

Health Letter

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Nine Reasons Why Older Adults Are More Likely Than Younger Adults to Have Adverse Drug Reactions

The following is excerpted from Chapter Two of the newly updated edition of our book, Worst Pills, Best Pills. This section addresses the increased danger adverse drug reactions pose to elderly populations. Over 2.25 million copies of Worst Pills, Best Pills, now in its fourth edition, have been sold since its first publication in 1988. New for this edition, the entire book is now available online as a searchable database at www.worstpills.org. For more information, or to order your copy of this invaluable compendium of prescription drug information, see the special offer on page 11 of this newsletter.

Many of the studies and much of the information concerning the epidemic of drug-induced disease focuses on people 60 and over. However, some of the changes that eventually lead to great numbers of adverse reactions in older adults (in combination with increased drug use) really begin to occur in the mid-thirties. In connection with the idea that drug-induced disease begins to get more common before age 60, it is interesting to note that in a number of studies comparing the way "older" people clear drugs out of the body with the way younger people do, the definition of older is above 50, and younger is below 50.

1. Smaller Bodies and Different Body Composition:

Older adults generally weigh less and have a smaller amount of water and a larger proportion of fat than younger adults. Body weight increases from age 40 to 60, mainly due to increased fat, then decreases from age 60 to 70, with even sharper declines from 70 on. Therefore, the amount of a drug per pound of body weight or per pound of body water will often be much higher in an older adult than it would be if the same amount of the drug were given to a younger person. In addition, drugs that concentrate in fat tissue may stay in the body longer because there is more fat for them to accumulate in.

2. Decreased Ability of the Liver to Process Drugs:

Because the liver does not work as well in older adults, they are less able than younger people to process certain drugs so that they can be excreted from the

body. This has important consequences for a large proportion of the drugs used to treat heart conditions and high blood pressure, as well as many other drugs processed by the liver. The ability of the body to rid itself of drugs such as Valium, Librium, and many others is affected by this decrease in liver function.

3. Decreased Ability of the Kidneys to Clear Drugs Out of the Body:

The ability of the kidneys to clear many drugs out of the body decreases steadily from age 35 to 40 on. By age 65, the filtering ability of the kidneys has already decreased by 30%. Other aspects of kidney function also decline progressively as people age. This has an effect on the safety of a large number of drugs.

4. Increased Sensitivity to Many Drugs:

The problems of decreased body size, altered body composition

continued on page 2

CONTENTS

Bereavement

A look at the grieving process.....3

Product Recalls

December 16, 2004 to January 12, 2005

Children's jewelry and toys are on this month's list.....6

Outrage of the Month

Take Drugs off the Market12

NINE REASONS, from page 1

(more fat, less water), and decreased liver and kidney function cause many drugs to accumulate in older people's bodies at dangerously higher levels and for longer times than in younger people. These age-related problems are further worsened by the fact that even at "normal" blood levels of many drugs, older adults have an increased sensitivity to their effects, often resulting in harm. This is seen most clearly with drugs that act on the central nervous system, such as many **sleeping pills, alcohol, tranquilizers, strong painkillers such as morphine or pentazocine (TALWIN), and most drugs that have anticholinergic effects. This latter group includes antidepressants, antipsychotic drugs, antihistamines, drugs used to calm the intestinal tract (for treating ulcers or some kinds of colitis) such as Donnatal, atropine, and Librax, antiparkinsonian drugs, and other drugs such as Norpace.**

For all of the drugs in the above-mentioned groups that are listed in *Worst Pills, Best Pills*, we include an "anticholinergic" warning as follows:

Anticholinergic Effects

WARNING: SPECIAL MENTAL AND PHYSICAL ADVERSE EFFECTS

Older adults are especially sensitive to the harmful anticholinergic effects of this drug. Drugs in this family should not be used unless absolutely necessary.

Mental Effects: confusion, delirium, short-term memory problems, disorientation, and impaired attention

Physical Effects: dry mouth, constipation, difficulty urinating (especially for a man with an enlarged prostate), blurred vision, decreased sweating with increased body temperature, sexual dysfunction, and worsening of glaucoma.

Yet another example of the marked increase in the sensitivity of older adults to drugs has to do with stimulant drugs that are in the same family as amphetamines, or "speed." Despite the dangers of these drugs for anyone, especially older adults, they are widely promoted and prescribed, including Ornade, Tavist-D, Entex LA, and Actifed. All of these contain amphetamine-like drugs such as pseudoephedrine. For any of these drugs discussed in the book, most of which are listed as **Do Not Use** drugs, the following warning is given:

WARNING

[Name of drug] can cause or worsen high blood pressure. It is especially dangerous for people who have high blood pressure, heart disease, diabetes, or thyroid disease. People over 60 are more likely than younger people to experience effects on the heart and blood pressure, restlessness, nervousness, and confusion.

5. Decreased Blood-Pressure-Maintaining Ability:

Because older adults are less able to compensate for some of the effects of drugs, there is yet another reason why they are more vulnerable to adverse effects of drugs and more sensitive to the intended effects. The most widespread example of older adults' decreased ability to compensate is seen when they get out of bed and/or suddenly rise from a seated position. As you rise, your blood pressure normally falls, decreasing the blood flow to your head and resulting in less blood flow to the brain. Younger people's bodies can compensate for this: receptors in the neck, sensing that the blood pressure is falling as the person rises, tighten up the blood vessels in other parts of the body, thus keeping the overall blood pressure high enough. In older adults, these receptors do not work as well. Often, upon standing, older adults feel giddy, lightheaded, and dizzy. They may even faint because the blood pressure in the head falls

too rapidly.

The ability to maintain a proper blood pressure is further weakened when you use any of a very long list of drugs, **the most common examples being high blood pressure drugs. Other categories of drugs that cause an exaggerated blood pressure drop include sleeping pills, tranquilizers, antidepressants, antipsychotic drugs, antihistamines, drugs for heart pain (angina), and antiarrhythmics.** (*Worst Pills, Best Pills* contains a list of drugs that can cause dizziness on standing.)

This problem of so-called postural hypotension — the sudden fall in blood pressure on standing, brought about by a combination of aging and drugs — can be catastrophic. The falls that often result can end in hip fractures, a leading cause of death in older adults, or other serious injuries.

6. Decreased Temperature Compensation:

Younger adults are more easily able than older people to withstand very high or very low temperatures. They sweat and dilate (widen) blood vessels to get rid of excess heat when it is hot, and constrict (narrow) blood vessels to conserve heat when it is cold. Older adults' bodies are less able to do this. As in the case of blood pressure compensation, this "normal" temperature-regulating problem of older adults can be significantly worsened by any of a large number of prescription and over-the-counter drugs, resulting in fatal or life-threatening changes in body temperature. **Many older adults' deaths during heat waves or prolonged cold spells can be attributed to drugs that interfere with temperature regulation. Most of these people did not know they were at increased risk.** All drugs in *Worst Pills, Best Pills* that contain a warning about anticholinergic effects can have this harmful effect on withstanding heat waves.

7. More Diseases That Affect the Response to Drugs:

Older adults are much more likely than younger adults

continued on page 3

Bereavement

At least 8 million Americans lose a relative to death each year, and the result, for the survivors, is called bereavement. Medical writer Peggy Eastman has turned her personal tragedy, and her own response to it, into articles which have comforted many others.

"Nothing is more devastating than losing someone close to you, especially a spouse," says Ms. Eastman. Her husband, James Eastman, was a passenger on a small commuter plane which crashed in Maine, killing him, young activist Samantha Smith, and six others. Her first reaction was "violent tears of protest," and she later had nightmares, bouts of depression, and spiritual struggles.

One month after her husband's death, she says, "I set out to research my condition, in a desperate attempt to understand what was happening to me...I felt it might be the only thing that would help."

Bereavement is defined as "loss through death." The inevitability of

death makes bereavement, like pregnancy, a common and natural occurrence which results in changes in both function and behavior. As each person is different, so each death is different, and every bereaved person has some unique reactions, which may depend on the deceased person's age, suddenness of death, and type of death. Each year, death of a spouse results in 800,000 new widows and widowers. Despite the advances of modern medicine, which have reduced childhood mortality, nearly 400,000 persons under age 25 die each year, leaving millions of siblings, parents, and friends in a state of grief. There are at least 27,000 suicides each year in the U.S. Experts feel that the loss of a spouse or the loss of a child are the two most difficult losses to adjust to.

Grief, defined as the behaviors and processes associated with bereavement, usually follows a common course. Grief, sometimes equated with mourning, is normal, and adap-

tive, allowing the affected person eventually to get on with their own life. Grief may have complications, however, which may require medical attention. Other adverse events, such as a divorce or loss of a limb, may initiate similar grieving patterns.

The Phases Of Grief

Grief is frequently described as occurring in phases, in which one follows another, although some people move back and forth between them. The boundaries between the phases may be blurred.

Phase 1

The first phase begins immediately after the loss, and may last up to a few weeks. The survivor experiences shock, numbness, and disbelief. Other common symptoms include crying, sighing, throat tightness, and a sense of unreality. The shock may be more pronounced if the death is sudden and unexpected.

continued on page 4

NINE REASONS, from page 1

to have at least one disease — such as liver or kidney damage (not just the decreased function of older age), poor circulation, and other chronic conditions — that alters their response to drugs. Little is known about the influence of multiple diseases on drug effects in the elderly.

One well-understood example, however, is the effect of heart failure on the way people can handle drugs. When the heart is not able to pump as much blood as it used to, the change that occurs in heart failure, there is also a decrease in the flow of blood to the kidneys. For the same reasons discussed in reason number 3, the reduced flow of blood to the kidneys decreases the kidneys' ability to rid drugs from the blood and excrete them in the urine.

8. More Drugs and, Therefore, More Adverse Drug Reactions and

Interactions: Since older adults use significantly more prescription drugs than younger people, they have greatly increased odds of having a drug reaction caused by the dangerous interaction between two drugs. Often, older adults take one or more over-the-counter drugs in addition to their prescription drugs. This further increases the likelihood of adverse drug interactions. One of the more common kinds of adverse drug interactions is the ability of some drug to cause a second drug to accumulate to dangerous levels in the body. At the end of the discussion of each drug in the book, except for the **Do Not Use** drugs, there is a list of other drugs that can cause serious adverse interactions.

9. Inadequate Testing of Drugs in Older Adults Before Approval:

Although older adults use a disproportionate share of prescription drugs, few of these drugs are

adequately tested in older adults before being approved by the FDA.

Dr. Peter Lamy of the University of Maryland School of Pharmacy has stated, "We test drugs in young people for three months; we give them to old people for 15 years." The FDA is slowly remedying this serious problem by requiring that the people on whom a drug is tested be representative of those who will use the drug if it is approved. Nonetheless, most drugs on the market today, which are heavily used by older adults, were not adequately tested in this age group.

In summary, there are significant differences between younger and older patients, often not realized by doctors or patients. Increasing awareness of these differences will result in the prescription of far fewer drugs to older adults, and those that are prescribed will be given at lower doses in most instances. ■

BEREAVEMENT, from page 4

Phase 2

The second phase of grief is characterized by preoccupation with the deceased and a yearning to recover the lost person. The survivor frequently re-examines the past relationship, including disagreements, conflicts, and unresolved anger. Emotions can fluctuate wildly, from intense sadness, to anger, to guilt. Dreams of the deceased may be intense and vivid. Weakness and fatigue are also common. If this phase extends beyond several months and does not progress to further stages, it may signal the need for treatment, as this constitutes "pathological grief."

Pathological grief may refer to several abnormal patterns of grief. Absent grief, delayed grief and distorted grief are three such forms. Distorted grief usually involves persistence of the second stage of grief. This may show itself through compulsive overactivity without a sense of loss, acquisition of the symptoms associated with the deceased, loss of health, social isolation or alienation, or severe depression. Any of these symptoms may require medical attention, or increased social support. However, cultural norms may differ, and in some cultures a single symptom listed above may not represent a true problem.

Phase 3

Disorganization and despair characterize the third phase, although the end result is that the survivor accepts the permanence and the fact of loss.

The survivor ceases attempts to recover the lost person. Sadness persists in this phase, along with feelings of emptiness, and loss of interest in usual activities.

Phase 4

The fourth phase involves resolution and reorganization of behavior. Normal activities resume, and the bereaved person regains interest in usual activities. Some new social contacts are made. Occasional feelings of sadness, emptiness, and crying spells may occur, but less frequently than before, or with less intensity. The result may not be a complete return to previous activities, but is a lessening preoccupation with the deceased. Past events with the deceased person can be recalled with some pleasure.

The distress of grief and mourning was formerly thought to be short-lived, but recent studies have shown that such feelings can persist for many years. In fact, some think that it normally can last a lifetime. This has prompted some to conclude, "You really don't get over it, you get used to it." As noted before, there is a tremendous amount of individual variation.

The Consequences of Bereavement

It has been a common observation, over many years, that the recently widowed are at increased risk for death. Medical studies of this phenomena have more recent origins. Many studies have looked at the death of a spouse, and according to a 1984

National Academy of Sciences review, "some bereaved persons are at increased risk for illness and even death." Risk factors for death include male gender (widowers) and living alone. Remarriage seems to protect against this effect, but it is not clear if remarriage itself is truly protective, or if those with better support systems tend to remarry and that this protects.

Recent research has shown that the immune system becomes slightly depressed during the grieving process. This may be due to general stress, depression, bereavement itself, or for some other reason. Infections may result from this suppressed immune system, ranging from colds to pneumonia, although this is by no means universal.

Other bereaved persons at increased risk of serious consequences include those who feel a lack of a support system, those in poor health (physical or mental) prior to the death, alcoholics, those with severe financial difficulties, and those under 65. Preventive efforts may avoid some of the serious results of bereavement. Someone with many of these risk factors is more likely to need support, counseling, or some other intervention. The suicide of someone especially close also increases risk.

Interventions

As noted, grief is normal and adaptive, and in most cases does not need to be "medicalized" into an illness. However, if help is needed, there are people to turn to.

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1. Support groups are where people who have had similar experiences meet and discuss topics of concern.

Peggy Eastman joined such a group about three months after the death of her husband. "My church started a new weekly support group for people who had experienced a loss of a loved one. It was made clear that this was to be a support group rooted in the healing power of love, not a psychotherapy group." Topics can include social adjustment, research discussions, the grieving process, and how to avoid stumbling blocks. She concludes, "Nonjudgmental, confidential, peer-directed support groups are one of the best ways to resolve loss because they reassure the griever that he or she is not alone."

As noted in a National Institute of Mental Health publication, "Mutual-help groups do not intend to replace physicians, therapists, and other skilled professionals. Rather, the groups function in the belief that many of our physical and mental health needs go beyond the bounds of formal care measures."

2. Counseling is another intervention which may help deal with grief.

At its simplest, counseling may be support from friends and family, however, health care personnel can provide this service. The basic goal is to facilitate passing through the phases of mourning, by accepting the reality of the loss, dealing with feelings and emotions, and readjusting to the new environment.

3. Medications are a controversial part of the bereavement process, particularly because of the risk of delayed or distorted grief.

Some people feel that the reason for the widespread use of medications is that physicians find it easier to write a prescription than to deal with feelings. Some bereaved persons, however, do legitimately need a *short* (7-10 day) course of sleeping pills or tranquilizers. Longer courses of treatment may lead to addiction, or other complications. Research into this area, as recommended by the

National Academy of Sciences, is sorely needed.

4. The hospice movement has initiated preventive efforts for those with loved ones who have a chronic and fatal disease.

They can help prepare for the eventual loss. Their effectiveness is under investigation, because they are so new.

Recommendations

The Institute of Medicine/National Academy of Sciences released a report in 1984 entitled *Bereavement: Reactions, Consequences, and Care*. They had several conclusions and recommendations for future work in this area, although only some of the actions have been taken so far. Two international conferences on bereavement have been organized in response to the report, and some additional research money has become available, according to Fred Solomon of the Institute of Medicine.

The report recommends:

- Health professionals and institutions have a continuing responsibility to the bereaved.
- Schools should train nurses and physicians to look for warning signs, and should refer people at high risk for pathological grief for counseling.
- The integration of social workers and chaplains into hospital settings, particularly those involving terminal illness, has improved the care at some medical institutions.
- Increased public education may offer support indirectly to bereaved persons. The report notes that institutional care for the dying, and geographic mobility have left many people unprepared to deal with death. Many people are surprised by the intensity of their emotional reaction to the death of a loved one.
- Further research is needed in several areas, notably the process and outcome of bereavement. The risk factors for death or disease following the death of someone close need to

be studied to effectively plan ways to prevent such problems. Health consequences of bereavement in children, in minority groups, and in other cultures, as well as expanded research into the biology and physiology of grieving, were all highlighted as major areas in need of research.

Research into the intervention strategies described above is needed to evaluate their effectiveness and whether they may be broadly applied to the general population. In particular, the panel noted the opportunities available to evaluate the rapidly evolving hospice movement. Finally, they recommended the establishment of a research review committee by the federal National Institute of Mental Health (NIMH) to coordinate bereavement studies of all kinds.

What You Can Do

Several resources are available for mutual support groups. The national groups listed below may be able to refer people in need to a local group. Larger groups may be listed in the local telephone directory, and names and phone numbers of many more are available from hospitals, and local health and social-service agencies.

The Compassionate Friends

P.O. Box 3696
Oak Brook, IL 60521
<http://www.compassionatefriends.org>
(for bereaved parents, peer support)

Widowed Persons

1909 K Street, NW
Washington, D.C. 20049
(for widowed and peer support)

International Theos Foundation

322 Boulevard of the Allies, Suite 105
Pittsburgh, PA 15222
(for widowed and their families, peer support)

A pamphlet for the general public, written by the Institute of Medicine for the National Institute of Mental Health, entitled "Understanding Bereavement Reactions in Adults and Children" is available from: Public Inquiries Branch, NIMH, Room 15C-05, Rockville, Maryland 20857 ■

Product Recalls

December 16, 2004—January 12, 2005

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

DRUGS AND 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 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

Advair Diskus 100/50mcg (fluticasone propionate 100 mcg and salmeterol 50 mcg inhalation powder), 60 Doses per unit, For Oral Inhalation Only, Rx only; Class II. Defective container; patients may not receive medication as it is advanced through the Diskus unit.

Bulk American Ginseng 550 mg Capsules containing 100% American Ginseng Powder (*Panax quinquefolius*), Bulk Product No. SW464, Nature's Value Bulk Lot # 035609. Product: Class II, pesticide contamination.

Calcitriol Injection, 2 mcg/mL, 1mL Single Dose Vial, 25 pack box, Rx only, For IV Use, Class III, Impurity failure (18 month stability).

a) **Dabso Gel Relieving Lotion**, Net Wt. 4 oz. (120 gm) and 16 oz. jars, b) **Fire In Ice Relieving Lotion**, Net Wt. 4 oz. (120 gm) and 16 oz. jars, Class II, Unapproved New Drug; contains Dimethyl Sulfoxide (DMSO).

a) **Dietary supplement labeled in part: NATURE**Sex. Plex for him**, b) **Dietary supplement labeled in part: **Nature**Sex. Plex for her**, c) **Dietary supplement labeled in part: **Viga**Saw Palmetto Extract 20mg, Androstenedione 10mg, Tribulus Terrestris Extract**, Class II, the products are adulterated per 21 USC 342 (f) because they contain androstenedione, which is considered a new dietary ingredient.

Doxepin Hydrochloride Oral Solution, USP (Concentrate), 10 mg/mL, 120 mL (4 fl.oz.) bottle, Rx only, Class III, Failed pH specification (6 month stability).

Enalapril Maleate Tablets, USP, 5mg, 100 and 1000 count bottles, Rx only, Class II, Stability Failure.

Lot #: Quantity and Distribution; Manufacturer

Lot No. B133672; Exp. 7/05; 19,120 units distributed nationwide; GlaxoSmithKline, Inc., Zebulon, NC.

Bulk Product No. SW464, Bulk Lot # 035609, Exp date 01/06; American Ginseng Caps, Lot #: 035609, this bulk lot was repackaged into 100 capsule bottles by Swanson Health Products under its own label and sold to its retail customers under lot 127338 BG, 149,000 capsules distributed; Nature's Value Inc., Bay Shore, NY.

Lot 03B139; 92,300 vials distributed nationwide; Sico Pharmaceuticals, Inc; Irvine, CA.

Lots 8050604A, 8AF06AEA, K072204B; b) V020304D; 24 16 oz and 65 4 oz containers distributed in AZ, TX, and FL; Unit Dose Packaging Inc; Chandler, AZ.

a) Lot no. 02040096; exp. date 04/2005; b) Lot no. 02040097 exp date 4/2005; c) Lot no. 04010010 exp date 01/2007; 22,542 distributed in Puerto Rico; Caribbean Nutraceuticals, Inc.; Las Piedras, PR.

Lot Number 21451; exp date Feb 2007; 8,618 bottles distributed nationwide; Teva Pharmaceuticals USA; North Wales, PA.

Lot # 109832A; exp date Dec 2004; Lot # 115188A; exp date April 2005; Lot # 117962A; exp date May 2005; Lot # 117962U; exp date May 2005; 26,424 bottles/units distributed nationwide; Ivax Pharmaceuticals, Inc.; Cidra, PR.

Name of Drug or Supplement; Class of Recall; Problem

Glyburide Tablets, USP, 2.5 mg, 1000 count bottles, Rx only, Class II, Presence of foreign tablet (Hydrochlorothiazide 25 mg).

Ipratropium Bromide Inhalation Solution 0.02% (0.5 mg/vial) 60 x 2.5 mL Unit-Dose Vials (12 vials per foil pouch), For Oral Inhalation Only, Rx Only, Class II. Exceeds impurity specification (terephthalic acid).

Pacerone (Amiodarone HCl) tablets, 300 mg, 100 tablets, Rx only, Class III, Mislabeling: Pacerone Unit dose carton is mislabeled in that UPC code scans as 100 mg strength instead of 300 mg strength which is the strength of the actual tablets. All human readable text of all labeling is accurate, including the unit dose card, carton and package insert.

Peri-Colace Tablets. (8.6 mg Sennosides and 50 mg Docusate Sodium), 60 count bottles, Class III, Presence of Foreign Tablet: One red tablet (Peri-Colase generic manufactured under the Time Capsules Lab label) was found in a 60 count bottle of Peri-Colase burgundy tablets.

Potassium Chloride Extended-Release Tablets, USP, 20mEqK, 500 count bottles, Rx only, Class III, Tablet weight.

Premarin (conjugated estrogens) Tablets, USP, 0.625 mg; Rx only, Class III, Dissolution Failure.

Prempro (conjugated estrogens/medroxyprogesterone acetate tablets), 0.45 mg/1.5 mg/ carton of 3 EZ DIAL Dispensers of 28 tablets each, Rx only, Class III, Dissolution Failure.

Rocaltrol Capsules (calcitriol) 0.5 mcg, bottle of 100 capsules, Rx only, Class III; Presence of Foreign Tablet; bottled labeled as Rocaltrol 0.5mcg capsules contained Rocaltrol 0.5mcg capsules and one Rocaltrol 0.25mcg capsule.

RU-21 Tablets Dietary Supplement, 20 count blister packages; Class II. Unapproved new drug.

Twice-a-Day 12 Hour Nasal Spray (oxymetazoline hydrochloride 0.05%), sold in 1/2 FL. OZ (14.8mL) and 1 FL. OZ. (30mL) bottles, MAJOR brand, Regular, NASAL DECONGESTANT — Also sold under other name brand as: DU brand Nasal Spray Atomizador, Maximum Strength, Nasal Decongestant Spray; Class I. Microbial Contamination; *Burkholderia cepacia*.

Visine Advanced Relief Eye Drops, (Dextran 70.0%, Polyethylene glycol 400.1%, Povidone 1%, Tetrahydrozoline HCl 0.05%), 1 fl oz (2). Class III, Defective bottle cap.

Lot #: Quantity and Distribution; Manufacturer

Lot 132255A; exp date Mar 2006; bottles distributed nationwide; Teva Pharmaceuticals USA; North Wales, PA.

Lot A4B031; Exp. 02/06; 176,400 vials distributed in New York; Alpha USP; Baltimore, MD.

Lot nos 0415326468, 0415906531, and 0415916532; exp date 08/06; 1,740 units distributed nationwide; Upsher Smith Laboratories; Maple Grove, MN.

Lot 4C7985 Exp. Date March 31, 2006; Dist. 25,196 bottles distributed nationwide by Purdue Products; The Purdue Frederick Company; Stamford, CT.

Lots 720E022; Exp date Jan 2006; 2,154 bottles distributed nationwide; Andrx Pharmaceuticals, Inc; Davie, FL.

Lots: A42766, exp date Sept 2005, A27633, exp date Mar 2005; 17,124 1,000 tablet bottles and 2,880 5,000 tablet bottles distributed nationwide; Richmond Division of Wyeth Pharmaceuticals; Richmond, VA.

Lot A50440; exp date Jun 2004; 17,468 cartons x 3 dial packs distributed to wholesalers nationwide; Richmond Division of Wyeth Pharmaceuticals; Richmond, VA.

Lot U2019; exp date Jul 2005; 6,601 bottles distributed nationwide; Hoffmann La Roche Inc; Nutley, NJ.

Numerous lots; 382,464 blister packages distributed nationwide; Spirit Sciences USA, Inc.; Beverly Hills, CA.

Numerous lots; 416,677 units distributed nationwide and in Puerto Rico; Propharma, Inc.; Miami, FL.

In Case Lot Nos: 010438802, 010438803, 010438804 — Unit Lot No. 0104388; In Case Lot No: 010440601 — Unit Lot No. 0104406; 49128 bottles distributed nationwide and in Australia; Pfizer Inc; Morris Plains, NJ.

continued on page 8

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Warfarin Sodium Tablets, USP, 7 1/2 mg, packaged in 100 count plastic bottles, Rx only, Class II, Subpotent (12 month stability).

Lot #: Quantity and Distribution; Manufacturer

Lot 408343001; exp 9/05; 10,281 bottles (100 count) distributed nationwide; Barr Laboratories, Inc.; Forrest, VA.

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 (800) FDA-1088. The FDA web site is www.fda.gov.

Name of Device; Class of Recall; Problem

a) **OTC Pregnancy Tests**. Name: Sure Check hCG, Midstream Pregnancy Test; Class II b) **OTC Pregnancy Tests**. Name: Sure Check hCG Cassette Pregnancy Test; Class II. Poor sealing of pouches and degradation of products. Investigation revealed invalid results (no control lines) and some false negatives.

Lot #: Quantity and Distribution; Manufacturer

Numerous lots; 359,610 units distributed nationwide and internationally; Chembio Diagnostic System Inc.; Medford, NY.

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 (800) 638-2772. The CPSC web site is www.cpsc.gov.

Name of Product; Problem

Air Pistols. The air pistols' safety might move from the engaged or "safe" position to the disengaged or "fire" position when the trigger is pulled once or more and then released. This poses a risk of serious injury if the air pistol is loaded and unintentionally fired.

Lot #: Quantity and Distribution; Manufacturer

Walther CP Sport, CP99, and Nighthawk CO2 Air Pistols; about 24,000 sold nationwide from February 2003 through July 2004; Crosman Corporation; East Bloomfield, NY; (866) 583-7340; www.crosman.com.

Avalanche Transceivers. The transceivers' plastic casing could crack, causing a malfunction if water were to enter the unit. If the transceiver fails to function properly in the aftermath of an avalanche, it could result in the buried victim not being found in time to avoid serious injury or death.

Mammut Barryvox Avalanche Transceivers; about 137 sold by authorized Mammut Dealers from August 2004 through November 2004; Systec AG, Eichthal, of Switzerland; (800) 451-5127.

Backpack Sprayers. The power plug can corrode after extensive exposure to water and corrosive chemicals, posing a fire hazard to consumers.

SHURflo ProPack Model SRS-540 rechargeable electric backpack sprayers; about 6,100 sold at pest control, turf care, sanitary maintenance and tool and equipment distributors nationwide from July 2003 through August 2004; SHURflo LLC, of Cypress, Calif.; (800) 854-3218; www.shurflo.com.

Bicycle Seats. The plastic scuff guard underneath the front of the seat, which secures the seat rails, may crack or break causing the rider to lose control and/or fall, resulting in a serious injury.

Bicycle seat part number 7403SXS 03 9072 installed on 2004 model year Recreational Equipment Inc. (REI) brand Novara Express bicycles; about 257 sold at REI stores nationwide sold bicycles with the affected seats from March 2004 through September 2004; (800) 426-4840.

Type of Product; Problem

Bike Attachment. The hardware used in the assembly of the universal hitch may come loose causing the unit to separate from the lead bicycle, which could lead to serious injury or death to the rider of the bicycle attachment.

Blower Vac. The air intake shield may be missing. Consumers can suffer lacerations if they come into contact with the intake blower wheel.

Children's Necklaces. The necklaces contain high levels of lead. CPSC regulations ban children's products from containing high levels of lead due to the risk of lead poisoning resulting from contact with these products. The necklaces also contain a sharp point, posing a laceration hazard to young children.

Costume Bracelets. The bracelets contain high levels of lead and pose a lead poisoning hazard to children.

Cribs. The Amber model crib included in this recall does not comply with crib safety standards due to a gap between the side rail and the crib mattress support, posing an entrapment hazard to infants.

Dining Chair. The welds on the chair's rear legs can crack and break apart, posing a fall hazard to consumers.

Golf Carts. Microscopic cracks in the brake equalizer rods on certain vehicles may cause the rods to fatigue and fail prematurely in continuous use. Such failure could result in a loss of braking ability.

Light Bulbs. Some of the bulbs have imploded or broken apart within the first several minutes after they are first illuminated. Broken glass particles pose a laceration hazard to consumers.

Lot #: Quantity and Distribution; Manufacturer

Adams Trail-a-Bike or Adams Slipstream Bicycle sold under the following models: Starter, Folder, Shifter, Shocker, Ultimate Tandem, Deluxe Folder, Me 2 and Original.; about 80,000 sold at independent bicycle stores nationwide from January 1996 through October 2004; Norco Products Ltd., of British Columbia, Canada; (800) 663-8916; www.trail-a-bike.com.

Ridgid(r) 16-Gallon, Model WD16650 2-In-1 Blower Vac; about 6,500 units sold at Home Depot stores and by RIDGE TOOL distributors nationwide from April 2004 through January 2005; Emerson Tool Co., of St. Louis, Mo; (800) 372-7759; www.emersontoolcompany.com.

Children's Metallic necklaces with medallions depicting frogs, dolphins with a small bead on the tail, a sunshine smiley face and an alien face on a starburst; about 155,000 sold through mail order catalogs nationwide and on the Internet from August 1998 through November 2004; Raymond Geddes Co. Inc.; of Baltimore, MD; (888) 431-1722; consumeraffairs@raymondgeddes.com.

Metallic costume bracelets with heart, oval, and rectangular shaped charms that have the phrases; "I like sports," "I like movies," "I like shopping" and "I like music" printed on them. The bracelet also contains various colored plastic trinkets; about 7,100 sold at Belk, Bloomingdales, Carson Pirie Scott, Kohl's, Parisians and Proffitts Department stores nationwide from October 2003 through November 2004; (800) 524-0110; www.rivieratrading.com.

Daniella, Leeat, Noa, Naomi, Gabriella, Amber and Series 300 model cribs; about 7,700 sold in juvenile furniture stores in New York and New Jersey from January 2003 through August 2004; Orbelle Trade Inc., of Brooklyn, N.Y.; (800) 605-8018; www.orbelle.com.

Residential Dining Chair; about 32,000 sold at independent furniture stores nationwide from January 2004 through September 2004; Poundex Associates Corp., of City of Industry, Calif; (800) 717-0484; www.poundex.com.

2004 and 2005 model year gasoline and electric powered DS Golf Cars, Hospitality, Utility & Transport Vehicles and Rough Terrain Vehicles; 19,663 sold at authorized Club Car dealers nationwide between April 6, 2004 and October 1, 2004; Club Car Inc., of Augusta, Ga.; (800) 227-0739 extension 3580; www.clubcar.com.

40 Watt Incandescent Mini Spot-light Bulbs included in two- and three-lamp accent lights in certain furniture hutch items manufactured by Sauder Woodworking Co; Model 9386 (three-lamp kit); Model 9549 (two-lamp kit); Model 9509 (two-lamp kit); about 22,600 sold at Office Depot stores from October 2004 through November 2004; Comtrad, Division of Waljon Ltd., Mississauga, Ontario, Canada; (800) 523-3987; www.sauder.com.

continued on page 10

OUTRAGE, from page 12

Decisions to approve or remove drugs must be based on adequate evidence of both benefits and risks. For Vioxx, Celebrex and Bextra — the three COX-2 inhibitor pain/arthritis drugs — at approval there was no evidence that they were more effective than older drugs.

Only Vioxx, now withdrawn because of a significant increase in heart attacks, proved to be less

dangerous to the gastrointestinal tract than older drugs. Celebrex and Bextra did not. Although at approval there was no evidence of increased cardiac risk from Vioxx or Celebrex, less than a year later a 2001 study on Vioxx found it was five times more likely than naproxen (Aleve) to cause heart attacks, and a Celebrex study prompted FDA concerns about cardiac risks for that drug.

Removing Celebrex from the

market will be a major step forward for public health. For naproxen, the evidence of its harm is preliminary at best, and it is unlikely to pose cardiac risks as high as those documented for Vioxx or Celebrex. There is no basis for removing it from the market.

Unique risks without unique benefits should always be the algorithm for removing drugs. ■

CONSUMER PRODUCTS cont.

Type of Product; Problem

Monitors. A ground clip inside the back plastic panel of these monitors can be incorrectly installed, posing a risk of electrical shock to consumers.

"Push" and Electronic Toys. The toys can easily break apart, exposing small parts. This poses a choking hazard to young children.

Slow Cookers. The handles on the base of the slow cookers can break, posing a risk of burns from hot food spilling onto consumers.

Snowboard Bindings. The pin used to secure the rear snaplock lever to the bindings can bend or break.

Sweeper Vac. The vacuum's rotor can lock and overheat during use causing a smoke and fire hazard.

Swing Seats. A manufacturing defect can cause the metal grommet securing the seat to break. If this happens, the user can fall to the ground.

Lot #: Quantity and Distribution; Manufacturer

Hewlett-Packard (HP) L2035 Flat Panel Monitor; about 15,000 sold by HP's Web site for business use and HP's Channel Partners from February, 2003 through October, 2004; PC Peripherals, of Colorado Springs, Colo; www.l2035recall.com; (800) 254-2280; North America Quality and Customer Care Manager, Philips PC Peripherals, Holly Sugar Boulevard, 2 North Cascade Ave, Suite 200, Colorado Springs, CO 80903.

Push Along Frog, Animal Organ, and Rock & Roll Kids Guitar Toys; about 5,200 sold in the Los Angeles area from July 2003 through October 2004; AA Importer Inc.; Los Angeles, CA; (866) 879-4667.

GE Oval and Double Dish Slow Cookers; about 600,000 units sold at Wal-Mart stores nationwide from August 2000 through December 2002; Hamilton Beach/Proctor-Silex Inc., of Glen Allen, Va; (888) 293-3343; www.walmart.com.

2004 Flow MK Series Snowboard Bindings; 2004 Flow MK series snowboard bindings; Model numbers MK03, MK04, MK05 and MK110; about 6,000 sold at snowboard shops nationwide including Gart Sports/TSA and REI from July 2004 through December 2004; (800) 691-7611; www.flow.com.

Dirt Devil(r) Sweeper Vac(tm) Model Number M083000, Plant Code J; about 20,000 sold nationwide from November 2003 through November 2004; Royal Appliance; Glenwillow, OH; (800) 805-9536; www.dirtdevil.com.

Extra-Duty and Heavy-Duty Swing-N-Slide(r) swing seats; 72,000 sold nationwide from January 2004 through June 2004; Swing-N-Slide(r) Corp.; of Janesville, WI; (800) 888-1232; www.swing-n-slide.com.

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Take Drugs off the Market

The following editorial by Sidney M. Wolfe, MD appeared in the December 27th, 2004 issue of USA Today.

Amid the furor involving pain drugs, it may be of interest to ponder the theoretical problem of the Food and Drug Administration prematurely deciding to ban a drug whose benefits outweigh its risks. But we must confront the reality that during the past 10 years, there is overwhelming evidence that the FDA repeatedly delayed withdrawing many drugs long after clear, unequivocal evidence of risks that outweighed any demonstrable benefits.

The often-failed FDA strategy of "risk management," a dangerous interim alternative to taking drugs off the market, has ensured that thou-

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sands of people were injured or killed after certain drugs should have been pulled.

A recent example is the diabetes drug Rezulin, first marketed in 1997.

By that December, it was taken off the market in the United Kingdom because of liver damage, many cases having occurred in the United States.

In July 1998, Public Citizen petitioned the FDA to ban the drug, which, although lowering blood sugar by a different mechanism than earlier diabetes drugs, had no evidence of improved mortality or morbidity. By July 1998, there were 560 reported cases of liver damage, including 26 deaths.

After failed efforts at "risk management," Rezulin was withdrawn from the market in January 2000, by which time there were hundreds of additional cases of liver damage and 63 deaths. Other belatedly banned drugs include the painkiller Duract, the blood-pressure drug Posicor and the cholesterol-lowering drug Baycol.

continued on page 10

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