PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR MAY 2013 – Vol. 29, No. 5

Grief and Antidepressant Use

The Diagnostic and Statistical Manual of Mental Disorders (DSM) is considered the bible for classifying psychiatric diagnoses and, consequently, for prescribing drugs to treat these disorders. It is intended primarily for psychiatrists but is used by professionals in many other medical disciplines. When the latest version — the fifth edition, called the DSM-5 — is published in May 2013, it will reflect a controversial change at the heart of a long-simmering debate among psychiatrists: Do people suffering from the recent loss of a loved one need an antidepressant to prevent major depression, or will time and the support of friends and family help them recover without the use of drugs?

The fourth version of the DSM, the DSM-IV, states that grief is a normal response to loss of a loved one, from which people will recover over time with help from family and friends — and without the need for antidepressant therapy. The so-called "bereavement exclusion" included in the DSM-IV states that the behaviors exhibited during the first few months of experiencing grief are excluded from being labeled as signs of major depressive disorder (MDD).

With the new publication of the DSM-5, a few psychiatrists have pushed hard, successfully, to change that sentiment by eliminating the bereavement exclusion. In their eyes, grief should be on the table for categorization as MDD, therefore rationalizing treatment with antidepressant drugs.

The use of antidepressants should be reserved for those who, after an adequate period of very normal, natural grieving, do not respond to the healing influences of support and time.

Revision authors and a potential conflict of interest

The Mood Disorders Work Group rewriting the DSM for 2013 was headed by Dr. Jan Fawcett, professor of psychiatry at the University of New Mexico, who in turn nominated the rest of the 11-member panel. One of the most significant members working on the bereavement exclusion was Dr. Sidney Zisook, a psychiatrist at the University of California, San Diego. Dr. Zisook has long studied bereavement issues and became the main force and key adviser on the Mood Disorders Work Group, as well as the individual primarily responsible for writing the new guidelines.

Dr. Zisook has written extensively on the subject of grief, including a major paper that he co-authored with a fellow member of the Mood Disorders Work Group, Dr. Kenneth Kendler, and published in 2007 in *Psychological Medicine*. Their review analyzed studies up to November 2006 (no starting date was provided). The Zisook and Kendler paper carried great weight in the revision process: It became the major reference supporting the new changes, as noted by one of the editors of the DSM-IV.

Zisook and Kendler stated at the end of their 2007 paper that "some subjectivity may have influenced which studies were included and how some of the data may have been interpreted. Few of the available studies used structured interviews, and even fewer incorporated the most appropriate control groups to answer our key question."

Nevertheless, they concluded that this data supported their proposed revision, stating that:

> Although the definitive study has yet to be completed, the preponderance of available data supports the hypothesis that BRD [bereavement-related depression] resembles typical cases of SMD [standard (nonbereavement-related) major depression] and therefore should be considered instances of SMD.

Essentially identical language was published the same year in the conclusions to another paper by Dr. Zisook and colleagues on this same subject.

In one of these 2007 reviews, Dr. Zisook listed himself as an adviser to

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LASIK Eye Surgery: Know the Risks, Not Just the Benefits

Laser-assisted *in situ* keratomileusis, or LASIK surgery, is often promoted as an effective, low-risk way to regain 20/20 vision and avoid glasses or contacts. Unfortunately, these claims can be misleading. The truth is, while most people who receive LASIK surgery are happy with the results, the procedure is not always as effective as patients hope it will be. There also are a number of rare but serious risks from LASIK surgery that can lead to permanent loss of vision quality and, in extreme cases, irreversible blindness. These risks are higher for certain groups of patients, and people in such high-risk groups should not undergo the procedure.

If you are considering undergoing LASIK surgery, you should find a good doctor and work with her or him to obtain a careful assessment; make informed choices; and ensure proper care before, during and after surgery. Learn the facts about the procedure beforehand and understand the right questions to ask to make smart decisions and avoid putting your eyes at risk.

How LASIK surgery works

In LASIK surgery, a laser is used to permanently change the shape of the cornea, the clear covering of the front of the eye. A typical LASIK procedure involves using a mechanical blade or laser to cut a flap in the outer part of the cornea, leaving a small part attached at the edge of the flap to provide a hinge. That flap is then folded back, revealing the middle section of the cornea that focuses light onto the back of the eye. Pulses from a computer-controlled laser reshape the section, after which the front flap of the cornea is replaced.

LASIK surgery is the most common form of surgery used to modify the shape of the cornea, but other surgeries also are available that may be better for particular patients.

Effectiveness of LASIK surgery

LASIK and related surgeries can be used to improve vision in those who are nearsighted, farsighted or have astigmatism. Most LASIK surgeries are successful, and it is not uncommon for clinical trials to report that 95 percent of patients or more have 20/20 vision 12 months after surgery.

Most patients report being satisfied overall with their LASIK results, but many are disappointed to find that they still require glasses after surgery, at least some of the time. Additional surgery to further improve vision may not be possible, and patients may be forced to continue wearing glasses or contacts to correct vision even after surgery. In 2009, the Consumer Reports National Research Center surveyed almost 800 adults who had undergone laser vision-correcting surgery over the prior eight years. While most patients were satisfied with their results overall, nearly two-thirds said they still had to wear glasses or contact lenses at least occasionally.

A large number of patients will not see as well without glasses following LASIK surgery as they did with glasses before undergoing surgery. In one study of a recently approved LASIK device, out of 160 people with farsighted eyes receiving LASIK surgery, about half could see as well or better without glasses or contacts one year following surgery than they had seen when wearing glasses or contacts before the surgery. The remaining half had worse vision, and 1 in 10 had vision that was much worse.

Risks of LASIK surgery

LASIK surgery usually causes minimal pain and the healing time is short, about a week in most cases (although people should avoid contact

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sports and swimming for a month or more). It is common to feel burning, itching and discomfort in the first few days after surgery, and some experience sensitivity to light, glare, starbursts or halos around lights, and bloodshot eyes. For most people, these symptoms diminish over time and should be gone entirely within six months of surgery.

However, for a small number of people who undergo LASIK surgery, impairment to vision can be long-term or serious. If these complications occur, they may require another procedure or medical treatment, which may not resolve the problem. As a result of treatment, some people lose lines of vision on a vision chart that cannot be corrected with glasses, contact lenses or additional surgery. For example, in the recent trial described earlier, 3 percent of eyes that were treated lost the ability to see two or more lines on an eye chart, even when corrected with glasses or contacts.

People who can see well on an eye chart may still develop other eye issues. They could experience glare, halos and/or double vision that can seriously affect nighttime vision or the ability to see in low-contrast environments (such as low light or fog). This can interfere with important tasks, such as driving at night. LASIK surgery also can prevent a person's eye from producing enough tears to keep the eye moist and comfortable. This condition, called "severe dry eye syndrome," can permanently reduce visual quality by causing intermittent blurring and other symptoms.

Other problems with LASIK surgery can lead to temporary loss of vision or even, in extreme cases, blindness. One such complication involves damaging or severing the outer flap of the cornea. The rate of these problems varies depending on the patient population, procedure and surgeon's level of expertise but is estimated to affect between 0.3 to 5.7 percent of participants in clinical trials. The flap of the cornea also can become detached or damaged after the surgery, something that occurs roughly 2 percent of the time. Also, the eye can become infected during or after surgery (which is estimated to have taken place in 0.03 percent of cases). Risks can be reduced by relying on a skilled surgeon, using only sterile products approved by the Food and Drug Administration (FDA), and ensuring proper eye care after surgery, but they cannot be eliminated.

If you are considering undergoing LASIK surgery, you should find a good doctor and work with her or him to obtain a careful assessment, make informed choices; and ensure proper care before, during and after surgery. Learn the facts about the procedure beforehand and understand the right questions to ask to make smart decisions and avoid putting your eyes at risk.

LASIK surgery is relatively new, so its long-term risks and benefits are still unknown. The first laser was approved for LASIK eye surgery in 1998, meaning that patients have only been receiving the procedure on a widespread scale for 15 years. Little is known about the effects the procedure might have beyond that time frame.

Who should avoid LASIK surgery?

People with either very poor vision or vision that is already very close to 20/20 may not be good candidates for LASIK surgery. The exact range of vision that is appropriate will vary according to the specific device being used to perform the operation and is described in the device's "indications for use," found on the product's FDA-approved professional labeling. People whose vision falls outside of the specified range should avoid surgery with the device.

Even slight deviations from the indication can have significant consequences. For example, one LASIK device was recently approved to treat people with hyperopia (farsightedness) of less than 5 diopters (a unit of measure of optical power) as well as other features. After the device manufacturer tested the device on patients with slightly worse hyperopia, up to 6 diopters, it decided not to share the efficacy data for these additional subjects with the FDA. Instead, the manufacturer requested a narrower indication that excluded the people with the most severe hyperopia. Though the outcomes for the patients who fell outside the narrower indication remain secret, it is not unlikely that the risks of surgery outweighed the benefits for these patients.

It is the eye surgeon's responsibility to become familiar with the approved indication for the device he or she uses. A surgeon should evaluate a patient's eyes prior to surgery and ensure that his or her condition is appropriate for the device's indication.

Other risk factors also can affect whether LASIK surgery is appropriate. Patients should not receive LASIK surgery if they have recently required changes in their glasses or contact prescription or in cases of:

- diabetes;
- eye disease, including glaucoma and herpes or other infection in the eye;
- eye injury or previous eye surgery;
- dry eyes, large pupils or thin corneas;
- diseases that affect the immune system, such as AIDS, lupus or rheumatoid arthritis; or
- certain eye conditions, such as keratoconus or thin corneas.

People who take steroids or medications that affect the immune system also may be poor candidates for LASIK surgery, because these medications may affect healing after the surgery. Patients taking medications that can cause changes in vision should not undergo LASIK surgery.

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GlaxoSmithKline (GSK) and a recipient of honoraria from GSK and Forest Laboratories, both manufacturers of antidepressant drugs. The Mood Disorders Work Group chairman, Dr. Fawcett, felt that financial ties to industry had no bearing on the work at hand, stating, "I don't think these connections create any bias at all. People can say we were biased. But it assumes we have no intelligence of our own."

The principles established in the Institute of Medicine's landmark 2009 report, *Conflict of Interest in Medical Research, Education, and Practice* are emphatic in stating that professional societies should "generally exclude individuals with conflicts of interest from the panels that draft the guidelines." This is due to the extensive influence such guidelines have in affecting "physician practice, quality measures, and insurance coverage decisions."

Opponents to the revision

On the other side of the bereavement-exclusion issue are the opinions of, among others, Dr. Allen Frances, chairman of the task force that created the DSM-IV. Now an emeritus professor at Duke University, Dr. Frances has been outspoken against the DSM-5's changes, fearing that "the revisions will medicalize normality and that millions of people will get psychiatric labels unnecessarily." Dr. Robert Spitzer, who oversaw the set of revisions that became the DSM-III, also has expressed concern, joining psychiatrists Dr. Jerome Wakefield of New York University and Dr. Michael First of Columbia University.

Dr. Frances is especially concerned that the change to the bereavement exclusion will promote overdiagnosis and overtreatment, with drug companies all too eager both to market drugs to physicians and convince the grieving that they need pharmaceutical help.

In an opinion piece published in *The New York Times*, he expressed additional fears of further ramifications, such as the notion that people receiving an MDD diagnosis might have difficulty getting a job or health insurance. Dr. Frances also stated that because most people recover from grief without antidepressants, once they begin taking the drugs, they may believe that it was the medicine that caused their recovery and feel compelled to continue taking them. Besides being expensive, antidepressants can cause serious side effects, and medication that was unneeded in the first place can end up causing physical harm.

It may be true that every person has a unique reaction to losing a loved one, but grief itself is a normal, adaptive process that allows the affected person eventually to get on with life.

Dr. Wakefield and Dr. First share Dr. Frances's concerns and feel strongly that the bereavement exclusion should remain in DSM-5. They even feel it should perhaps be lengthened in duration, such that an MDD diagnosis would not take place until after the currently specified time frame of two months. Both doctors emphasize the importance of distinguishing between the normal, intense grief caused by bereavement and major depression. They recommend improving the wording of the bereavement exclusion, proposing that the text list specific features that distinguish major depression from normal grief, such as suicidal ideation and morbid preoccupation with worthlessness. They state that the text as written can be misinterpreted by clinicians not trained in grief counseling.

Furthermore, Wakefield and First suggest adding "other life stressors," such as divorce or job loss, as additional circumstances to be excluded from MDD diagnosis. In other words, they believe individuals should have a chance to recover from difficult life events with the help of family and friends before starting treatment for a major depressive episode. They conclude an analysis of the Zisook et al. papers by stating that there is no empirical evidence supporting the proposed change to the DSM which thus "has no basis in scientific fact."

Nevertheless, in December 2012, the American Psychiatric Association unfortunately voted in favor of changing the DSM, thereby embracing the suggestion that treatment with antidepressants would be the best approach to bereavement for many people.

Public Citizen agrees with those psychiatrists favoring the less medicalized approach to bereavement. The use of antidepressants should be reserved for those who, after an adequate period of very normal, natural grieving, do not respond to the healing influences of support and time. ✦

Understanding and supporting the process of grief

It may be true that every person has a unique reaction to losing a loved one, but grief itself is a normal, adaptive process that allows the affected person eventually to get on with life. Recent studies have shown that feelings of grief can persist for many years, and some think they can last a lifetime. In most cases, grief does not need to be "medicalized."

Grief is frequently described as occurring in phases, one following the other. Some people move back and forth between phases, and the boundaries between the phases may be blurred.

- *Phase 1* begins immediately after the loss and may last up to a few weeks. The survivor experiences shock, numbness and disbelief, accompanied by crying, sighing, throat tightness and a sense of unreality.
- *Phase 2* is characterized by preoccupation with the deceased, a yearning to recover the lost person and an examination of the past relationship, including disagreements, conflicts and unresolved anger. Wildly changing emotions and intense dreams of the deceased may be experienced, as well as physical weakness and fatigue. (If this phase extends beyond several months and does not progress to further stages, it may signal the need for treatment, as a prolonged continuation of this stage constitutes pathological, or abnormal, grief.)
- *Phase 3* is characterized by disorganization and despair but also acceptance of the permanence and the fact of loss. Sadness persists in this phase, along with feelings of emptiness and loss of interest in usual activities.
- *Phase 4* involves resolution and reorganization of behavior, in which normal activities and interests resume. Occasional feelings of sadness and emptiness, as well as crying spells, may occur, but less frequently than before or with less intensity.

Familiarizing yourself with the natural, common phases of grief, and possibly recognizing in them your own feelings and behaviors, could help you to understand that a potentially risky pharmaceutical approach to handling grief may not be necessary.

Support groups and counseling, from family and friends or a mental health professional, may help you pass through the phases of mourning by accepting the reality of the loss, dealing with feelings and emotions, and readjusting to the new landscape.

In 1984, the Institute of Medicine and National Academy of Sciences released a landmark report entitled *Bereavement: Reactions, Consequences, and Care*. The report recommended the implementation of a series of societal supports involving:

- Health professionals and institutions, which have a continuing responsibility to the bereaved;
- Schools, which should train nurses and physicians to look for warning signs and refer people to counseling; and
- Social workers and chaplains, who should be made available in hospital settings.

Additionally, the report stated that increased public education could help offer support indirectly to bereaved persons, noting that many people are surprised by the intensity of the emotional reaction to the death of a loved one.

A network of care for those experiencing grief, as well as a basic understanding of what to expect, can offer crucial aid in helping the bereaved overcome suffering.

How to Check Your Blood Pressure at Home

The following article by Dr. Erin Marcus appeared on the website New America Media, www.newamericamedia.org. It is reprinted with permission.

A "Call to Action" from the American Heart Association (AHA), the American Society of Hypertension (ASH), and the Preventive Cardiovascular Nurses Association (PCNA) recommends that most people who have been diagnosed with high blood pressure, as well as people whose blood pressure is slightly elevated but not yet in the "high blood pressure" range, get a monitor and check their blood pressure regularly at home.

Sometimes, the simplest tools in medicine are the ones that give us the most useful information.

Take the humble blood pressure machine, for example. It's been around for years, and it's cheap, compared to a lot of other medical devices. It's simple to use and doesn't require a medical or a nursing degree to operate, but the numbers it reports are valuable in helping predict a person's risk of a host of medical problems, including heart failure, stroke and kidney failure. It can also help doctors determine whether a person really needs to take medicine to control his or her high blood pressure.

In recent years, many physicians have concluded that just checking blood pressure in the doctor's office or clinic isn't sufficient.

A "Call to Action" from the American Heart Association (AHA), the American Society of Hypertension (ASH), and the Preventive Cardiovascular Nurses Association (PCNA) recommends that most people who have been diagnosed with high blood pressure, as well as people whose blood pressure is slightly elevated but not yet in the "high blood pressure" range, get a monitor and check their blood pressure regularly at home.

Because they're taken in a familiar environment, home blood pressure readings tend to be lower than the measurements taken in a doctor's office or clinic, and better reflect a person's true blood pressure. They give doctors and nurses a better sense of how well a person's treatment is working, compared to sporadic readings taken in the office, and may enable some people to avoid medication entirely.

In a few cases, they also help detect the opposite: blood pressure that's in an abnormally high range at home, even though it seems normal during visits to the office. Home blood pressure monitoring can also help people save money and avoid missing work time, by reducing the number of visits they have to make to the doctor's office or clinic.

"There's emerging evidence that home blood pressure readings are good predictors of cardiovascular outcomes for most people," said Dr. Mahboob Rahman, an associate professor and hypertension researcher at Case Western Reserve University and University Hospitals Case Medical Center in Cleveland. "Patients are probably further along [in the habit of checking home blood pressure] than physicians, but we need to provide them with guidance."

Don Wiggins, a 60-year-old radio host and sales manager, uses a $50, battery-powered machine to check his blood pressure and says it's an important part of his daily routine. He began recording his blood pressure three years ago, after he underwent emergency heart bypass surgery.

A home nurse showed him how to use his blood pressure monitor. "At that point, I was ready to listen to anybody," he recalled recently. "But the machines are so easy. There's really no excuse for anyone not to check his or her blood pressure," he added.

"High blood pressure is very prevalent, especially among African-American men," he said. "It's a silent killer, and it's important to keep it under check."

How to take your own blood pressure

Below are some suggestions from Dr. Rahman, as well as from the AHA/ASH/PCNA "Call to Action" statement, regarding the best way to check your blood pressure accurately:

1. Pick a blood pressure machine that gives automatic readings and that's been "validated," meaning it's been tested for accuracy according to a widely accepted set of standards.

Dr. Rahman recommends a nonprofit website, Dableducational.org, which lists monitors that have been tested according to the standards of the European Society of Hypertension. It's also helpful to get a machine that will keep a log of your readings so that you'll have something to show your doctor or nurse practitioner.

2. Use arm monitors rather than wrist monitors.

Arm monitors, meaning machines with a "cuff," or sleeve that fits on the upper arm, tend to be more accurate than wrist monitors, according to the "call to action" statement, and finger monitors should generally be avoided. Wrist monitor readings can change with the position of the wrist. The wrist needs to be held at the level of the heart to get the most accurate reading.

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3. Make sure the cuff is the correct size.

The cuff, or sleeve of the machine that fits around your arm, needs to be the correct size for your arm. The inflatable part of the sleeve should fit around 80 percent of your upper arm. If your arms are large, you may need to buy a separate large cuff.

4. Follow the basic rules.

The basic rules, whether in the clinic or the home, start with sitting in a chair that supports the back, with both feet in a comfortable position on the ground, for five minutes before taking the measurement.

Smoking, exercising and drinking coffee should be avoided for half an hour prior to the reading, since these can make blood pressure levels rise transiently. If you need to use the toilet, do so before you check your blood pressure — don't take a reading when your bladder is full. Try to relax.

5. Check your blood pressure two to three times a week, at times when you are relatively calm.

The "Call to Action" statement recommends that doctors review at least 12 recordings prior to making any decisions about beginning, stopping or adjusting medication. The statement also says that a home value of 135/85 or above is high, as opposed to the 140/90 level that's usually considered elevated. For people with diabetes and other conditions that increase their risk of heart disease, the goal blood pressure is 130/80 or lower.

6. The goal is keeping an overall record.

Remember, the goal of checking your blood pressure at home is to keep an overall record that will help your doctor or nurse decide on what treatment to recommend.

Home monitoring is not meant to figure out why you might feel ill at any one particular moment. "Some people get in the habit of 'I'm not feeling well, so I'll check to see if my blood pressure is high or low,'" Dr. Rahman said. "That's not the best use of the blood pressure machine." If you're not feeling well, call your doctor or nurse so that they can diagnose the reason why.

7. Don't panic if the levels fluctuate.

In most people, blood pressure tends to be a bit higher in the morning and at work, and it's normal for it to ebb and flow. "The variability of readings is high," the joint statement explains. "Individual high or low readings have little, if any, significance."

8. Get your machine regularly checked.

Remember to bring your machine back to your doctor's office every year, so that the staff can make sure it's still working accurately.

Before using the machine, bring it to your clinic or doctor's office so that the staff can check its accuracy and make sure you know how to operate it correctly. The American Academy of Family Physicians and British Hypertension Society also post online instructions that can help orient you when you begin using your machine.

9. Pharmacy and grocery store monitors aren't best.

Don't rely on the blood pressure monitors available at the grocery store or pharmacy, as they aren't always accurate. If you can't afford to buy your own machine, check with your local fire department to see if they offer "drop-in" times when you can get your blood pressure checked. ✦

HRG Works for You!

Our latest work includes an unethical clinical trial involving premature infants, a link between certain diabetes drugs and cancer, and an illegally marketed weight-loss device

The work of Public Citizen's Health Research Group (HRG) doesn't end with its *Health Letter* and *Worst Pills, Best Pills News* publications. HRG uses current academic research, government data and information from whistle-blowers to advocate for consumers by:

- petitioning the government to remove unsafe drugs or medical devices from the market, and to require warnings of dangerous side effects on other drugs;
- testifying before government committees and arguing against approval of unsafe or ineffective drugs and medical devices;
- writing letters to government agencies about the adverse effects of drugs and medical devices; and
- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy includes:

- **Letter to Secretary of Health and Human Services Regarding Ongoing Clinical Trials Conducted by the Neonatal Research Network — 4/15/2013 —** In a letter to Health and Human Services (HHS) Secretary Kathleen Sebelius, Public Citizen demanded that in light of disturbing revelations about the unethical SUPPORT study involving premature babies (see more below and on page 12), HHS should release details about ongoing clinical trials involving infants conducted by the Neonatal Research Network and suspend enrollment in them until they are independently assessed by ethicists and others.
- **Letter to Secretary of Health and Human Services Regarding Unethical Trial Involving Premature Infants — 4/10/2013 —** In a letter to HHS Secretary Kathleen Sebelius, Public Citizen urged the secretary to personally apologize to the parents of 1,316 premature infants who were exposed to an increased risk of blindness and death as part of a clinical trial funded by the National Institutes of Health and held throughout the U.S. several years ago. The parents who enrolled their children in the study were not informed about the risks or true nature and purpose of the research.
- **Press release: New Study Underscores Increased Dangers of Certain Diabetes Treatments — 3/22/2013 —** New scientific evidence reveals an association between the development of precancerous lesions in the pancreas and use of a class of diabetes drugs known as incretins, which include Byetta (exenatide), Victoza (liraglutide) and Januvia (sitagliptin). These new findings are in accord with the rapidly increasing number of reports to the Food and Drug Administration (FDA) of pancreatic cancer in patients using these drugs compared with diabetics using different drugs for diabetes.
- **Press release: Good Move, But Years Late: FDA Warns Maker of 'Fat-Burning' Device to Stop Marketing Unapproved Product — 3/19/2013 —** HRG Deputy Director Michael Carome issued a statement indicating that the FDA is doing the right thing by warning RevecoMED International to stop marketing its LipoTron "fat-burning" device. The device was not approved for the use for which it was being promoted, and it poses a risk of burns. Though the FDA was right to act, the action comes years after the illegal distribution and promotion were first brought to the agency's attention.

Visit www.citizen.org/hrgpublications to read full reports and testimonies as HRG fights for government accountability in the interest of the public's health.

Product Recalls

March 6, 2013 – April 2, 2013

This section includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements (www.fda.gov/Safety/Recalls/EnforcementReports/default.htm), and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

ABILIFY (aripiprazole) Tablets, 30 mg. Volume of product in commerce: 21 blister packs. CGMP Deviations: A drum of Abilify 30-mg tablets rejected during the compression stage was not segregated from the other portion of the lot and was inadvertently shipped, packaged and distributed. Lot #: 2E69023A, expiration date 2/28/15. Bristol-Myers Squibb Manufacturing Company.

Citalopram Tablets, USP, 10 mg, 30-count bottle. Volume of product in commerce: 27,805 bottles. Chemical contamination: The product is being recalled due to complaints reporting a strong garlic odor or strong chemical smell. Lot #: C201028, expiration date 12/13. Dr. Reddy's Laboratories, Inc.

Citalopram Tablets, USP, 20 mg, 30-count bottle. Volume of product in commerce: 86,093 bottles. Chemical contamination: The product is being recalled due to complaints reporting a strong garlic odor or strong chemical smell. Lot #: C201922, expiration date 1/14. Dr. Reddy's Laboratories, Inc.

Citalopram Tablets, USP, 40 mg, 30-count bottle. Volume of product in commerce: unknown. Chemical contamination: The product is being recalled due to complaints reporting a strong garlic odor or strong chemical smell. Lot #s: C108376, C108634; expiration date 11/13. Dr. Reddy's Laboratories, Inc.

Dextroamphetamine Sulfate Extended Release Capsules, 5 mg, 90 capsules. Volume of product in commerce: unknown. Failed dissolution specifications: The affected lots may not meet the specifications for dissolution over the product shelf life. Multiple lots affected. Amedra Pharmaceuticals LLC.

Isoniazid Tablets, 300-mg tablets USP, 30-tablet and 100-tablet bottles. Volume of product in commerce: 77,531 bottles. Failed dissolution specifications; 36-month stability timepoint. Lot #s: 67079A, 67079B, 67079C; expiration dates unspecified. West-Ward Pharmaceutical Corp.

Meprobamate Tablets, USP, 200 mg, 100 tablets. Volume of product in commerce: 9,824 bottles. Failed impurities/degradation specifications: Out-of-specification result for an impurity, diphenyl sulfone. Lot #s: 386585A, expiration date 02/13; 429104A, expiration date 06/13; 474487A, expiration date 11/13; 491671A, expiration date 01/14. Watson Laboratories Inc.

Meprobamate Tablets, USP, 400 mg, 100 tablets. Volume of product in commerce: 20,587 bottles. Failed impurities/degradation specifications: Out-of-specification result for an impurity, diphenyl sulfone. Lot #s: 387879A, expiration date 02/13; 429105A, expiration date 06/13; 474488A, expiration date 11/13; 491672A, expiration date 01/14; 529095A, expiration date 04/14. Watson Laboratories Inc.

Terazosin Hydrochloride Capsules, 2 mg, packaged in: (a) 100-count bottles, and (b) 1,000-count bottles. Volume of product in commerce: unknown. Presence of foreign tablets/capsules: Recall is being conducted due to a foreign capsule found in one bottle. Multiple lots affected. Teva Pharmaceuticals USA, Inc.

ZARAH® Drospirenone/ Ethinyl Estradiol Tablets, 3.0 mg/0.03 mg. Volume of product in commerce: 136,720 cartons. Failed tablet/capsule specification: tablet breakage while pushing through the blister pack (dispenser). Lot #s: 401536AA/401536A, 401537AA/401537/A, 401538AA/401538/A, 406985AA/406985A, 432058AA/432058A, 512685AA/512685A; expiration dates unspecified. Watson Laboratories Inc.

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 CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Aqua Lung Buoyancy Compensators With SureLock II Weight Pocket Handles. The rubber handles can detach as divers are trying to remove the weight pockets to rise to the surface in an emergency, posing a drowning hazard. Aqua Lung at (855) 355-7170 or www.aqualung.com.

Baby High Chairs. The front opening between the tray and seat bottom of the high chair can allow a child's body to pass through and become entrapped at the neck. This poses a strangulation hazard to young children when the child is not harnessed. BabyHome USA Inc. at (888) 758-5712 or www.babyhome.es.

Basic Beat BB201 Standard Egg Shaker. The outer "end cap" that is glued onto the top, smallest part of the egg can come off, posing a small part choking or aspiration hazard. West Music at (800) 397-9378 or www.westmusic.com.

Bass Guitar Amplifiers. A nut inside the chassis can come loose and fall between the electrical coils, posing an electrical shock hazard to consumers. tc electronic at (800) 349-4699 or www.tcelectronic.com.

Battery-Powered BrightLight™ Blankets. The batteries in the blanket can overheat, posing a burn hazard. IdeaVillage at (866) 655-4342 or www.brightlightblanketrecall.com.

Bell Full Throttle Bike Helmets. The buckle on the helmet's safety strap can release in an accident and allow the helmet to fall off the rider, posing a risk of head injury. Bell Sports Inc. at (866) 892-6059 or www.bellbikestuff.com.

Bicycle Hydraulic Disc Brakes. The brakes can fail in low temperatures, posing a collision hazard. Magura USA at (800) 448-3876 or www.maguradirect.com.

Break-Barrel Air Rifle. The air gun can discharge while the safety is engaged, posing a risk of injury to consumers and those nearby. Soft Air USA at (866) 763-8247 or www.softairusa.com.

Bugaboo Cameleon3 Strollers. The stroller's carrying handle can break and detach posing a fall hazard. Bugaboo Americas at (800) 460-2922 or www.bugaboo.com.

Cargo Bike. Passengers' feet can get caught in the rear wheel, posing a foot injury. Yuba Bicycles at (877) 889-9822 or www.yubabikes.com.

Cha Cha and Cha Cha 2 Girls' Boots. The zipper pulls on the boots can become entangled posing a fall hazard. Stuart Weitzman, Synclaire Brands U.S.A. at (888) 998-0702 or www.synclaire.com.

Cherry Model Strollers. The opening between the bumper bar and seat bottom of the stroller can allow an infant's body to pass through and become entrapped at the neck, posing a strangulation hazard to young children when a child is not harnessed. iCandy America at (877) 484-4179 or www.icandyworld.com.

Children's Pajamas. The pajamas fail to meet federal flammability standards for children's sleepwear, posing a risk of burn injuries to children. UNIQLO at (877) 486-4756 or www.uniqlo.com.

Filtrete™ Room Air Purifiers.The ion generator in the air purifiers can overheat, posing a fire hazard. 3M Company at (800) 388-3458 or www.filtrete.com/roomairpurifiers.

Garlic Slicers. A blade on the garlic slicer can unexpectedly dislodge during use, posing a laceration hazard to the consumer. The Pampered Chef at (877) 917-2433 or www.pamperedchef.com.

Imaginarium Activity Walkers. The small bolt and spacer that attaches each front wheel to the walker can detach, posing a choking hazard to young children. Toys R Us at (800) 869-7787 or www.toysrus.com.

LED Light Bulbs. The bulbs can overheat during use, posing a fire hazard. Lighting Science Group at (855) 574-2533 or www.lsgc.com/recall.

Martinique LX Jr. Youth Snorkeling Mask Sets. Notches in the tempered glass lens on the mask can break under certain water pressure, posing a laceration hazard to the user. U.S. Divers at (888) 606-6162 or www.usdivers.com.

Nu-Flame Vivo and Vivido Wall-Mounted Fireplaces. Overfilling or spilling fuel while attempting to refill fireplace fuel cups while in place can lead to the fuel cup being ejected from the fireplace, posing a fire or burn hazard to the user, bystanders or items nearby. Bluworld/Nu-Flame at (888) 499-5433 or www.nu-flame.com.

PT Domusindo Perdana Drop-Side Cribs. The cribs' drop sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop-side incidents can also occur due to incorrect assembly and with age-related wear and tear. Modus Furniture International at (800) 827-2129 or www.savannababy.com.

Santa Cruz Jr. Youth Snorkeling Masks. Notches in the tempered glass can cause the lens to break under certain water pressure, posing a laceration hazard to the user. U.S. Divers at (888) 606-6162 or www.usdivers.com.

LASIK, from page 3

Finally, pregnant or nursing women should wait to undergo LASIK surgery until their infants have been weaned. Hormones produced during pregnancy and lactation can affect eyesight, and LASIK devices are generally not tested on women who are pregnant or nursing.

Misleading advertisements

Patients should be cautious about selecting a doctor for LASIK surgery. It is important to shop around and select a doctor who is experienced with LASIK surgery and has a low rate of complications. It is a good idea to avoid surgeons promising "20/20 vision or your money back" or who advertise promises of no-risk surgery.

The FDA has received numerous complaints about eye care professionals and surgery centers that fail to inform consumers of the indications, limitations and risks associated with the LASIK procedure. In 2009, 2011 and 2012, the FDA issued warning letters to eye care professionals urging them to eliminate deceptive or misleading advertising, but some providers continue to publish misleading advertising that fails to explain the risks of LASIK surgery.

Advice for patients

If you have decided to pursue LASIK surgery, you should first obtain a baseline evaluation by an ophthalmologist to determine if you are a good candidate. Ask the opthalmologist whether you fit the indication for the surgical device they will use, and discuss any medications you are on or conditions you have. Also discuss the type of vision improvement you can expect to experience after surgery, as well as what types of risks may be involved.

It may be a good idea to consult at least two opthalmologists before deciding whether to have the procedure. These visits can be time-consuming and may cost money, but remember that results of your surgery will be permanent and not all surgeons will provide you with an adequate and honest assessment.

Expertise is extremely important in surgery. When you visit an opthalmologist, ask questions to determine his or her level of experience, including whether he or she is using a new technique and is experienced working with people who have your condition. Also ask if the surgeon is board certified. Learn how the surgeon keeps track of short- and long-term results for patients, and find out what percentage of prior patients had successful outcomes or experienced risks such as vision loss.

Also, confirm with the opthalmologist that the products he or she will use are FDA-approved. There have been several recent outbreaks of infection caused by drugs used in eye procedures that were made at compounding pharmacies or manufacturers selling "sterile" eye products that were not FDA-approved and not actually sterile.

Your surgeon should be willing to discuss severe or permanent side effects, even if the risk of experiencing these effects is very low. He or she also should provide you with a patient information booklet from the LASIK device manufacturer that can explain the procedure, describe risks and benefits, and instruct you on how to prepare for surgery and care for your eyes afterwards to prevent complications. Read this booklet carefully, and also read through the consent form your doctor will give you before surgery. Do not be afraid to ask questions about anything you do not understand.

The FDA has a useful website providing more detail on the benefits and risks of LASIK surgery, as well as what to expect before and after the procedure. Visit www.fda.gov and type the word "LASIK" into the search box on the upper right-hand corner of the website. ✦

CONSUMER PRODUCTS (CONTINUED)

SuperCube 2000 Powered Subwoofers. An internal failure with the subwoofer's level input jack (RCA jack) results in a shock hazard to consumers. Definitive Technology at (800) 228-7148 or www.definitivetechnology.com.

Whitewater Kayaking and Rafting Helmets. The chinstrap buckle can fail, posing a head injury hazard to users. WRSI at (888) 441-1041 or www.whitewaterhelmets.com.

Women's High-Heel Shoes. The heels on the shoes can become unstable, posing a fall hazard. White House | Black Market at (877) 948-2525 or www.whitehouseblackmarket.com.

PUBLICCITIZEN Health Letter

Outrage of the Month:
Unethical Studies on Premature Babies

Last month, Public Citizen sent a letter to the Department of Health and Human Services (HHS) requesting the details of seven new HHS-funded research studies about which we have serious ethical concerns and which are scheduled to involve 4,500 infants. These concerns derive from a previous study that has recently made front-page news, also funded by HHS and implemented by the same group of academic medical researchers.

Public Citizen first exposed the details of an unethical, HHS-funded medical experiment on premature babies that put them at risk of blindness or death without any semblance of adequate informed consent by their parents. Known as the SUPPORT trial, the study involved randomly assigning 1,300 very premature infants to one of two experimental groups. Researchers tried to keep blood oxygen levels in a higher range for one group and a lower range for the other. Depending on the group to which a baby was assigned, he or she faced substantial risks of blindness, brain injury and death, but parents were not adequately warned of any such risks.

The SUPPORT trial was implemented by 23 prominent research facilities throughout the country, including the Stanford University School of Medicine, Yale University School of Medicine, Brown University, Duke University and University of Alabama at Birmingham, all part of the Neonatal Research Network (NRN) established by the National Institutes of Health (NIH) in 1986.

We wrote to HHS Secretary Kathleen Sebelius, asking her to apologize to each of the parents involved and to inform them of the risks, about which they had never been told.

We later learned that at least seven newer NRN randomized trials involving newborns, also funded by NIH, are either ongoing or about to begin. These studies, expected to involve 4,500 infants, include testing experimental anemia treatments using blood transfusions in extremely premature infants, and examining the safety and effectiveness of cooling the body (hypothermia) for 72 hours in premature infants who had moderate-to-severe brain injury at birth.

In most of these studies, the likelihood of death is one of the primary outcomes being measured.

A forthcoming issue of *Health Letter* will feature a much longer article explaining further details about all of these experiments, as well as the subsequent actions that we have taken. ✦

PUBLICCITIZEN
Health Letter, Public Citizen Health Research Group
1600 20th Street NW, Washington, DC 20009

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