



Choosing Wisely Project

Campaign Highlights Unnecessary Use of Many Medical Tests and Treatments

In an effort to curb the unnecessary use of many potentially harmful medical procedures, a group of nine medical specialty societies representing more than 370,000 U.S. physicians have issued 45 recommendations regarding commonly overused tests and treatments in clinical practice. The list of recommendations was released in April as part of a new multiyear educational campaign called Choosing Wisely, led by the American Board of Internal Medicine Foundation and Consumer Reports.

Each of the participating medical societies (see the shaded box on this page) produced a list of the five tests or treatments most prone to overuse in their specialty fields, along with recommendations intended to appropriately reduce the use of those tests and treatments. In several cases, the same overused test or treatment appeared on the lists of more than one society. According to the campaign’s sponsors, the “lists represent specific, evidence-based recommendations physicians and patients should discuss to help make wise decisions about the most appropriate care based on their individual situation.”

The target audience of the Choosing Wisely initiative includes physicians (who are encouraged to limit the use of these medical services) and patients (who are encouraged to challenge their doctors about the necessity and appropriateness of these medical services whenever they are ordered or prescribed).

In addition to wasting time, money

Medical specialty societies participating in the initial phase of the Choosing Wisely campaign*

- American Academy of Allergy, Asthma and Immunology
- American Academy of Family Physicians
- American College of Cardiology
- American College of Physicians
- American College of Radiology
- American Gastroenterological Association
- American Society of Clinical Oncology
- American Society of Nephrology
- American Society of Nuclear Cardiology

** More organizations have since joined the campaign.*

and clinical resources, unnecessary medical tests and treatments expose patients to risks of complications and adverse events directly connected to the procedure or treatment (for example, an allergic reaction to an antibiotic) without providing sufficient benefits.

Unwarranted diagnostic tests can also lead to misdiagnosis or overdiagnosis, either of which can result in patient anxiety and more needless medical procedures and treatments that present additional risks of harm and unnecessary costs. Misdiagnosis may occur when a patient undergoes a diagnostic test and has a false-positive result (the test result is abnormal, but the patient does not have the disease being tested for). Overdiagnosis occurs when a test result shows a true abnormality that will never cause symptoms or result in death (for example, many men are diagnosed with, and subsequently treated for, early stage, nonaggressive prostate cancer that would have progressed so slowly that it

would never have caused symptoms or death).

Examples of commonly overused diagnostic tests

Imaging tests for back pain: Low back pain is the fifth most common reason for visits to a physician. Many physicians order a variety of unnecessary imaging studies for patients with sudden-onset low back pain, including plain X-rays, CT scans and MRIs. The American College of

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Physicians observed that imaging studies in patients with nonspecific low back pain have not been shown to improve patient outcomes. Likewise, the American Academy of Family Physicians noted that such imaging studies are rarely helpful unless the patient has certain "red flags," such as severe neurological deficits (for example, loss of sensation or significant weakness in one or both legs) or evidence of a bone infection in the spine. In the absence of such red flags, imaging should be done only if the low back pain persists for more than six weeks.

Imaging tests for headache: Another frequent reason for doctor visits is headaches. As is the case for those suffering with low back pain, many headache patients undergo unnecessary imaging tests, such as head CT scans or MRIs. Most headaches are either tension headaches or migraine headaches, both of which can be diagnosed by a careful medical history. The American College of Radiology identified imaging tests for headache on its list of commonly over-used medical tests, emphasizing that in the absence of specific risk factors for structural problems within the brain or surrounding structures, imaging studies are unlikely to alter patient management. It also pointed out that such imaging can detect incidental findings (unrelated to the headache) that lead to additional, unnecessary medical procedures and expenses that do not improve patient well-being.

Annual electrocardiograms (EKGs) or other cardiac screenings: Several medical societies made recommendations designed to reduce the number of unnecessary cardiac disease screening tests that many people at low risk for heart disease routinely undergo. Such tests include periodic resting EKGs, exercise EKGs and more advanced stress cardiac imaging. An EKG is a simple test that measures the electrical activity of the heart using electrodes placed on the chest, arms and legs. EKGs can be done when the patient is at rest or as part of a stress test (during

exercise on a treadmill or stationary bike). Stress cardiac imaging tests can involve undergoing an echocardiogram (ultrasound pictures of the heart) or nuclear medicine scan of the heart at rest and again following exercise or administration of a drug that increases the heart rate.

The American Academy of Family Physicians recommended against annual EKG and other cardiac screening tests in those patients at low risk for cardiovascular disease because false-positive results are common enough that the risks of the tests fail to outweigh their benefits. That medical society noted a high likelihood of false-positive tests is likely to lead to harm through unnecessary additional invasive procedures (such as a cardiac catheterization procedure), overtreatment and misdiagnosis.

Similarly, the American College of Physicians opposed routine exercise EKG screenings in low-risk, asymptomatic individuals because there is no evidence that such screenings improve patient outcomes. Risk factors for cardiovascular disease include hypertension, high cholesterol, diabetes, smoking and a family history of coronary artery disease (such as a heart attack) at an early age in a first-degree relative (parent or sibling).

Finally, the American College of Cardiology recommended that physicians not order stress cardiac imaging or advanced imaging during the initial evaluation of patients without cardiac symptoms (such as chest pain or shortness of breath) unless high-risk markers (such as diabetes in someone older than age 40 or evidence of peripheral vascular disease) are present.

The college also advised against performing annual stress cardiac imaging or advanced noninvasive imaging as part of the routine follow-up of asymptomatic patients who have had a heart procedure such as a coronary artery stent placement or coronary artery bypass surgery. The organization pointed out that such serial testing rarely yields any meaningful change in

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patient management and may, in fact, lead to unnecessary invasive procedures and excess radiation exposure without any proven impact on patient outcomes. An exception to this rule would be testing patients more than five years after a bypass operation.

Examples of commonly overprescribed treatments

Antibiotics for mild to moderate acute sinusitis: Every year, millions of patients with acute sinusitis visit their physicians and receive a prescription for an antibiotic. However, both the American Academy of Allergy, Asthma and Immunology and the American Academy of Family Physicians recommended that antibiotics not be prescribed for uncomplicated acute sinusitis.

This condition is usually caused by a virus and will resolve on its own. Because antibiotics have no effect on viruses, treatment of viral sinusitis with antibiotics offers no benefits but does expose patients to risks of adverse events that can range from mild (rash or diarrhea) to severe (anaphylaxis, shock). Furthermore, widespread overuse of antibiotics contributes to the development of bacterial antibiotic resistance, which, over time, results in antibiotics becoming ineffective for those bacterial infections that do require this therapy.

Coronary artery stenting procedures in patients who have had a heart attack: Patients who have had a heart attack (also called a myocardial infarction) routinely undergo a cardiac catheterization procedure soon after admission to the hospital to look for blockages or narrowing in the coronary artery supplying blood to the part of the heart that suffered the infarction. Cardiologists usually will place a stent (a small wire mesh tube) in the narrowed artery to prop it open and improve blood flow to the damaged heart muscle. During such procedures, doctors frequently find partial blockages or narrowing in arteries supplying blood to other parts of the heart not affected by the heart

If your doctor orders one of the tests or treatments discussed in the Choosing Wisely recommendations, ask for an explanation of why the test or treatment is necessary and appropriate in your case and for the evidence to support the explanation.

attack, and many cardiologists will also place stents in these arteries during the same procedure. However, the American College of Cardiology recommended against performing such additional stenting procedures in patients who are clinically stable following an uncomplicated heart attack (the patient did not suffer a cardiac arrest or develop heart failure or an abnormal heart rhythm). The college reported that such additional stent placements may increase the chances of complications and death and have not been shown to be beneficial in stable patients.

Why are medical tests and treatments commonly overused?

An April *Journal of the American Medical Association* commentary published online, written by Dr. Christine Cassel and James Guest, highlighted some of the factors that contribute to the overuse of tests and treatments:

To reduce unnecessary tests and procedures, physicians will need to play a leading role — their decisions account for about 80% of health care expenditures. Yet physicians do not always have the most current effectiveness data, and despite acting in good faith, they can recommend diagnostic or therapeutic interventions that are no longer considered essential. Also, research shows that physicians may need help communicating these matters to their patients. This may be especially difficult when clinicians and consumers are deluged with advertising and promotion. Clinicians often report feeling compelled to accommodate patients' requests for interventions they know

are unnecessary. At the same time, patients need trustworthy information to help them better understand that more care is not always better care, and in some cases can actually cause more harm than good.

Another important — and more troubling — factor not mentioned by these commentators is the financial incentive many physicians have for ordering more tests, such as getting a large fee for performing the additional procedure or, in addition, owning a financial stake in the testing lab or X-ray facility.

Recommendations for patients

If your doctor orders one of the tests or treatments discussed in the Choosing Wisely recommendations, ask for an explanation of why the test or treatment is necessary and appropriate in your case and for the evidence to support the explanation. If you are not satisfied with the explanation, consider declining the test or treatment or asking for a second opinion from another health care provider.

To read the entire list of recommendations issued by the Choosing Wisely campaign, visit <http://choosingwisely.org/>.

*In the March 2012 Health Letter, Public Citizen reviewed Dr. H. Gilbert Welch's book *Overdiagnosed*, which provides an excellent overview, including specific examples, of common tests that are expensive and can needlessly lead to dangerous treatments. ♦*

Biased Data Can Lead to Substandard Drug Treatment

Patients assume that, in providing care, their doctors are relying on the best available knowledge. But what if the available knowledge on a particular treatment is not the full story? This question has been increasingly asked in recent years in light of several concerning studies finding that pharmaceutical companies sometimes make available only the data that shows their lucrative medications in a favorable light. This phenomenon, known as publication bias, has been clearly demonstrated in the case of at least one widely used class of drugs: antidepressants. The implications for informed doctor and patient choice could mean the difference between an effective treatment and snake oil.

Many factors are considered when study authors or funders decide whether to publish trial results. Among these considerations is a pervasive inclination of many researchers and journal editors not to publish negative findings. Further, and perhaps reflecting an innate human propensity to show interest only in novel discoveries, studies confirming prior research — positive or negative — are generally of less interest.

However, these ever-present tendencies are greatly amplified when financial considerations (such as how research outcomes might affect profits) enter the equation. Over the past three decades, pharmaceutical companies have emerged as the biggest funders of medical research, and concerns have naturally arisen as to whether this has created an inherent conflict of interest regarding publication decisions. In an environment where publication of drug trial results is a choice and not a requirement, critics worry that companies will inherently gravitate away from publishing unfavorable research in the medical literature, the primary source of information (in addition to the biased information doctors obtain from drug company salespeople and promotional

materials) for doctors who prescribe drugmakers' billion-dollar products.

Effectiveness of antidepressants and other treatments exaggerated in medical literature

There are few drugs that have been as financially rewarding for pharmaceutical companies as antidepressants, that ubiquitous class of drugs used to treat everything from severe depressive episodes to mild cases of the blues. In 2008, a study published in *The New England Journal of Medicine* called into question the prevailing medical wisdom on the effectiveness of antidepressants. The review examined all studies conducted on 12 antidepressants on the market at the time, comparing the complete trial data required to be submitted to the Food and Drug Administration (FDA) with data published in medical journals.

The authors found that almost one-third (31 percent) of all completed studies on these antidepressants had not been published at all. The studies that were published were, on average, more favorable to the drugs than those that were not published. For example, 37 of 38 studies in which the FDA deemed the drug effective were published, while only 14 of 36 studies in which the FDA determined that the effectiveness of the drug was negative or questionable were published. Of those 14 negative or questionable published studies, 11 portrayed the drug as effective, contrary to the FDA's determination. Overall, the publication bias led to a 32 percent greater "effect size" (a rough estimate of the drug's effectiveness in treating depression compared to a placebo) than would have otherwise been the case had

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all studies been accurately published.

These findings on antidepressants were confirmed for other treatments in a comprehensive 2009 examination of whether publication bias is evident on a wider scale. The authors of that study, published by the Cochrane Collaboration, found that research showing a positive effect of medication or other health care interventions is almost four times more likely to be published than research that shows no significant, or harmful, outcomes.

A study in the journal *Public Library of Science Medicine* on second-generation antipsychotics (medications to treat schizophrenia and other severe mental illnesses) released this year revealed a similar disparity in publication frequency between positive and negative studies. Unlike in the case of antidepressants, there was no statistically significant publication bias and no impact of publication choice on the representation of effectiveness of second-generation antipsychotics in the published material. Still, three-fourths of the published trials were positive, compared to only one-fourth of the unpublished trials. This resulted in a treatment effect size in published trials twice that of unpublished trials.

Escalation from publication bias to fraudulent concealment of study data

Publication bias clearly compromises the integrity of medical evidence, but concealment of study data from the federal and state governments poses at least as great a danger to informed prescribing, in addition to being illegal. Over the past 20 years, there have been

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at least seven cases in which pharmaceutical companies have settled allegations that they concealed vital study data from government agencies or consumers.

The most prominent settlement was reached with GlaxoSmithKline (GSK) for \$3 billion this past July, as part of the largest federal health fraud settlement in history. The company pleaded guilty to concealing from the FDA several studies that were under way to examine the link between rosiglitazone (brand name Avandia, used to treat diabetes) and several adverse cardiovascular events. GSK hid progress of the studies for six years.

But in 2007, a review published by two researchers from the Cleveland Clinic showed that rosiglitazone clearly increased the risk of heart attack in patients with diabetes. This prompted GSK to take the unusual step of releasing interim results of a still unfinished trial to attempt to counteract those findings. The Cleveland Clinic researchers' conclusions were ultimately validated, however, when the FDA placed a black box warning on rosiglitazone for the cardiovascular risks and eventually severely restricted the drug's use in this country (Europe banned the drug outright). For the concealment of these critical study data for so long, GSK ended up paying a criminal fine of \$243 million (part of the larger \$3 billion settlement).

Despite the seemingly large fines in this and other cases, the settlement monies paid out for fraudulently concealing study data are dwarfed by the overall profits generated from the medications, which continue to be prescribed based on incomplete and biased knowledge. Because of this, and the lack of accountability on the part of company officials responsible for hiding the evidence, the fraudulent activity has continued unabated in recent years.

ClinicalTrials.gov: a woefully neglected good idea

The federally run website www.clinicaltrials.gov, established in

Concealment of Vital Study Data by Pharmaceutical Companies, 1999-2012*

Company	Year of Settlement	Total of Settlement/Fine	Drug Involved	Violation
BASF	1999	\$41.8 million**	Synthroid	Tried to stop publication of a study showing that Synthroid and generic levothyroxine products were bioequivalent.
Glaxo-SmithKline	2004	\$2.5 million	Paxil	Conducted at least five studies on the use of Paxil in children and adolescents but only released one of these studies, which showed mixed results on efficacy, while suppressing results of the other four negative studies.
Bayer	2007	\$8 million	Baycol	Failed to adequately warn consumers that the risk for muscle damage associated with Baycol was significantly higher compared to other statin medications.
Merck	2009	\$5.4 million	Vytorin	Delayed for two years the release of clinical trial results showing that Vytorin was no more effective than the cheap, generically available cholesterol-lowering drug simvastatin.
Astra-Zeneca	2011	\$68.5 million**	Seroquel	Withheld negative information contained in studies concerning Seroquel's safety and effectiveness.
Abbott	2012	\$1.5 billion**	Depakote	Waited nearly two years to notify its sales force about a study failing to show any significant added benefit of Depakote in patients with schizophrenia who were already on other antipsychotic drugs, and did not publish those results for another two years.
Glaxo-SmithKline	2012	\$243 million	Avandia	Failed to include certain safety data about Avandia, a diabetes drug, in reports to the Food and Drug Administration, including two studies concerning the cardiovascular safety of Avandia.

* Through July 18, 2012. Many of these settlements were resolved with no admission of guilt on the part of the companies involved.

** All financial penalties paid as part of the settlement, including those for violations other than concealment of study data.

1997, is a potential remedy for both publication bias and ongoing fraud regarding concealment of study data. It was initially proposed by Congress as a centralized, publicly available repository for information on clinical trials of drugs for "serious or life-threatening" diseases for which FDA approval was sought. The scope of the website has since been expanded, most extensively by the 2007 Food and Drug Administration Amendments Act, and now requires almost all U.S.-based clinical trials to be registered on the site before getting under way.

Unfortunately, the laws and regulations governing which trials must be registered contain a number of loop-

holes. For instance, trials conducted entirely outside the U.S. are exempt from the website's reporting requirements, an increasingly important point as the pharmaceutical industry outsources more and more clinical trials to overseas firms. In addition, only trials on drugs that have already been approved by the FDA are required to post summary results within one year of trial completion. Trials on drugs that are not yet FDA-approved are exempt from this requirement and can issue "delayed submissions" with no apparent reporting deadline. Legislation introduced this year by Rep. Ed

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Markey (D-Mass., H.R. 6272) would close both of these loopholes, but it is unlikely to pass.

Meanwhile, compliance with the legal provision requiring one-year summaries of results has been abysmal. A 2012 study in the *British Medical Journal* found that only 22 percent of trials on already approved drugs had reported summary results on ClinicalTrials.gov within one year of trial completion. Industry-funded studies had a reporting rate of 40 percent, while studies federally funded by the National Institutes of Health (NIH) had an even lower rate of 9 percent. The law outlines penalties for noncompliance, such as civil monetary fines of up to \$10,000 every day that results are not reported in a timely fashion, but given that the enforcement agency (NIH) is even less compliant than industry, it is not surprising that no penalties have been issued.

Even if ClinicalTrials.gov were to contain complete information, it is highly unlikely that very many doctors would visit the site for the latest research on a particular drug. The medical literature would still be the primary source for the best available evidence. Conversely, it is unlikely that privately funded medical journals with subscription and prestige concerns would ever fully eliminate their preference for studies that show some positive effect of a drug

or medical device. Everyone wants to be the first to publicize the results of a groundbreaking trial showing a new and improved benefit of a blockbuster drug. But the interests of journal editors (and company executives) do not align, in this case, with the needs of physicians and patients for accurate and comprehensive drug information.

This institutional inertia, which breeds reliance on biased information, will remain unless the results on a site such as ClinicalTrials.gov are actively disseminated to doctors and the public, so unpublished trial results can reach the same level of importance as those in the literature. For doctors, this could be done in a manner similar to the Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report*, which informs physicians of the latest epidemiological research on a regular basis and is a respected and widely used source in the medical community.

More enforcement necessary to ensure complete transparency

Patient safety is compromised when doctors do not have complete data on pharmaceuticals. Physicians may administer treatments that appear effective from a review of the literature but are actually ineffective and/or dangerous for certain conditions.

Publication bias also poses an ethical

dilemma for clinical trial research. Studies that show a drug to be ineffective or dangerous may be repeated in the future by other researchers unaware of the prior negative findings (because the results were not published), thereby needlessly exposing more study subjects to harm.

ClinicalTrials.gov is a first step toward complete transparency of pharmaceutical and medical device data, but clearly more needs to be done to ensure the repository's integrity. Current compliance rates effectively nullify the website's purpose, and in the absence of enforcement (even regarding the authoritative agency's own researchers), noncompliance will undoubtedly continue. Meanwhile, fraudulent concealment of study data from the federal and state governments, a related problem, will undoubtedly continue as long as the penalties fail to match the crime.

Only through improved and properly implemented initiatives — such as ClinicalTrials.gov, with user-friendly dissemination of its findings — will physicians become more completely aware of current evidence about the benefits and risks of drugs, thereby helping to counteract the pharmaceutical industry's monopoly on comprehensive drug data. ♦

Are your medicines SAFE?



Find out which drugs are safe — and which you should avoid — with Public Citizen's WorstPills.org and *Worst Pills, Best Pills News*. To subscribe to WorstPills.org, our online database, for only \$15 a year, visit www.WorstPills.org and type in promotional code **PNSEP12** when prompted.

To subscribe to the monthly print edition of *Worst Pills, Best Pills News* for a special rate of only \$10 a year, please mail a check payable to "Pills News" to 1600 20th St. NW, Washington, DC 20009.

www.WorstPills.org



HRG Works for You!

Our latest work involves: illegally marketed devices and opioid labels

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 whistleblowers 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:

- **Illegally Marketed Medical Device — 7/23/2012 to 8/1/2012** — HRG director Dr. Sidney Wolfe and deputy director Dr. Michael Carome took further action after urging the Food and Drug Administration (FDA) to expedite its investigation into a California company illegally marketing the LipoTron medical device as a therapeutic massager, when it is actually used for the removal of fat and other purposes. In letters to the health departments and/or medical boards of Alabama, Arkansas, California, Florida, Michigan, New Jersey, Oklahoma and Texas, HRG asked them to investigate the health care professionals using this device.
- **Label Change Needed for Opioids — 7/25/2012** — Along with a coalition of doctors, researchers and public health officials, Public Citizen co-signed a petition calling for a revision of opioid (for example, oxycodone [OXYCONTIN]) labels to reduce overprescribing and an epidemic of addiction. Currently, the labels on opioid analgesics simply state that the drugs are approved for moderate to severe pain. The signers of the petition urged the FDA to strike the term "moderate," add a suggested maximum dose equivalent to 100 milligrams of morphine and insert a suggested duration of use. If the requested changes are adopted, drug companies no longer would be able to promote these pain medications as safe and effective for long-term use by noncancer patients.

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

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and that they probably had a higher likelihood of medical incompetence.

Although it is probably more difficult to find physicians willing to work full time in prisons, Dr. Don Kern, president of the Society of Correctional Physicians, told the *Times-Picayune*: "I don't think it would be desirable to take a state's lowest-quality physicians and specifically have them deal with the most vulnerable population, whether it's corrections or the developmentally disabled. ... As a whole, it would seem like there may be a concern here because that's striking me as an unusually high proportion of people who have some kind of license problem."

Dr. Kern mentioned the developmen-

tally disabled because doctors restricted by the Louisiana State Board of Medical Examiners to practicing in an institutional setting are not only limited to prisons, but also can practice in mental health facilities and homes for developmentally disabled children. There is no information available regarding the percentage of physicians who serve in these latter types of facilities and have previous medical board disciplinary actions.

The National Commission on Correctional Health Care (NCCHC) has issued a position statement condemning institutional restrictions because of the implication that inmates do not deserve the same care as the general population.

The *Times-Picayune* also ran an

editorial on Aug. 5, 2012: "Louisiana prisoners also deserve good doctors." The editorial quoted the NCCHC president's statement that allowing these questionable doctors to practice "gives the impression that somehow a physician is good enough to work on inmates ... but not good enough to work on other patients, as if inmates are less worthy of adequate care." The editorial concluded by saying that this "should not be the position of Louisiana's government or the state medical board. For all these reasons, officials should work to reduce the number of sanctioned doctors working in our prisons." We could not agree more. But are additional states also allowing doctors "not good enough" for other patients to treat inmates? ♦

Bereavement: A Look at the Grieving Process And How to Cope With Loss

The following article originally appeared in the April 2009 Health Letter.

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 that have comforted many others. “Nothing is more devastating than losing someone close to you, especially a spouse,” says Eastman. Her husband, James Eastman, was a passenger on a small commuter plane that crashed in Maine, killing him, young activist Samantha Smith and six others. Eastman’s 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 that 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. And 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 and 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. Sometimes equated with mourning, grief is normal and adaptive, allowing the affected person eventually to get on with life. Grief may have complications, however, which may require medical attention. Other traumatic 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, one following the other, although some people move back and forth between phases. 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.

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 a continuation of this stage 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 display of 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

Phase 4 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 and 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 a reduced 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,

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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 of death. Many medical studies have looked at the effects of the death of a spouse, and according to a 1984 National Academy of Sciences (NAS) review, “[S]ome bereaved persons are at increased risk for illness and even death.” Risk factors for death include male gender 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 distress, depression, bereavement itself or some other reason. A suppressed immune system may result in infections ranging from colds to pneumonia, though this is by no means universal.

Other bereaved persons at increased risk of serious consequences include those who feel they lack a support system, those who suffer from poor health (physical or mental) prior to the death, those who are addicted to alcohol, those who have severe financial difficulties and those who are under age 65. Employing preventive efforts may help avoid some of the serious results of bereavement. Someone with many of these risk factors is more likely to need support, counseling or another intervention. The suicide of someone especially close also increases risk.

Intervention

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 whom bereaved persons can turn.

1. *Support groups* are where people who have had similar experiences meet

to discuss topics of concern. 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. Eastman 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 (NIMH) 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 that 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 (seven to 10 days) course of sleeping pills or tranquilizers. Longer courses of treatment may lead to addiction or other complications. Research into this area is sorely needed and was recommended by the NAS.

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 and NAS released a report in 1984 entitled *Bereavement: Reactions, Consequences, and Care*. They had several conclusions and recommendations for future work in this area, though 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 should have a continuing responsibility to the bereaved.
- Schools should train nurses and physicians to look for warning signs and should refer counseling for people at high risk of pathological grief.
- The integration of social workers and chaplains should be executed into hospital settings, particularly those involving terminal illness. This 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 the 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. ♦

Product Recalls

July 19, 2012 – August 8, 2012

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

Daytrana (Methylphenidate) Transdermal System Patch, 10 mg over nine hours (1.1 mg/hour), one patch per pouch, packaged in 30-count patches per box. Volume of product in commerce: 335,190 patches. Miscalibrated and/or defective delivery system: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #: 41843, expiration date 11/2011. Noven Pharmaceuticals Inc.

Daytrana (Methylphenidate) Transdermal System Patch, 15 mg over nine hours (1.6 mg/hour), one patch per pouch, packaged in 30-count patches per box. Volume of product in commerce: 244,320 patches. Miscalibrated and/or defective delivery system: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #: 43783, expiration date 01/2012. Noven Pharmaceuticals Inc.

Daytrana (Methylphenidate) Transdermal System Patch, 30 mg over nine hours (3.3 mg/hour), one patch per pouch, packaged in 30-count patches per box. Volume of product in commerce: 242,100 patches. Miscalibrated and/or defective delivery system: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #: 43008, expiration date 01/2012; 48591, expiration date 10/2012. Noven Pharmaceuticals Inc.

Dr. Reddy's Amlodipine Besylate and Benazepril Hydrochloride Capsules, 5 mg/20 mg, 500 capsules. Volume of product in commerce: 122,1656 bottles. Adulterated presence of foreign tablets:

Dr. Reddy's Laboratories has received complaints of mislabeled bottles of amlodipine besylate and benazepril hydrochloride capsules and ciprofloxacin tablets. Lot #: C201293, expiration date 08/2013. Dr. Reddy's Laboratories Inc.

Dr. Reddy's Ciprofloxacin Tablets, USP, 500 mg, 500-count bottle. Volume of product in commerce: 1,656 bottles. Adulterated presence of foreign tablets: Dr. Reddy's Laboratories has received complaints of mislabeled bottles of amlodipine besylate and benazepril hydrochloride capsules and ciprofloxacin tablets. Lot #: C201293, expiration date 08/2013. Dr. Reddy's Laboratories Inc.

Metformin Hydrochloride Tablets, USP, 1,000 mg, 1,000-count bottle. Volume of product in commerce: 1176 bottles. Presence of foreign substance(s): A product complaint was received from a pharmacist who discovered that several tablets displayed brown specks. The same complainant also reported that metal shaving-like material was observed on the surface of one tablet. Lot #: ML9605, expiration date 10/2013. Zydus Pharmaceuticals USA Inc.

Prefera-OB One Gel Capsules, 30 softgels. Volume of product in commerce: 478,569 softgels. Labeling: presence of undeclared color additive. The product is being recalled because several inactive ingredients were not included in the labeling for this product: Undeclared D&C Red #33, FD&C Blue #1, Titanium Dioxide Suspension, Purified Water USP. Lot #: 249814, samples; 249816, samples; 260393, expiration date 04/30/2012; 255345, expiration date 11/30/2011; 000001, expiration date 08/31/2012; 261827, expiration date 05/31/2012; 50004, expiration date 11/30/2012; 50005, expiration date 11/30/2012; 500007, expiration date 12/31/2012; 000002, expiration date 09/30/2012. Meda Pharmaceuticals 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

200 Mini Lights. The light sets do not meet the UL standard for this product and pose a fire and shock risk. Family Dollar Services Inc., at (800) 547-0359 or www.familydollar.com.

Alex Model 786X Little Jumpers Trampoline. The handlebar can break, causing a fall hazard. Panline USA Inc., at (800) 666-2539 or www.alextoys.com/safety.

CONSUMER PRODUCTS (continued)

Chicco Polly High Chair. Children can fall on or against the pegs on the high chair's rear legs, resulting in a bruising or laceration injury. Artsana USA Inc., at (800) 807-8817 or www.chiccousa.com/pollykit.

Children's Pajamas. The pajamas fail to meet the federal flammability standards for children's sleepwear and pose a risk of a burn injury to children. My Clothes Inc., at (855) 776-6641 or www.pjsbymyclothesinc.com.

Contours Options LT Tandem Strollers. The front wheel assembly can break, posing a fall hazard to the child in the stroller. In addition, for strollers manufactured in January and February 2012, the nuts that hold the stroller's basket support screws in place can detach. Detached nuts can pose a choking hazard to young children. Kolcraft Enterprises Inc., at (800) 453-7673 or www.kolcraft.com.

Flexible Flyer Swing Sets. The seesaw seats can break away from the bolt fasteners during use, posing a fall hazard. Troxel Co., at (888) 770-7060 or www.regcen.com/flexibleflyer.

Folding Beach Chairs. The recalled children's beach chairs have exposed, sharp metal rivets, posing a laceration hazard. Downeast Concepts Inc., at (800) 343-2424 or www.downeastconcepts.com.

Folding Step Stool. The folding step stools can break or collapse unexpectedly when in use, posing a fall hazard to consumers. Molenaar LLC, at (877) 719-4442 or www.miline.com.

Full- and Twin-Size Bordeaux Collection Bed Frames. The hardware holding the headboard and footboard can loosen or detach, posing a fall hazard. Poh Huat Furniture, at (888) 572-9889 or www.slf-co.com.

GE, GE Adora, GE Eterna, GE Profile and Hotpoint Dishwashers. An electrical failure in the dishwasher's heating element can pose a fire hazard. GE Appliances, at (866) 918-8760 or www.geappliances.com/recall.

Golf Cars and Transport Vehicles. The fuel hose can separate from the fuel tank, posing a fire hazard. Club Car LLC, at (800) 227-0739, ext. 3831, or www.clubcar.com.

Green Toys Mini Vehicles. The wheels and hubcaps on the toy cars can detach, posing a choking hazard to young children. Green Toys Inc., at (888) 973-3421 or www.greentoys.com/recall.

Kenmore Dehumidifiers. The dehumidifiers can overheat, smoke, melt and catch fire, posing fire and burn hazards to consumers. LG Electronics (Tianjin) Appliance Co., at (855) 400-4641 or www.kenmoredehumidifierrecall.com.

Kenta and Kenta Plus Child Carriers. The side strap's seam can unravel and cause the strap to separate, posing a fall hazard to the child in the carrier. VAUDE Sport GmbH and Co., at (800) 366-2666 or www.vaude.com.

Lush Life Power Strips. The power strips have undersized wiring, which poses a risk of shock to consumers. In addition, the wiring and plastic strip fail to meet fire-resistance safety standards and pose a fire hazard to consumers. Lush Life, at (888) 223-2628 or www.burlingtoncoatfactory.com.

Miter Saw. The lower guard can break and come into contact with the blade during use, posing a laceration hazard to users. Robert Bosch Tool Corp., at (888) 727-6109 or www.skiltools.com.

Motion Security Lights. Internal wiring can be damaged during installation, bulb replacement or adjustment, posing an electric shock hazard. HeathCo LLC, at (855) 833-8657 or www.heath-zenith.com/hzproductnotice.

Nikon Digital SLR Camera Battery Packs. The battery packs can short-circuit, causing them to overheat and melt. This poses a burn hazard to consumers. Nikon Inc., at (800) 645-6687 or www.nikonusa.com.

Old Navy Toddler Girl Aqua Socks. This style of Aqua Socks have less traction when worn on wet or smooth surfaces, such as hardwood or tile. Users could slip and fall. Old Navy, at (866) 580-9930 or custserv@oldnavy.com.

Ondal AC2000 Television Mounting System. The arm joints on the television mounting system do not have a washer at the top joint. This can result in excessive wear of the stop pins on the arm and can allow the arm system and items connected to the arm to fall and injure the user or bystanders. TRUMPF Medical Systems Inc., at (888) 474-9359 or Lindsey.ronnenberg@us.trumpf.com.

Patio Bistro Sets. When the chair support bar is not fully engaged, the chair poses a fall hazard to a consumer who sits in the partially engaged chair. Midas Lin Co. Ltd., at (877) 556-0886 or www.cobernbistroset.com.

Twist'n Sparkle Home Beverage Carbonation System Plastic Bottles. The plastic bottles can explode under pressure, expelling plastic parts and resulting in an injury hazard to anyone nearby. iSi North America Inc., at (800) 645-3595 or www.twistnsparkle.com.

Outrage of the Month!

Substandard Doctors Should Not Treat Louisiana Prisoners

By Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group

Would you be worried and upset if someone you loved — a relative or friend — was in an institution in which the doctors caring for them had been disciplined by the state's medical board at a rate 30 times higher than that of the average rate for physicians in that state? Examining this issue, an extraordinary investigation by New Orleans *Times-Picayune* reporter Cindy Chang, published in late July, had the following lead:

Of the 15 doctors working full-time at Louisiana state prisons, nearly two-thirds have been disciplined by the state medical board for issues ranging from pedophilia to substance abuse to dealing methamphetamines.

The latter physician referenced above was in jail for two years for buying \$8,000 of crystal methamphetamines from an informant. His license was then restored with the condition that he practices only in an "institutional" setting.

One Louisiana physician, while serving an 18-month federal probation sentence for medical fraud,

issued multiple narcotics prescriptions, violating a medical board order. Another had been arrested for illegally discharging a weapon and for criminal trespassing, and had steroid-induced psychosis, delusions and dependence on sedatives and narcotics. Still another, while on probation with the medical board for an earlier sex offense, molested yet another female patient and admitted to touching her inappropriately and engaging in a sexual relationship with her.

When contacted by the reporter to comment on these alarming findings, I stated that, in addition to being unethical, allowing these doctors to continue to practice is potentially dangerous for the inmate patients who are being taken care of by physicians with demonstrably substandard records. After being told that the prison system has claimed they would not hire such doctors if their records included "medical incompetence," I replied that it was unreasonable to believe that the doctors' poor judgment was limited to the areas, such as criminal behavior and inappropriate sexual activity, that had led to their being imprisoned or seriously disciplined by the medical board

see **OUTRAGE**, page 7

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