PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JULY 2013 – Vol. 29, No. 7

Study: Overuse of Risky Screening Colonoscopies in Elderly

A recent study in *JAMA Internal Medicine* demonstrated that colonoscopies to screen for colorectal cancer are being performed in the elderly (those over 75) despite robust evidence that routine colonoscopy screenings do more harm than good in that population.

For those between the ages of 50 and 75, colonoscopy screening can be life-saving. However, the procedure can cause serious complications and is not recommended routinely for those older than 75.

If you are between the ages of 76 and 85, you no longer need to be routinely screened, unless your doctor determines otherwise after a detailed discussion of the risks and benefits, as well as ... history. No one 86 or older should be screened under any circumstances.

Study overview

The *JAMA Internal Medicine* study examined the records of almost 75,000 Texas Medicare beneficiaries age 70 and older who underwent colonoscopy in that state between October 2008 and September 2009. The authors looked at claims data to determine whether a colonoscopy had been performed for the purposes of routine screening for colorectal cancer in a person who appeared healthy, rather than to assist in the diagnosis or treatment of another suspected condition (including suspected colon cancer, based on symptoms or on the results of a recommended screening test). Such routine "screening" colonoscopies are not recommended in healthy patients 70 to 75 years old if they have already had a negative colonoscopy within the past 10 years, and they are not recommended at all in patients 75 and older. The authors therefore considered all routine screening colonoscopies to be potentially inappropriate if they were conducted in patients 76 and older. For patients 70 to 75 years old, the screening was considered potentially inappropriate if the patient had already had a negative colonoscopy between 2001 (the date of the oldest record in the study) and the date of the screening.

The authors found that 23 percent of all screening colonoscopies were potentially inappropriate. Approximately 10 percent of all screening colonoscopies in those ages 70 to 75 were considered potentially inappropriate because they were conducted too soon after a previous clean bill of health from a prior colonoscopy. Much higher rates of inappropriate colonoscopies were found in the age groups of 76-85 (39 percent) and 86 and older (25 percent).

Surgeons and more senior physicians were slightly more likely to perform a large number of inappropriate colonoscopies, while more recent medical school graduates and those trained in a nonsurgical specialty (e.g., gastroenterology) were less aggressive in this regard.

Federal recommendations

The U.S. Preventive Services Task Force (USPSTF), a quasi-governmental body tasked with formulating evidence-based federal diagnostic and therapeutic recommendations, concluded in 2008 that although routine screening colonoscopies every 10 years are recommended and potentially life-saving for adults between the ages of 50 and 75, they are contraindicated for those 76 and older.

The USPSTF detailed its reasoning in a report accompanying its 2008 recommendations on colorectal cancer screening. The group explained that the "lead time," or the time between detecting a small, early-stage tumor (known as a colonic polyp) and the transformation of that polyp into a life-threatening cancer, is long — on the order of years, or even decades, into the future. As a person gets older, his or her life expectancy decreases,

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Protect Others by Reporting Your Child's Problems With Medical Products

In February 2013, the Food and Drug Administration (FDA) issued a statement that parents and caregivers of small children play a critical role in helping to identify dangerous side effects from drugs or medical devices. The agency is encouraging consumers to report kids' problems with medical products to catch these problems earlier and better protect children.

Indeed, consumer reports made a difference in 2009, when the FDA added a new black-box warning to products containing testosterone gel to prevent children from being exposed to side effects from the hormones. The new warnings were added following eight reports of infants, toddlers and young children developing disturbing symptoms of abnormal growth and extremely early puberty after coming into contact with an adult who used the product.

Only a small proportion of adverse events in children are ever reported, but the FDA relies heavily on such information to identify problems affecting this vulnerable population. Learn how you can help identify problems more quickly by staying vigilant for drug side effects in children and working with your child's pediatrician to report these issues to the FDA when they occur.

Reporting works: Case study

Jacob* was 6 months old when his mother noticed that he had started growing hair in his pubic area. The hair started out so light that it was barely noticeable, but by the time Jacob was 16 months old it had thickened and grown dark enough that his mother became nervous and pointed the issue out to his pediatrician. She also told the doctor she was concerned that his genitalia seemed larger than normal.

** Names added to a case that was reported anonymously to preserve patient privacy.*

The pediatrician administered an X-ray and physical exam. Jacob's medical team told his parents that the infant's bones had developed beyond the appropriate stage for a boy of his age and that he was growing more quickly than normal. After ruling out central precocious puberty, a condition usually caused by problems with the central nervous system, the doctor took blood tests that revealed a potential clue to

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Overdiagnosis Of 'Low T'

Testosterone products (such as Androgel and Testim) are FDA-approved to raise testosterone levels in adult men who have been diagnosed with a condition known as hypogonadism, which results in low testosterone levels, sometimes called "low T." Unfortunately, it is easy for doctors to mistakenly diagnose hypogonadism in patients who do not really have the condition, due to its commonly experienced symptoms, such as fatigue, loss of energy and decreased sexual desire. These symptoms, especially decreased sexual desire, can have a psychological cause for which treatment with testosterone is not appropriate. Older men are especially vulnerable to overdiagnosis because testosterone levels decrease naturally with age. Overdiagnosis and overprescribing of testosterone raise serious health concerns as the hormone may be associated with increased risk of prostate cancer, infertility and certain cardiovascular risks.

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Jacob's condition: the boy's testosterone levels were six times higher than the normal range for an infant.

Jacob's father, Adam, immediately thought about his own medication. Adam had been using a testosterone cream twice a day, hoping to increase his sex drive, which was diminished as a result of his depression. Jacob had been sleeping in the same bed as his parents, and Adam would hug Jacob and hold the child on his bare chest for skin-to-skin contact.

Adam read the package insert for the testosterone gel and learned that testosterone can be transmitted to other people by touching the skin where the gel has been applied. He thought he may have exposed Jacob by accident, but he was too embarrassed to tell Jacob's pediatrician about his concerns. Instead, he stopped sleeping in the same bed with Jacob and made sure not to hug or hold his son without a shirt on. At Jacob's next doctor's visit, his condition had improved but was not fully resolved.

Luckily, Adam was eventually able to admit to his son's pediatrician that he had been using testosterone gel and had taken steps to protect Jacob. The doctor shared this information with the medical community by writing up Jacob's story in a "case report" that was published in a pediatric medical journal.

Jacob's case report became one of eight cases prompting the FDA to investigate testosterone gel to see if it was causing problems in children. All eight of these cases involved boys or girls younger than 6, with strikingly similar symptoms, who were exposed to testosterone through skin contact with their fathers. When the fathers eliminated exposure to the gel, for example by protecting their children with clothing to avoid skin contact, some (but not all) of these signs and symptoms improved.

Testosterone is not approved for use in children, and its safety and efficacy have not been established in this age group. During clinical trials of testosterone for adults, researchers noticed elevated testosterone levels in women who had experienced skin-to-skin contact with a male partner for as little as 15 minutes a day. This transfer of testosterone could be prevented by wearing clothing to cover the area on which the cream had been applied (usually the arms and shoulders). The risk of transfer through skin contact was described in the professional labeling for testosterone products, which also warned patients to wash their hands after applying the cream and avoid contact with pregnant women. However, at the time, these warnings were not prominent on the label.

At the FDA's request, the manufacturer of one testosterone product, Androgel, reported 17 additional cases of adverse events in children and more than 100 cases of adult exposure. It is not clear why the manufacturer did not report the additional cases until the FDA's request.

Thanks to the case reports, the FDA announced in May 2009 that it would require testosterone products to carry a boxed warning to help prevent accidental exposure in children. The products also now include a medication guide that more clearly outlines the risks to children and instructs men on how to avoid these risks by washing hands and wearing protective clothing.

"Those reports from consumers made a difference," said Jo Wyeth, a safety evaluator at the FDA, in a recent FDA statement to consumers. Wyeth worked with the families and doctors who had reached out to the FDA to raise concerns about the testosterone products. "We want to prevent these harmful situations from happening to others," said Wyeth.

How to Report an Adverse Event

You can submit a report to the FDA using the MedWatch reporting system by calling 1-800-FDA-1088 or by visiting www.fda.gov and typing in MedWatch in the search box. You also can submit a report by contacting the drug's manufacturer, which is required by law to pass the report along to the FDA.

Remember: If you do report an adverse event in more than one place, include the same detailed information in each report so the FDA can identify duplicates.

Low reporting rates

In 2012, the FDA received nearly 900,000 adverse event and medication error reports (reports of injuries or negative effects seen in patients taking a drug), but only 5 percent were associated with children younger than age 18. The reporting probably represents only a small fraction of the true number of adverse events occurring in children. To boost these numbers, the FDA is encouraging more consumers to report adverse events directly to the agency.

The FDA relies heavily on post-market adverse event reports to learn critical information about drug side effects in children. This is because it is relatively rare for drug manufacturers to conduct pre-market clinical trials in the more vulnerable pediatric population. Even when a manufacturer does conduct a pediatric trial, the test group tends to be smaller than in trials enrolling adults and may cover a limited age range.

Adverse event reports are thus especially helpful for detecting risks in children. Consumers and pediatricians can help the FDA identify problems and warn other families more quickly by staying vigilant and reporting negative events when they occur.

Quality matters

Adverse events can be reported to the FDA using the agency's MedWatch reporting program (see text box on this page).

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

The article on page 2 of Health Letter *discusses negative effects of drugs in children and the importance of reporting these adverse events. Another population, the elderly, also is especially vulnerable to harm from drugs. As with young people, it is crucial to report any adverse drug effects involving older adults to the Food and Drug Administration (FDA) MedWatch program. Please find the contact information on page 3.*

The following article originally appeared in the February 2005 issue of Health Letter.

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-30s. 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 percent. 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 (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 aforementioned groups that are listed on WorstPills.org, an anticholinergic warning appears, 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, TavistD, Entex LA and Actifed. All of these contain amphetamine-like drugs such as pseudoephedrine. For any of these drugs profiled on WorstPills.org, most of which are listed as Do Not Use drugs, the following warning is given:

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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.

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.

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.

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 on WorstPills.org 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 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 alter 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 on WorstPills.org, 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

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and death from other causes becomes more likely before the transformation to cancer occurs. Therefore, the benefit of removing any polyps diminishes with age. By age 76, the USPSTF concluded, this diminishing benefit becomes outweighed by the myriad risks of colonoscopies, which increase with age.

Risks and costs

The 2008 USPSTF report found that serious complications of the colonoscopy itself occur in 25 of every 10,000 colonoscopies performed. Such complications include "deaths attributable to colonoscopy or adverse events requiring hospital admission, including perforation, major bleeding, diverticulitis, severe abdominal pain, and cardiovascular events. …"

These risks are compounded by the anesthesia increasingly administered to some patients to help them tolerate the procedure. Traditionally, patients have been administered a mild sedative, such as a benzodiazepine or narcotic, for the duration of the procedure. This medication allows a patient to tolerate the procedure more comfortably, usually not remembering it, but does not induce a state of unconsciousness. Though no medication is risk-free, such a one-time dose of a short-acting benzodiazepine or narcotic, administered under supervised conditions, is relatively innocuous.

Over the past decade, however, an increasing number of patients have opted instead for general anesthesia, preferring to remain unconscious during the colonoscopy. According to

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Table 1: Current USPSTF recommendations for colorectal cancer screening (using colonoscopy, sigmoidoscopy or fecal occult blood testing [FOBT])*

Patients	Recommendation
Adults 50 to 75 years old	Recommend screening for colorectal cancer using one of three procedures in Table 2.
Adults 76 to 85 years old	Against routine screening for colorectal cancer. There may be considerations that support colorectal cancer screening in an individual patient, after detailed discussions with a physician of the benefits and risks of the screening and history.
Adults older than 85	Against routine screening for colorectal cancer in all circumstances.

** Last updated October 2008. These recommendations apply only to routine colorectal cancer screening in healthy patients and not to cases in which a colonoscopy is necessary to assist in the diagnosis or treatment of another suspected condition (including suspected colon cancer based on symptoms or on another screening test listed in Table 2).*

Table 2: Current USPSTF-recommended options for colorectal cancer screening*

Recommended Procedures	Description	Recommended Interval**	Pros	Cons
Colonoscopy	A camera is inserted into the colon via the rectum and visualizes the entire colon and rectum	Every 10 years	• Most sensitive technique for finding a tumor anywhere in the colon or rectum	• Highest-risk of all procedures • Colonic perforation, bleeding and risks from general anesthesia, if given • Most expensive
Flexible sigmoidoscopy*** (must be done in combination with fecal occult blood testing (FOBT)	A camera is inserted into the last part of the colon (sigmoid colon) via rectum and visualizes only the sigmoid colon and rectum	Every five years (with FOBT every three years)	• Sensitive for visualizing tumors within the sigmoid colon and rectum • Less invasive, lower rates of serious complications compared to colonoscopy	• Colonic perforation and bleeding (but less likely than with a colonoscopy) and risks of general anesthesia, if given • If used alone, without FOBT, may miss tumors in the rest of the colon (66-72 percent of all colonic tumors)
FOBT***	Stool samples are collected at different times and examined for blood that might indicate a potential tumor somewhere in the colon or rectum	Annually (if alone) or every three years (if in combination with flexible sigmoidoscopy)	• Lowest-risk and lowest-cost among all three procedures • Can be done from home	• Highest chance among all three procedures of missing a tumor • Least specific of all three procedures (highest rate of false positives)

** Two other procedures, CT colonography and fecal DNA testing, are not currently recommended by the USPSTF due to a lack of evidence assessing the benefits and harms of these procedures in screening for colorectal cancer.*

*** Assuming negative initial tests. If a tumor or malignant polyp is found, repeat tests may need to be performed more frequently.*

****A positive result on either the flexible sigmoidoscopy or the fecal occult blood test warrants a colonoscopy to further investigate the results.*

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a 2012 study of Medicare and privately insured patients, use of general anesthesia for either colonoscopies or upper endoscopies (an imaging study similar to a colonoscopy, but of the stomach and esophagus) increased from 14 percent in 2003 to 30 percent by 2009. More than two-thirds of general anesthesia use was in low-risk patients who did not warrant this treatment.

Though more comfortable for patients, general anesthesia is far riskier than sedatives, particularly for patients with a history of cardiovascular or pulmonary disease or those who smoke. In addition, because it requires the services of an anesthesiologist, general anesthesia typically adds about $150 (for Medicare patients) to $500 (for privately insured patients) to the cost of a colonoscopy or endoscopy. The overall cost of general anesthesia services for these procedures in the U.S. more than tripled from 2003 ($0.4 billion) to 2009 ($1.3 billion), with most of this cost ($1.1 billion, or 85 percent in 2009) for "potentially discretionary" use in low-risk patients.

Advice for patients

Colonoscopy is not the only method to screen for colon cancer, and screening is not recommended for all age groups. Table 1 on page 6 provides the most current recommendations from the USPSTF regarding colorectal cancer screening. Table 2, also on page 6, describes three screening options, including colonoscopy screening.

If you are between the ages of 50 and 75 and have never been screened for colorectal cancer or were last screened more than 10 years ago, make an appointment with your doctor to get screened as soon as possible. If you are between the ages of 76 and 85, you no longer need to be routinely screened, unless your doctor determines otherwise after a detailed discussion of the risks and benefits, as well as any history of an abnormal colonoscopy or other test. No one 86 or older should be screened under any circumstances. Colonoscopy, flexible sigmoidoscopy and fecal occult blood testing are the only screening procedures recommended at this time. ✦

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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. ✦

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The FDA requires high-quality reports to identify issues with drugs. Reports that lack essential information, such as the patient's age or length of exposure to the medical product, may not be helpful to the FDA.

"What I have found to be most helpful in reports from consumers is a clear statement about the event, followed by a more detailed description of what happened," Wyeth told consumers in the FDA's recent announcement. The FDA also recommends including information regarding:

- Product name, type, dose and how it was administered;
- How long the product was used;
- Age of the child;
- Other medications or medical conditions present at the time of the event;
- Outcome (such as what happened to the child if the medical product was stopped); and
- Contact information for the person submitting the report and for the child's health care professional.

You can ask your pediatrician for help filling out an adverse event reporting form. Your child's doctor will be best able to recognize the type of information the FDA will need, including technical information such as results from blood tests or X-ray results.

If FDA safety evaluators find something significant in your report, they may contact you or your child's doctor with follow-up questions. Do not get discouraged if you do not hear back from the FDA after submitting your report; it usually takes multiple reports of similar incidents before the FDA will investigate a problem. When you take the time to report, you are taking an important step toward ensuring that children across the country stay protected from serious risks. ✦

HRG Works for You!

Our latest work involves a risky medication, pharmacy compounding legislation and dangerous bedrail devices

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 our own research, 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
- urging Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest research-based consumer advocacy includes:

- **Testimony to the FDA Peripheral and Central Nervous Systems Drugs Advisory Committee on Suvorexant — 5/22/2013 —** Public Citizen urged the Food and Drug Administration (FDA) not to approve the latest sleep medicine, suvorexant, because the drug's long-lasting risks outweigh any short-term benefits on sleep.
- **Public Citizen to Congress: New Bill on Pharmacy Compounding a Major Step Backward for U.S. Drug Safety — 5/16/2013 —** On May 3, 2013, Public Citizen expressed grave concerns to the Senate Health, Education, Labor & Pensions (HELP) Committee that its draft proposal on pharmacy compounding would weaken existing laws governing drug manufacturing. The proposal would create a new regulatory class of drug manufacturers, confusingly called "compounding manufacturers," that would be exempt from federal premarket approval and related labeling requirements. The bill on pharmacy compounding introduced in the Senate on May 15 offers no significant improvement over the draft. The American public deserves much better.
- **Public Citizen Petitions the Consumer Product Safety Commission to Ban Adult Portable Bedrails Due to Strangulation Risks — 5/9/2013 —** Public Citizen sent a petition to the Consumer Product Safety Commission (CPSC) asking for a ban on adult portable bedrails. Portable rails are designed to slip under an ordinary mattress and are advertised as making beds "safer" for seniors who have trouble getting in and out of bed unassisted. The CPSC reported in 2012 that bed rails have been associated with at least 155 fatalities, mostly from strangulation incidents where an elderly victim became stuck, wedged, or trapped between the mattress and bed rail. There is also no evidence that bedrails actually help prevent falls. Public Citizen has asked the CPSC to ban adult portable bedrails because the product cannot be redesigned to eliminate the strangulation risk.

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

Product Recalls

May 1, 2013 – May 28, 2013

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

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

BLUE Diamond Pill, male sexual enhancement pill, 1-, 5- and 10-count blister packs. Volume of product in commerce: 213,000 capsules. Marketed without an approved NDA/ANDA: Product may contain undeclared sildenafil, tadalafil and analogues of these FDA approved active ingredients, making them unapproved drugs. Performance Plus Marketing, Inc.

BLUE Diamond PLATINUM Capsules, 1,000 mg, supplied in 1-, 5- and 10-count blister packs. Volume of product in commerce: 1,000 capsules. Marketed without an approved NDA/ANDA: Product may contain undeclared sildenafil, tadalafil and analogues of these FDA-approved active ingredients, making them unapproved drugs. Multiple lots affected. Contact your pharmacist. Performance Plus Marketing, Inc.

CASANOVA Capsules, 450 mg, male sexual enhancer, supplied in 1-count blister packs. Volume of product in commerce: 96,000 capsules. Marketed without an approved NDA/ANDA: Product may contain undeclared sildenafil, tadalafil and analogues of these FDA-approved active ingredients, making them unapproved drugs. Lot #: 030112, expiration date 03/15. Performance Plus Marketing, Inc.

Libigrow Capsules, supplied in 1-, 5- and 10- count blister packs. Volume of product in commerce: 610,000 capsules. Marketed without an approved NDA/ANDA: Product may contain undeclared sildenafil, tadalafil and analogues of these FDA approved active ingredients, making them unapproved drugs. Multiple lots affected. Contact your pharmacist. Performance Plus Marketing, Inc.

Libigrow XXXTREME Capsules, MAXIMUM STRENGTH FORMULA, 1,000 mg, supplied in 1-, 5- and 10-count blister packs. Volume of product in commerce: 686,000 capsules. Marketed without an approved NDA/ANDA: Product may contain undeclared sildenafil, tadalafil and analogues of these FDA-approved active ingredients, making them unapproved drugs. Multiple lots affected. Performance Plus Marketing, Inc.

Mojo Nights and Mojo Nights for Her, 1 capsule. Volume of product in commerce: 1,000 blister packs. Marketed without an approved NDA/ANDA: The products were found to contain FDA-approved ingredients and analogues of FDA-approved ingredients used to treat male erectile dysfunction, making them unapproved new drugs. All lots, all expiration dates. Evol Nutrition.

Mojo Nights SUPREME Capsules, 1,000 mg, 1-count blister packs. Volume of product in commerce: 70,000 capsules. Marketed without an approved NDA/ANDA: product may contain undeclared sildenafil, tadalafil and analogues of these FDA approved active ingredients, making them unapproved drugs. Lot #: 01MJS0712, expiration date 07/15. Performance Plus Marketing, Inc.

Super Power Capsules, Proprietary Blend 570 mg, packaged in 2-count capsules per blister pack. Volume of product in commerce: 40,480 capsules. Marketed without an approved NDA/ANDA: This dietary supplement has been found to contain sildenafil, an FDA approved drug for the treatment of male erectile dysfunction making this an unapproved new drug. Lot #: L08108, expiration date 06/15. D&S Herbals, LLC.

WOW, Health Enterprises, Dietary Supplement, 30 caplets. Volume of product in commerce: 17,555 bottles. Marketed without an approved NDA/ANDA: Contains undeclared drug ingredients, making it an unapproved drug. FDA sample analysis has found the product to contain methocarbamol, dexamethasone, and diclofenac. All lots, all expiration dates. Brower Enterprises Inc.

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

Amoxicillin Capsules, USP 500 mg, 500- and 30-count bottles. Volume of product in commerce: 8,286 30-count and 37,108 500-count bottles. Presence of foreign substance: Certain lots of amoxicillin capsules are being recalled due to potential contamination with fragments of stainless steel wire mesh. Multiple lots affected. Contact your pharmacist. Sandoz Inc.

Donnatal Extentabs, 0.3888mg/46.8mg, 100-count bottle. Volume of product in commerce: 1,258 bottles. Labeling: Incorrect or missing lot and/or expiration date: Bottled product is labeled with an expiration date of Apr 2015. The correct expiration is Apr 2013. Lot #: 68864, expiration date 04/13. West-ward Pharmaceutical Corp.

Glimepiride Tablets, USP, 2 mg, 100-count tablets per bottle. Volume of product in commerce: 10,373 bottles. Failed Tablet/Capsule Specifications: One oversized tablet was found in a sealed 100-count bottle of glimepiride at the retail level. Lot #: C0671212A, expiration date 12/14. Qualitest Pharmaceuticals.

Pantoprazole Sodium Delayed Release Tablets, USP, 40 mg, 90 count bottles. Volume of product in commerce: 12,770 bottles. cGMP deviations: Oral products were not manufactured in accordance with Good Manufacturing Practices. Lot #s: PA22028, expiration date 5/14; PA22029, expiration date 5/14. Jubilant Cadista Pharmaceuticals Inc.

Pentrexcilina Tablets (acetaminophen, chlorpheniramine maleate and phenylephrine HCl), 20-count tablets per carton. Volume of product in commerce: 11,580 cartons. Labeling: Not elsewhere classified: Pentrexcilina tablets and pentrexcilina liquid are being recalled because the product labels are misleading because they may be confused with pentrexyl, a prescription antibiotic used to treat respiratory illnesses in Mexico. Lot #: 11611B0, Batch # 114039, expiration date 10/14. Distributed by Laboratorios Norimex Co.

Walmart Amlodipine Besylate Tablets, USP 10 mg, 30 tablets. Volume of product in commerce: 484,236 cartons. Labeling: Labeling error on declared strength; Product label incorrectly states amlodipine 5 mg instead of amlodipine 10 mg. Tablet strength is 10 mg. Lot #s: 130251, 130252, 130253, expiration date 11/14. Legacy Pharmaceutical Packaging LLC.

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

5-Tray Dehydrator with Digital Timer. The fan can fail, causing the unit to overheat and pose a fire hazard. LEM Products Distribution at (877) 536-7763 or www.lemproducts.com.

Anywhere Lounger Bean Bag Chairs. Bean bag chairs without a permanent zipper closure allow young children to unzip, ingest or inhale the small beads inside of the bean bag chair, posing a suffocation and strangulation hazard. Powell Company at (800) 622-4456 or www.powellcompany.com.

Area Rugs. The rugs fail to meet federal flammability standards, posing a fire hazard to consumers. Nourison at (800) 223-1110 or www.nourison.com.

Children's Two-Piece Pajama Sets. The pajamas fail to meet federal flammability standards for children's sleepwear, posing a risk of burn injuries to children. Vive La Fete at (800) 535-7396 or www.vivelafete.com.

Children's Water Bottles. The water bottle's spout can break off, posing a choking hazard to children. H&M toll-free at (855) 466-7467 or www.hm.com.

Competition/Closed Course and Enduro Motorcycles. During use, the throttle cable can malfunction and result in an uncontrollable throttle. This poses a crash hazard to the rider. KTM North America Inc. or Husaberg North America toll-free at (888) 985-6090 or www.ktm.com.

Deezo boys and girls zip-up hoodies. The sweatshirts and jackets have drawstrings through the hood which pose a strangulation hazard to young children. Zulily, Inc. at (877) 779-5615 or www.zulily.com.

GNU Snowboard Bindings. The ankle straps can break posing a fall hazard. Mervin Manufacturing at (800) 905-0551 or www.mervin.com.

Insolroll Solar Powered and Rechargeable Motor Roller Shades. The motor of these roller shades has a built-in lithium battery that can overheat while being charged, posing a fire risk. Insolroll at (800) 447-5534 or www.Insolroll.com.

Lea Panel, Loft and Bunk Beds. The bed's side mattress support rails can break, posing a fall hazard. Lea Industries at (888) 770-7116 or www.leaindustries.com.

Louisville Slugger® OneX Fastpitch Softball Bat. The bat's barrel can separate from the handle during use and strike people nearby. Hillerich & Bradsby at (800) 282-2287 or www.slugger.com.

Microwave Popcorn Makers. When cooked too long, the popcorn can overheat in this popcorn maker and ignite, posing a fire or burn hazard to consumers. Avon Products at (800) 367-2866 or www.avon.com.

Portable Heaters. The heaters can overheat, posing a fire hazard. Family Dollar Stores at (800) 547-0359 or www.familydollar.com.

Portable Infrared Radiant Quartz Electric Space Heaters. The heater design can fail to prevent ignition of nearby combustible materials that come in contact with the unit, posing a fire hazard to the consumer. Optimus Enterprise Inc. at (888) 672-5832 or www.optimusent.com.

Surly Pugsley Bicycle Forks. The bicycle fork can bend above the disc brake mount, posing a fall hazard to the rider. Surly Bikes at (877) 946-9333 or www.surlybikes.com.

Sweet Lambie Crib Bumper. The thread in the decorative stitching on the bumper can loosen, posing an entanglement hazard to infants. Pottery Barn Kids at (855) 323-5138 or www.potterybarnkids.com.

Teavana Glass Tea Tumblers. The glass tea tumblers can break or shatter unexpectedly, posing laceration and burn hazards. Teavana at (877) 261-1509 or www.Teavana.com.

Toro® Z Master® Riding Mowers. The idler pulley can rub against the mower's fuel tank, posing a fire hazard. Toro at (855) 493-0090 or www.toro.com.

Touch Point Portable Baseboard Convection Heaters. The heaters can overheat, posing a fire hazard to consumers. Meijer at (800) 927-8699 or www.meijer.com.

PUBLICCITIZEN Health Letter

Outrage of the Month: Avandia

The diabetes drug rosiglitazone (Avandia) was removed from the European market in 2010 by the European Medicines Agency (EMA) due to the cardiovascular risks the drug posed. So why is it that thousands of Americans (132,000 since 2010) continued to be prescribed the dangerous medication, likely resulting in hundreds or more serious, even fatal, adverse reactions, including heart failure and heart attacks?

The "reason," if it can be called reasonable, was that although both authorities had access to the same safety studies, the Food and Drug Administration (FDA) and the EMA reached very different conclusions in September 2010 regarding the fate of this once top-selling diabetes drug. The EMA concluded that new data support the drug's posing an increased cardiovascular risk. Since that agency "could not identify additional measures that would reduce the cardiovascular risk," they "concluded that the benefits of rosiglitazone no longer outweigh its risks and recommended the suspension of the marketing authorisation of the medicine." Furthermore, the EMA was so concerned about Avandia's dangers that when it banned the drug, it stated that the only way it could ever be marketed again was if the manufacturer could "provide convincing data to identify a group of patients in whom the benefits of the medicines outweigh their risks."

After a July 2010 advisory committee meeting, the FDA, in contrast, decided not to ban the drug but to institute a risk evaluation and management strategy (REMS) to limit the use of the drug to those the agency "believed" could benefit. The patient-reckless conclusion was not to approve a REMS until May 2011. (It was not fully in place until six months later). However, there has never been any evidence that those getting the drug in this country have been patients for whom the benefits of the medicines outweighed their risks.

Once again, instead of banning a drug — as recommended by 12 FDA advisory committee members —because it lacks unique benefits but poses unique risks, the FDA has hidden behind a REMS program that has reduced the number of people using the drug to 2,400 in 2012. Unfortunately, the 132,000 people who used Avandia in the U.S. since 2010 represent hundreds of preventable injuries and deaths.

REMS should be reserved for drugs that need to remain available. By no stretch of the imagination is Avandia such a drug. Ask the EMA. Unfortunately, the FDA is considering relaxing its restrictions. We continue to advise patients not to use this dangerous drug.

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

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