.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Liquid Oxygen, Medical, Refrigerated, transfilled into Cryogenic Home Units; Class II; Firm failed to perform identity and potency testing prior to distribution	All units transfilled and distributed from 1/22/02 through 1/30/02; 140 home units and 11 dewars distributed in Ohio; Medico Medical Equipment & Supplies Inc., Berea, Ohio
Marinol (Dronabinol) Capsules, 2.5 mg, and 10 mg, bottles of 60, Rx only; Class III; Container defects—some bottles are missing their inner foam seal	Lots 11110010A, 11110011A, 11110012A, all expire 10/03; 8,696 bottles distributed nationwide; Banner Pharmacaps, Inc., Chatsworth, California. Recalled by Unimed Pharmaceuticals, Inc., Deerfield, Illinois
Metoclopramide Oral Solution, 5 mg/5 mL and 10 mg/10mL dose cups; Class III; Subpotency	Lots 101030, 102015, 101028, 101029, 101038, 102002, 102016; 12,068 cases distributed nationwide; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois. Recalled by Unit Dose Laboratories Inc., Rockford, Illinois
Microgestin Fe 1/20 Tablets, (Norethindrone Acetate and Ethinyl Estradiol Tablets, and Ferrous Fumarate Tablets), 28-day regimen, 6 tablet dispensers, 28 tablets each, Rx only; Class III; Impurity specification failure (stability)	Lot 63002H01, EXP 6/03; 21,372 cartons distributed nationwide; Watson Pharmaceuticals Inc., Corona, California
Oxygen, Compressed D Size Cylinders; Class II; Product was manufactured in the absence of Good Manufacturing Practice Regulations (GMPs) including, but not limited to, the lack of potency testing	All lots; 9 cylinders distributed in Iowa; William Burke LTD (Main at Locust Pharmacy), Davenport, Iowa
SPES Capsules, Herbal Dietary Supplement, Immune System Formula, 30 capsules per bottle, 300 mg each, containing 15 different herbs; Class II; Product contains the undeclared prescription drug alprazolam	Lots 5311214 and 5431249; Undetermined quantity distributed nationwide and internationally; Botanic Lab, Brea, California
Tegretol Tablets, (Carbamazepine), 200 mg., 100 tablet bottles; Class II; Dissolution failure	Lot numbers 9243162 and 9245086; 5 bottles distributed in Iowa and Hawaii; Novartis Pharmaceutical Company, East Hanover, New Jersey. Recalled by Allscripts Healthcare Solutions, Libertyville, Illinois
Trihexyphenidyl Hydrochloride Tablets, 5 mg, Rx only, bottles of 100 and 1000 tablets; Class II; Mispackaging—2 mg tablets mixed in bottles of 5 mg tablets bearing 5 mg labeling	Codes 07419A, 074019B, 074019C, 074019D, 074019E; 1,457 bottles distributed in Alabama; Vintage Pharmaceuticals Inc., Charlotte, North Carolina

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call 1-800-FDA-1088. The FDA web site is *http://www.fda.gov.*

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Dermabond Topical Skin Adhesive; Class II; Inadequate seal in the blister packaging	Model No. BD12, Lots 061057, 061058, 061059; 130,116 units distributed nationwide; Closure Medical Corp., Raleigh, North Carolina
Infant Apnea Monitors; Class II; Monitor may shut down and audible alarm may fail to sound	AMI 9700, AMI 9700A, AMI Plus 9700B; 5,282 units distributed nationwide, and in Canada, Brazil, Argentina and the Netherlands; Cas Medical Systems Inc., Branford, Connecticut
Supreme Blood Glucose Test Strips, Product Number 880050, 50-count bottles and **Select GT Blood Glucose Test Strips,** Product Number 660100, 100-count; Class II; Product gives abnormally low readings when samples have high glucose levels	Supreme: Lots 12150B, 12220B, 12280B, 12290B, and 01031B; Select GT: Lot 12290A; 11,625 bottles of 50 strips distributed nationwide, Hypoguard (USA) Inc., formerly Chronimed Inc., Edina, Minnesota

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at 1-800-638-2772. The CPSC web site is *http://www.cpsc.gov.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Children's Books; Books have plastic abacus-like toy attached to back cover that contains plastic beads which can separate from cover, posing a choking hazard to young children	Zowie's 123 12-page white board book; 5,180 sold at bookstores nationwide from January though February 2002; Disney Children's Book Group, LLC, also known as Disney Press, New York, New York (866) 203-8070
Children's Books; Snap that secures the book could detach, posing a choking hazard to young children	Monsters In The Closet title, printed in English and Spanish; 39,000 sold nationwide from October 2001 through January 2002; Random House Inc., New York, New York (800) 493-0009 www.randomhouse.com
Fondue Sets; Plastic ring with handles attached to upper rim of pot can crack during normal heating or cooling, posing burn and fire hazards	Distinction by Trudeau and Trudeau Fondue Set, blue or white metal; 20,000 sold nationwide from October 2001 through January 2002; Trudeau Corp., Woodbridge, Illinois (800) 465-8909
Handheld Saws; Handles can separate from the body, causing the user to be cut	Revolution model serial #s 01 through 1,145,000, Rebel model serial #s 01 through 415,000 and Solaris model serial #s 01 through 270,000; 1.9 million sold nationwide from December 1999 through January 2002; Roto Zip Tool Corporation, Cross Plains, Wisconsin (800) 920-1467 www.rotozip.com
Humidifiers; Motors can overheat, posing a fire hazard	Care Free and Care Free Plus, 3, 3.3 and 5 gallon; 100,000 sold nationwide from August 2000 through February 2002; Hunter Fan Co., Memphis, Tennessee (800) 207-5982 www.hunterfan.com
Ice Cream Scoops; Cap at end of handle can fly off with substantial force, especially if the scoop is immersed in hot water, posing a risk of impact injury to nearby consumers	Silver-colored, aluminum with 4.5 inch handle; 190,000 sold at Dansk Factory Outlet Stores and Lenox Warehouse Clearance Centers nationwide from January 1988 through November 2001; Dansk International Designs Ltd., White Plains, New York (866) 855-9303 www.dansk.com

CONSUMER PRODUCTS *cont.*

Name of Product: Problem	*Lot #: Quantity and Distribution: Manufacturer*
Newborn Girls' Garments; Heat-sealed flowers on the front can detach after washing, posing a choking hazard to young children	Lavender velour jumpsuit and lavender terry and velour top, sold in sizes 0-3, 3-6, and 6-9 months; 21,800 sold nationwide from August through December 2001; OshKosh B'Gosh, Inc., Oshkosh, Wisconsin (800) 282-4674 www.oshkoshbgosh.com
Pedal Cars; Paint coating on some of these pedal cars contains high lead levels, presenting a potential lead poisoning hazard	17 different models of fire trucks, police cars and sedans, all made of metal and in a variety of colors; 75,000 sold at Raley's supermarkets and other stores nationwide from November 1999 through January 2002; Alpha International Inc., also known as Gearbox Pedal Car Company, Cedar Rapids, Iowa (800) 368-6367
Portable Air Compressors; Internal corrosion to the inner wall of the air receiver tank can cause air tank to unexpectedly rupture allowing pressurized air to suddenly and forcefully escape	Brands include Ajax, Charge Air Pro, Energair, Guardian Power, MacTool, Power Force, Rallye, Rand 4000, and Steel Driver; 458,000 sold nationwide from 1983 through 1991; Ingersoll-Rand Company, Woodcliff Lake, New Jersey (877) 552-2952 www.air.ingersoll-rand.com
Power Cord Sets; Connector can break, exposing electrical contacts and posing a shock hazard	Sold with Hewlett-Packard Deskjet 800 series and 900 series, HP Photosmart 1000 series, 1100 series, 1200 series, and 1300 series inkjet printers; 2.5 million sold nationwide from April 2001 through February 2002; Longwell Electronics, Brea, California (877) 917-4378 www.hp.com
Recumbent Bicycles; Seats can crack and break, causing the seat to come off the frame resulting in injury to the rider	1999 through 2001 model BikeE bicycles with 27-inch-tall seat backs, silver-colored seat frames with black mesh seat backs; 13,500 sold nationwide from February 1999 through February 2002; BikeE Corp., Corvallis, Oregon (800) 231-3136 www.bikee.com
Riding Lawn Mowers; Fuel tank can crack and leak fuel, posing a burn or fire hazard to consumers	Murray, Murray Select, Craftsman and Wizard brands with numerous model numbers; 89,500 rear-engine and 6,200 mid-engine mowers sold nationwide from January 1995 through January 2002; Murray Inc., Brentwood, Tennessee (800) 246-5896 www.murray.com
Snack and Activity Trays (New instructions); If suction cups are not properly attached, they can detach, posing a choking hazard to young children	Attaches to high chairs, strollers, swings and other flat surfaces; 8,900 sold nationwide from August 2001 through February 2002; Graco Children's Products, Inc., Elverson, Pennsylvania (800) 345-4109 www.gracobaby.com
Snuggle Bears; Eyes and noses can come off, posing a choking hazard to young children	Plush, cream-colored, 5, 8, and 10 inch sizes, 4 styles; 4 million sold and given away nationwide from May 1997 through May 1998; Unilever Home and Personal Care USA, of Greenwich, Connecticut (800) 896-9479 www.snuggletime.com
Stainless Steel Kettles; Cover traps steam inside of the kettle causing an increase in pressure, forcing hot water to rise and escape through the spout, posing a serious burn hazard	Stainless steel, with glass cover, model number 4302; 13,000 sold nationwide from October 2001 through January 2002; Calphalon Corp., Toledo, Ohio (800) 233-0753 www.calphalon.com

NURSING HOMES, *from page 6*
cedures for overseeing nursing home care quality. We visited three states with relatively large nursing home populations—Georgia, Illinois, and Pennsylvania. During these visits, we interviewed state officials—including those in survey agencies and MFCUs—who are responsible for responding to, and investigating, allegations of abuse. We also reviewed relevant federal laws and regulations, as well as the state laws and regulations pertaining to these three states.

To learn more about the manner in which abuse investigations are conducted, we judgmentally selected and reviewed files documenting Georgia, Illinois, and Pennsylvania state survey agency investigations of 158 physical and sexual abuse allegations, mostly from 1999 and 2000. Our findings cannot be generalized or projected. Where the files indicated that states had cited the nursing homes for deficiencies, we obtained subsequent surveys conducted to determine what, if any, sanctions had been imposed. We also determined the states' policies and procedures concerning employees with criminal backgrounds and examined records of survey agencies' actions related to nurse aides who had allegedly abused residents. All three states we visited had established dedicated telephone lines exclusively devoted to reporting complaints. We called these lines to verify that they were working properly and to verify that complaints of physical and sexual abuse would be accepted.We also made similar calls to other organizations we identified in local Georgia, Illinois, and Pennsylvania telephone books to determine whether these entities would accept complaints regarding the abuse of nursing home residents or make referrals to other organizations. Finally, to learn about law enforcement's role in responding to and investigating abuse allegations, we interviewed officials in these states who represented 19 local police departments and four local prosecutors' offices.

We conducted our work from July 2000 through February 2002, in accordance with generally accepted government auditing standards.

Results in Brief

Allegations of physical and sexual abuse of nursing home residents frequently are not reported promptly. Local law enforcement officials indicated that they are seldom summoned to nursing homes to immediately investigate allegations of physical or sexual abuse. Some of these officials indicated that they often receive such reports after evidence has been compromised. Although abuse allegations should be reported to state survey agencies immediately, they often are not. For example, our review of state survey agencies' physical and sexual abuse case files indicated that about 50 percent of the notifications from nursing homes were submitted two or more days after the nursing homes learned of the alleged abuse.These delays compromise the quality of available evidence and hinder investigations. In addition, some residents or family members may be reluctant to report abuse for fear of retribution while others may be uncertain about where to report abuse. Although state survey agencies in the three states we visited had designated telephone numbers for reporting abuse, we found it difficult to identify these numbers in the government and consumer pages of local telephone books for some of the major and mid-size cities in these states. However, we did find a wide variety of other organizations that, by their name, appeared to be able to address abuse complaints, but, in fact, had no authority to do so. Although CMS requires nursing homes to post these numbers, it is not clear that this ensures that residents and family members have access to this information when it is needed. In recognition of the need to better inform residents and family members about abuse reporting, the agency initiated an educational campaign in 1998. The campaign included development of a new poster with removable information cards containing appropriate numbers for reporting abuse. Although a pilot test was conducted, the poster has not been approved for distribution nationwide.

Delays in investigations, as well as in trials, reduced the likelihood of successful prosecutions.

Few allegations of abuse are ultimately prosecuted. The state survey agencies we visited followed different policies when determining whether to refer allegations of abuse to law enforcement. As a result, law enforcement agencies were sometimes either not apprised of incidents or received referrals only after long delays. When referrals were made, criminal investigations and, thus, prosecutions were sometimes hampered because witnesses to the alleged abuse were unable or unwilling to testify. Delays in investigations, as well as in trials, reduced the likelihood of successful prosecutions because the memory of witnesses often deteriorated.

Safeguards to protect residents from potentially abusive individuals are insufficient at both the federal and state level. There is no federal statute requiring criminal background checks of nursing home employees nor does CMS require them. Although the three states we visited required background checks to screen potential nursing home employees, they do not necessarily include all nursing home employees nor are they always completed before

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NURSING HOMES, *from page 10*
an individual begins working. They also focus on individuals' criminal records within the state where they are seeking employment. Safeguards at the state level are also insufficient. While nursing homes are responsible for protecting residents from abuse, survey agencies in the states we visited rarely recommended that certain sanctions—such as civil monetary penalties or terminations from federal programs—be imposed. Twenty-six homes were cited for deficiencies related to abuse from the 158 case files we reviewed. The survey agencies recommended a civil monetary penalty for one home, while the remaining 25 nursing homes faced less punitive sanctions such as a requirement to develop corrective action plans. State survey agencies also play a role in preventing homes from hiring potentially abusive care givers through the states' nurse aide registries. These registries, among other things, identify aides that have previously abused residents. A finding of abuse should prevent a home from hiring an aide. However, delays in making these determinations can limit the usefulness of these registries as a protective safeguard. In addition, findings of abuse for several nurse aides could not be found in one state's web-based registry, compromising its protective value. As a result, aides who the state survey agency had already determined had abused residents could have been hired by unsuspecting nursing homes. Finally, none of the three states we visited had a safeguard in place—similar to a nurse aide registry—to professionally discipline those nursing home employees who do not need certifications or licenses to perform their duties, such as maintenance or housekeeping personnel.

Recommendations for Executive Action

We are making recommendations to the CMS administrator to facilitate the reporting, investigation, and prevention of abuse and thus help ensure the protection of nursing home residents. In comments on a draft of this report, CMS generally agreed with our recommendations and said that it is committed to protecting nursing home residents from harm. It also elaborated on its initiatives to ensure their safety and described steps it would take in response to our recommendations.

To better protect nursing home residents, we recommend that the CMS administrator:

- Ensure that state survey agencies immediately notify local law enforcement agencies or MFCUs when nursing homes report allegations of resident physical or sexual abuse or when the survey agency has confirmed complaints of alleged abuse.
- Accelerate the agency's education campaign on reporting nursing home abuse by (1) distributing its new poster with clearly displayed complaint telephone numbers and (2) requiring state survey agencies to ensure that these numbers are prominently listed in local telephone directories.
- Systematically assess state policies and practices for complying with the federal requirement to prohibit employment of individuals convicted of abusing nursing home residents and, if necessary, develop more specific guidance to ensure compliance.
- Clarify the definition of abuse and otherwise ensure that states apply that definition consistently and appropriately.
- Shorten the state survey agencies' time frames for determining whether to include findings of abuse in nurse aide registry files.

OUTRAGE, *from page 12*
vs 6.0 percent—and accounted for 74.1 percent of all uninsured health personnel.

Children residing with a health care worker accounted for an increasing percentage of all uninsured children. In 1988, 7.52 million children lived in a household with an adult health care worker. Of these children, 9.4 percent—or 705,000 children—were uninsured. Ten years later, 9.77 million children lived in a household with a health care worker. Of these children, 11.5 percent—or 1.12 million children—were uninsured, accounting for 10.1 percent of all uninsured children in 1998.

The authors found that insurance coverage was diminished for virtually every health occupation in every type of institution, suggesting a widespread deterioration in the quality of health care jobs. African American women, who traditionally have sought work in health care, may be particularly vulnerable to these changes—19.2 percent of working African American women were employed by the health care sector in 1993 and concluded "we believe that the increasing reliance on market forces in medicine has eroded the quality of health care jobs. In pursuit of minimal labor costs, market medicine denies health benefits to health workers and their children. The profits accruing to chief executive officers and shareholders might be viewed as a transfer of compensation to them from their workers." (We would add that this represents a most perverse form of income redistribution—from the poor to the rich.)

The authors continue "health care institutions' escalating dependence on uninsured workers raises troubling questions about medical quality and ethics. Can an uninsured health aide with limited access to care for back pain, seizures, or cough safely lift and feed frail patients?...And can those denied health coverage and care for themselves and their children be expected to care compassionately for strangers?

"Uninsured adults and uninsured U.S. children are more likely to be inadequately immunized, to lack a usual source of care or physician, and to have unmet medical needs than their privately insured counterparts. In denying care to care givers, our increasingly market driven health care system subverts an intuitive and universal ethical instruction: do unto each as you would have done unto you."

No Care for the Care Givers

Declining Health Care Coverage for Health Care Personnel and Their Children

In the March 2002 issue of the American Journal of Public Health *is a study which documents that one of the most rapidly growing groups of employed workers in the U.S. who lack health insurance coverage is, ironically, health care workers. The following data are excerpted from the article.*

Using federal Census Bureau data from 1988 and 1998, the authors, Harvard medical student Brady Case and our colleagues Drs. Steffi Woolhandler and David Himmelstein of Cambridge Hospital and Harvard Medical School, found that 1.36 million health care personnel—defined as persons employed in the offices of physicians or other health practitioners, in hospitals, in nursing and personal care facilities, or in other health services—lacked health insurance in 1998, up 84 percent from 1988.

Coverage of health care workers varied by place of employment. Twenty percent of nursing home personnel were uninsured in 1998, compared with 8.2 percent of hospital workers, 8.7 percent of those employed in medical offices, and 15.9 percent of workers at other health care establishments. Among the various types of health workers, among occupational groups, nurses aides had the highest uninsurance rate in 1998—23.8 percent—and accounted for 37 percent of the uninsured health personnel. Food service, cleaning, building service, and laundry workers also had relatively low rates of health coverage—19.7 percent were uninsured in 1998. The proportion of uninsured licensed practical nurses rose steeply between 1988 and 1998, from 7.3 percent to 14.5 percent and uninsurance among physicians increased from 3.3 percent to 5.4 percent.

In 1998, 20.5 percent of black health care workers were uninsured, compared with 10.4 percent of white health personnel. Black women, who constituted 12.9 percent of the health care workforce in 1998, accounted for 22.5 percent of the uninsured personnel. Hispanic workers—who may be of any race—were twice as likely as non-Hispanics to be uninsured: 24.7 percent vs 11.2 percent.

Workers earning less than $25 000 annually, who constituted 52.7 percent of the health care personnel, were more than 3 times as likely as higher income workers to lack coverage—19.1 percent

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