PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR AUGUST 2010 – VOL. 26, No. 8

JAMA Survey Finds Doctors Unwilling to Report Negligent Peers

A survey published in the *Journal of the American Medical Association* (JAMA) documented that 36 percent of a nationwide random sample of 1,891 physicians do not agree with their professional commitment to report "physicians who are significantly impaired or otherwise incompetent to practice."

In addition, 17 percent of those surveyed "had direct personal knowledge of a physician colleague who was incompetent to practice medicine in their hospital, group or practice." Yet, of those with this knowledge, only 67 percent reported this to the relevant authority.

One out of three doctors aware of an incompetent colleague did not report this to the authorities.

In other words, one out of three doctors aware of an incompetent colleague did not report this to the authorities. The reasons stated included their belief that someone else was taking care of the problem (19 percent); this was followed by the belief that nothing would come of the report, i.e. no action would be taken (15 percent). The remaining reasons for failure to report were: fear of retaliation (12 percent), belief that reporting was not their responsibility (10 percent), and the concern that the physician would be too harshly punished (9 percent).

These findings are very troubling because self-regulation of physicians through hospital peer review and other mechanisms that rely on the profession itself (e.g. physician complaints to state medical boards or to hospital medical staff) are critical mechanisms for holding questionable physicians accountable and assuring patient safety. The article notes that (1) many states have mandatory reporting laws that require physicians to report colleagues who may be impaired or incompetent and (2) the American Medical Association, the Charter on Medical Professionalism and the European Federation of Internal Medicine have a firm policy stating that doctors have an "ethical obligation to report" and to engage in the process of "self-regulation."

For the two-thirds of the responding physicians who supported reporting, women were significantly more likely than men to completely agree, as were graduates of U.S. medical schools compared with graduates from non-U.S. medical schools. Interestingly, physicians practicing solo or in group practices were least likely to fully support reporting while physicians practicing in hospitals or clinics were most likely to completely endorse reporting. The study further found that the malpractice environment in a community plays a role in physicians' willingness to report. In areas with a low number of malpractice claims, physicians were more likely to support reporting than those in areas with medium or high numbers of malpractice claims.

According to the authors of the study, "it is clear that a reliance on self-regulation is not sufficient to ensure that reporting will occur. This suggests the need for more external regulation." The authors' suggestions include the need for a greater role for professional organizations, licensing groups and patient groups.

The study findings should come as no surprise to those familiar with ineffectiveness of hospital peer review, as demonstrated by the failure of almost 50 percent of hospitals in the U.S. to report a problem doctor to the National Practitioner Data Bank (NPDB). Hospitals are required to report to the NPDB whenever they revoke or restrict a physician's clinical privileges for more than 30 days for problems involving performance or conduct. Although the healthcare industry estimated that there would be about 10,000 hospital reports to the NPDB each year, the average number of annual reports has been only 650.

The authors of the JAMA article note that greater external regulation may

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be necessary. Public Citizen believes that one focus of increased external regulation should be the hospital peer-review process itself. The Medicare Conditions of Participation (COPs) are the minimum standards that hospitals are required to meet to participate in Medicare. In a June 2010 report, the Medicare Payment Advisory Commission (MEDPAC) called for the strengthening of the COPs. The Joint Commission, through its accreditation process, is responsible for reviewing hospitals' compliance with the COPs.

Almost 50 percent of hospitals in the U.S. fail to report a problem doctor to the National Practitioner Data Bank.

Although a hospital may comply with most of the Medicare COPs for hospital peer review, a violation of one element of the COPs is not sufficient to rule the entire Condition a violation. This happened at Redding Medical Center, where peer review for cardiac services was violated but no action against the hospital was taken. As a result, hundreds of patients had unnecessary bypass and valve surgery.

In addition to better external regulation, it is important to have external regulation with greater sanctions. A May 2009 Public Citizen report called for the COPs to be modified to address hospitals' reporting responsibilities to the NPDB. A 1995 report from the Office of Inspector General (OIG) at the Department of Health and Human Services recommended a statutory and regulatory change to the COPs so that hospital compliance with the NPDB reporting requirement would become an integral part of the Joint Commission survey process.

In addition, the OIG has recommended a civil money penalty for hospitals that fail to report to the National Practitioner Data Bank (NPDB). The Joint Commission itself has acknowledged (in an email to Public Citizen) that "the hospital industry is well aware of this history of no penalty and well understands that there is no significant punishment associated with not following the requirement."

None of these recommendations have been implemented.

Finally, where state laws require physicians to report impaired or incompetent colleagues, states should sanction those practitioners who fail to report such problem physicians. ✦

Cracks in FDA's Medical Device Approval Process Allow Unproven Devices to Slip Through

The government's system of approving medical devices is broken, allowing potentially ineffective devices on the market largely because approval rules are too lax, contain loopholes and are inadequately enforced, according to a paper by Public Citizen researchers published in the July 2010 *Public Library of Science Medicine.*

The authors of the paper outline eight weaknesses in the device-approval process and recommend significant changes that both the Food and Drug Administration (FDA) and Congress should make. They illustrate these weaknesses with examples of devices that were approved despite questions about their safety or effectiveness.

> **Fees paid by the medical device industry for FDA reviews make the agency beholden to the industry it is supposed to regulate.**

"The FDA's mission is to protect public health, but allowing questionably effective products onto the market is inconsistent with that mission," said Dr. Sidney Wolfe, a director at Public Citizen and one of the authors.

Added the lead author, Dr. Jonas Hines, a former Public Citizen health researcher who is doing a medical residency at the University of California, San Francisco, "Medical devices are becoming increasingly important in health care. It is vital that devices are shown to be safe and effective before they are used in patients."

There are two general approval procedures for devices. One, the "premarket approval" (PMA) pathway, is analogous to the drug approval process. In the other, termed "premarket notification" submission and often referred to as "510(k)," a manufacturer need only demonstrate that the new device is "substantially equivalent" to a marketed device. While PMA application is reserved for high-risk and novel devices, the vast majority of devices proceed down the 510(k) route.

The weaknesses of the device-approval process identified by the authors include:

- A lower device approval standard than their drug counterparts;
- Lax interpretation of the requirements for the 510(k) pathway;
- A loophole that allows manufacturers to circumvent the PMA or 510(k) pathways;
- Failure of the FDA to appropriately regulate many types of devices that were first marketed prior to the 1976 enactment of the current regulatory scheme; and
- A superfluous appeal mechanism which gives manufacturers a second go for approval after the FDA has rejected a device.

To make matters worse, the law directs the FDA to consider the "least burdensome" means of showing effectiveness for devices, giving manufacturers recourse to challenge many FDA requests it considers onerous. And fees paid by the medical device industry for FDA reviews make the agency beholden to the industry it is supposed to regulate.

As a consequence of these weaknesses, devices can reach the market when in fact they shouldn't, the authors wrote.

For example, the vagus nerve stimulator is a surgically implanted device approved to treat severe depression. The trial submitted to the FDA for approval showed no statistically significant benefit for patients in the primary outcome. Even though FDA reviewers initially said it shouldn't be put on the market, the director of the FDA device center reversed direction and approved the device. The Centers for Medicare and Medicaid Services has since said the device is of such questionable value that it refuses to reimburse for it. Still, it remains on the market.

Also cited is ReGen's collagen scaffold, a device implanted to replace a damaged meniscus in the knee. The trial conducted for approval showed no benefit for the scaffold over traditional surgery. However, this crucial fact was obscured when the agency allowed the company to use the less-stringent 510(k) process, comparing the device to multiple approved devices of questionable similarity. The FDA eventually approved the device; a subsequent FDA report documented a flawed review process, influenced by pressure from the company and Congress. The prestigious Institute of Medicine is now conducting a review of the 510(k) process following the highly publicized ReGen controversy. This device also remains on the market.

The paper's authors – Hines, Wolfe, Dr. Peter Lurie and Eunice Yu – recommend that these weaknesses be addressed through a combination of legislation, regulation and changes in agency practice.

"The American public is best served when the FDA rigorously reviews devices, particularly those used to treat diseases or [those that] are permanently implanted. Only through a multi-tiered approach to tighten the device-approval process can we adequately protect the public's health," Hines said. ✦

Author Dr. Peter Lurie testified in front of the Subcommittee on Health of the Committee on Energy and Commerce of the U.S. House of Representatives about some of these problems in June, 2009. His testimony is available at www.citizen.org.

In the Public Interest

The following article was written by Ralph Nader; it has been reprinted with permission.

The festering corporate government in Washington, D.C. is a theater of the absurd. Some of the acts of this tragedy follow:

1. Start with the often hapless Centers for Medicare and Medicaid Services (CMS), the agency that administers Medicare. Medicare pays $1,593 per injection of Lucentis for wet age-related macular degeneration as well as $42 per dose for Avastin, a drug that has a similar molecular structure, used by ophthalmologists.

Both drugs are made by Genentech. Lucentis is FDA approved for the vision problem and the other, Avastin, is approved to treat cancer. Doctors can also use Avastin for vision treatment. A study by three officials of CMS and Dr. Philip Rosenfeld, a retina specialist at the University of Miami, reported that for Medicare patients 60 percent of eye injections were Avastin, while 40 percent used Lucentis. Note this: Medicare paid $537 million for Lucentis in 2008 and only $20 million for Avastin!

2. Saving about half a billion a year by using Avastin is small potatoes to another CMS shortcoming. For fiscal year 2009, CMS paid $65 billion in erroneous payments — to deceased doctors, fraudsters, delinquent or imprisoned contractors and other suspended or debarred firms.

Organized fraud of Medicare is becoming more systemic. So President Obama wants CMS to use a new fraud-detection program. Professor Malcolm Sparrow of Harvard University, the nation's leading expert on healthcare billing fraud, told the CMS how to do this many years ago, but they were not listening.

The President wants to reduce throughout the government "payments in benefits, contracts, grants and loans to ineligible people or organizations," Better trillions of dollars late over the decades, than never!

3. Five oil company executives admitted at a Congressional hearing this week that they did not have contingency plans worked out for catastrophic failures. What is, by comparison, the worst case scenario for offshore windfarms or solar/thermal conservation, or passive solar architecture? Energy Secretary Stephen Chu still does not note such criteria to differentiate between energy supply priorities.

4. President Obama now, belatedly, recognizes that the notorious oil industry patsy, the Minerals Management Service in the Department of Interior, was a washout non-regulator of offshore drilling inherited from the Bush and Clinton Administrations. Well he also better take a hard look at the Federal Railroad Administration, the Office of Pipeline Safety and the Nuclear Regulatory Commission, which are variously pleased with being captured by the very industries they are supposed to regulate. Too many agencies, in essence, allow the companies to "self-regulate" — an oxymoron.

Each of these agencies may wake up some day to witness a catastrophic hazardous materials disaster that they should have prevented with stronger standards, inspection and law enforcement. Heed this caution, Mr. President!

5. Another $50-billion request by the White House was just whisked through Congress for the brutal, spreading, futile war in Afghanistan — the historic graveyard of empires. Republicans loved to vote for this raid on the taxpayers.

But in June 2010, a united Republican cabal, joined by Senators Joseph Lieberman (D-CT) and Ben Nelson (D-NE), blocked a $120-billion package (the threat of filibuster again) to extend unemployment benefits, preserve Medicare payments, extend tax credits for corporate research and raise taxes on oil companies, other big companies and investment partnerships. The bill also included $24 billion to aid state governments in preventing thousands of state layoffs, including teacher layoffs.

The point here is not arbitrarily to decry Republican questioning of this domestic bill. It is to show how an overall ignorant, rubberstamping Congress is not heeding the lessons from Vietnam and Iraq — the immense casualties, the destruction and poisoning of these countries by detonations while laying waste to the environment, and the imperialist policies that also harmed our country in so many ways.

6. Dana Milbank, the Washington Post reporter-satirist, was at the House of Representatives' hearing this week where Congressman Joe Barton (R-TX) apologized to BP's CEO, Tony Hayward, saying the White House's demand that BP set aside $20 billion for its huge, toxic contamination to the Gulf coast and its people was "a shakedown." He added, for good supplicant measure, that he doesn't "want to live in a country" that treats a private corporation this way. He later apologized for his apology, at the behest of Republican House leaders.

The Barton outburst illustrates why it should be easy for the Democratic Party to landslide the Republicans in the 2010 Congressional elections. Probably the most craven version of the Republican Party ever, this team takes huge slurries of corporate money while blocking any safeguards for workers, consumers, small taxpayers and the environment. They even defeated investor rights for shareholders, who own these companies, but whose bosses pay themselves obscenely to control them.

The Democrats have their hand out to the same commercial interests. But if they want to win, they'd better formulate the language of standing with the people over big business by November. And if the Democrats don't want November to mark their curtain call, their language of standing with the people needs to be followed by action. ✦

To Mitch McConnell: We're Already Rationing Care

The following article was written by Erin Marcus, M.D., and originally appeared July 8, 2010 on the Huffington Post's *Living Section: www.huffingtonpost.com/living/. You can also follow Erin Marcus on Twitter: ErinNMarcusMD.*

As someone who works with low-income patients, I have to scratch my head a bit at Senator Mitch McConnell's complaint that Dr. Donald Berwick shouldn't be appointed to run Medicare and Medicaid because he supports "rationed health care."

McConnell's opposition to Berwick purportedly stems from a statement Berwick made last year, in which he said the following: "The decision is not whether or not we will ration care — the decision is whether we will ration with our eyes open. And right now, we are doing it blindly."

To which the logical response of anyone who has spent any time in an urban health care setting ought to be, "Let's state the obvious!"

Now, I could offer up a litany of examples supporting my hypothesis. There's the middle-aged mechanic with blood in his stool who can't get a colonoscopy because he lacks the $1,000 needed to pay the upfront cost. The cancer patient waiting months to see the specialist for treatment at the jam-packed, over-subscribed charity clinic. The lines of people waiting around the block to see a first-year medical student at a health fair because they see it as their only opportunity to get treatment, when the purpose of the fair is really just to offer some basic screening tests.

But those are just my personal observations, and for all I know they might not represent what's really going on in our world-renowned health care system. So let's try to look at some more objective analyses:

For starters, there's the Kaiser Health Foundation's nationally representative 2009 survey of 1,200 adults, in which six of 10 respondents said they or a member of their household delayed or skipped care in the past year due to cost, and one of three skipped filling a prescription due to cost.

An analysis of 23 million children by researchers at Johns Hopkins found that being uninsured increases a hospitalized kid's risk of death by 60 percent versus an otherwise similar hospitalized kid with insurance — leading, over the past 18 years, to the deaths of more than 16,000 children in the U.S.

There's the finding that 65 to 74 year olds who lack insurance and then get Medicare are more likely to be hospitalized for complications of cardiovascular disease and diabetes than comparable Medicare beneficiaries who had insurance all along, and that Medicare spends about $1,200 more annually on the "previously uninsured" with these conditions than on people with the same conditions who had been insured. The paper doesn't make any conclusions about why, but these findings lead one to suspect that diabetes and heart disease fester and get out of control in folks who can't afford care, so that when they finally get coverage, their problems are more difficult to treat.

Finally, there's the analysis of National Health and Nutrition Examination Survey data that found that adults younger than 65 who lack health insurance are 40 percent more likely to die than similar people with insurance. (This was found after matching the two groups for age, gender, smoking status, income, education, body mass, alcohol use, ethnicity and "health status" as described by both the subjects' doctors and themselves.)

These are just a handful of the many studies conducted in the past few years demonstrating how our discombobulated system doles out care to those with and those without good insurance.

It's not that I think the Obama Health Plan, which offers a treasure trove of profit to the pharmaceutical and insurance industries, is such a great solution either. But really, Senator, can't you come up with a better reason to oppose Berwick? Rationing isn't "looming." It arrived at the train station a long time ago. ✦

Guidelines for the Perplexed

The following article by Nortin Hadler, M.D., was posted on www.thehealthcareblog.com on July 20, 2010. He is a professor of medicine and microbiology at the University of North Carolina - Chapel Hill. Dr. Hadler is the author of numerous articles and essays and a series of popular books on the state of medicine today. His most recent book is Stabbed in the Back: Confronting Back Pain in an Overtreated Society.

There has been much progress in the understanding of the biology of Alzheimer's disease. Chemicals detected in the blood and spinal fluid of patients with Alzheimer's and findings with new brain imaging techniques are the long sought-after "biomarkers" of the disease. They are clues to its cause that are already targets for drug development. But there is a great public health danger in jumping the gun and prematurely using biomarkers in clinical practice for diagnosis or prognosis. It is for this reason that I have serious reservations about the new diagnostic guidelines proposed for the diagnosis of Alzheimer's disease.

The current guidelines, which have served as well as possible for 26 years, are based entirely on the patient's narrative. The diagnostic label is applied when there is no better explanation for a severe and global compromise in cognition that developed insidiously. The diagnosis of Alzheimer's when it is full blown is not a challenge. The challenge is in making the diagnosis when it is less obvious — when it is but "possible" or "probable." These categories are confronted in the old criteria by considering the degree to which elements of cognition are compromised.

The application of these qualified diagnostic labels provokes as much anxiety in the clinician as it does angst in the patient and foreboding in the patient's intimate community. Maybe the fact that grandpa occasionally forgets his keys or his neighbor's name is all there is to it; "grandpa's losing it" or has a touch of "senility." That would call for a supportive community and not the specter of a slide to a dreadful fate denoted by Alzheimer's.

The National Institute of Aging and the Alzheimer's Association sponsored three panels of prominent clinical and basic scientists with relevant expertise to improve the guidelines in light of scientific advancements. The panels propose dividing Alzheimer's into three stages: preclinical (no symptoms, but positive biomarkers), mild impairment and classic dementia. While such a categorization makes great sense and may offer an advance in the design of drug trials, it offers no advantage to our patients today. Rather, it is far more likely to engulf the patient in spurious inferences at great personal expense.

No one should have a diagnostic test unless the test is accurate, the result is clinically meaningful and something important can be done as a consequence to improve the patient's outcome.

Biomarkers have been tested only in small and carefully selected groups of patients where they have impressive rates of false positive results. That portends a great deal of over-diagnosis in a broader range of patients. Furthermore, all biomarker tests are expensive, some are very expensive and some have medical risks. None are near ready to be used in routine clinical practice. The following is an object lesson:

A study was published by the Alzheimer's Disease Cooperative Study Group in 2005. Nearly 800 people between the ages of 70 and 79 volunteered. All had complained of insidiously progressive cognitive impairment but none qualified even for "possible" Alzheimer's by the old criteria. Three years later, 28 percent qualified for "possible" or "probable," but none had definite Alzheimer's. APOE ε4 is one of the "biomarkers;" it is a genetic marker for predisposition to Alzheimer's. It was present in about half of the volunteers. It was present in 163 (77 percent) of the 212 who progressed and in 260 (47 percent) of those who did not progress. This difference is likely real, but hardly enough to inform medical decision making. The APOE ε4 biomarker is present in too many that don't progress and absent in too many who did progress to justify using it for diagnosis or prognosis. The APOE ε4 biomarker offers no basis for either labeling or reassuring a person without symptoms or a patient with mild symptoms.

That begs the question of what would we do differently if we could identify early Alzheimer's patients. No drug has been shown to improve the prognosis. The study discussed above was actually a drug trial comparing the likelihood of progression if these volunteers were treated with vitamin E, donepezil (Aricept) or a placebo. There was no difference.

No one should have a screening or a diagnostic test unless the test is accurate, the result is clinically meaningful and something important can be done as a consequence to improve the patient's outcome. "Biomarkers" for Alzheimer's fail, many by all three standards. "Biomarkers" may be ready for prime time to learn about etiology and even learn about prognosis, but not for labeling patients in the clinic. ✦

Practical Diabetes Tips for the Budget-Conscious

The following article was written by Erin Marcus, M.D., and originally appeared on www.newamericamedia.org. You can also follow Erin Marcus on Twitter: ErinNMarcusMD.

"Self-management" isn't a term doctors use much when they talk to patients about illnesses such as cancer or pneumonia. But when it comes to diabetes, self-management, with guidance from a medical professional, is key.

Diabetes is a chronic condition involving blood sugar that affects more than one in 10 U.S. adults. To stay healthy, most diabetics need to make lots of changes in their everyday lives. These changes usually include modifying the foods they eat, getting more physical activity and checking blood-sugar levels frequently.

These changes sound daunting, but many diabetics have been able to incorporate them into their daily lives — without giving up their favorite foods or changing jobs. Al Whitaker, a 54-year-old associate church pastor in Boston, was diagnosed with diabetes nine years ago, after he found himself too thin to fit into a suit he had purchased five days earlier. He had lost 30 pounds in eight months, but had avoided getting a checkup because he was afraid he might have cancer and felt unprepared to cope. Instead, his doctor told him that his sugar was four times the normal level, and that he had type 2 diabetes, the most common type.

"I had never thought about diabetes," he said recently. "And lo and behold, my sugar was 450."

The diagnosis was unsettling, and initially wasn't easy to manage. Al knew of a diabetic cousin who had had a toe amputated, and he experienced several episodes of low blood sugar after beginning medication. But he found comfort as he read about diabetes on the internet and in brochures he found at his pharmacy.

"The fear I had subsided once I realized that if I changed my diet I could manage diabetes," he said. "There's such a wealth of knowledge out there."

Two years ago, Al took a job with the American Diabetes Association organizing community programs to educate the public about diabetes. Below is some of his advice, as well as tips from other diabetics and from Kellie Rodriguez, a veteran nurse educator at the Diabetes Research Institute at the University of Miami Miller School of Medicine (full disclosure: I work for the same school, in a different department). This is not a comprehensive list, and you should discuss your individual circumstances with your doctor.

Regularly check your blood sugar; write the results in a log book

This is important because your blood sugars can be dangerously high or low without your experiencing any symptoms. Persistently elevated sugars increase your risk of heart disease, stroke, blindness, kidney failure, and circulation and nerve problems in your feet.

Glucometers, the machines that test blood sugar levels, usually cost less than $100, and sometimes you can get one for free from a diabetes educator. But the test strips, which cost up to $1 each, can add up. Medicare and Medicaid and private insurance plans usually cover test strips and glucometers. If you lack insurance and can't afford to test your sugars every day, Kellie recommends checking at different times — one day before breakfast, another day before lunch or dinner and another day two hours after your largest carbohydrate meal. If you and a family member are trying to economize, it's OK to share a glucometer machine, but you should never share the lancets that you use to stick your fingers, since the blood could transmit disease.

The American College of Endocrinology recommends a blood sugar goal of 110 or less in the morning before eating and no more than 140 two hours after a meal. Kellie urges people to think of their sugars as "high," "low," or "target," not "good" or "bad." If your numbers are not at goal, it's important to remain calm and make sure your doctor knows. "Don't be afraid to go to the doctor because you're embarrassed," Kellie said. "We need the numbers to identify the problem. It's not about me being happy; it's about your sugar."

Learn to recognize high-glycemic index foods (which make your blood sugar rise quickly), and to read food labels

High-glycemic index foods include breads, cereals, fruit juices, pastas, refined rice, sugar-containing sodas and sweet desserts. Kellie advises people to shop mainly on the perimeter of the supermarket, where they're more likely to find fresh produce, meats and fish, and to avoid the center, where processed foods are usually stocked. Al said he always eats a meal before going to the grocery store, because if he's hungry he's more likely to buy impulsively.

If you lack insurance and need a place to go for primary care, the Needy Meds website (www.needymeds.org) lists clinics that are free or charge fees based on a sliding scale.

Product Recalls

June 22, 2010 - July 21, 2010

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

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is www.fda.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

MasXtreme Herbal Supplement for Men, Maximum Sexual Enhancement, Herbal Supplement for Men, 1 capsule per blister carton, 750 mg Proprietary Blend, UPC 0 94922 30080 5; Supplement Facts Serving Size: 1 Capsule Servings Per Container: 1 Amount per Capsule, Proprietary Blend: Chuchuhuasi (Bark), Maca (Root), Huanarpo Macho (Bark) (Jatropha macrantha), Catuaba (Bark), Evodia (Fruit) & Long Jack (Root) (Eurycoma longifolia) 750 mg. Volume of Product in Commerce: 202,176 capsules. Marketed Without an Approved NDA/ANDA: Product contains undeclared amounts of Ailedenafil, an analog of Sildenafil. Sildenafil is the active pharmaceutical ingredient in an FDA-approved drug that is used to treat erectile dysfunction (ED). Product also contains the drug Phentolamine, which is used to expand blood vessels to increase blood flow. Lot #: 911035. Natural Wellness, LLC.

STUD Capsule For Men, Herbal Supplement, packaged in blister packs containing 1 capsule, UPC 7 83259 00051 8 Supplement Facts Serving Size: 1 Capsule; Servings Per Container: 1. Rhodiola Rhizome Extract 65 mg, Lycium Fruit Extract 35 mg, Chinese Yam Rhizome Extract 40 mg, Cnidium Fruit Extract 20 mg, Poria Sclerotium Extract 25 mg, Tienchi Ginseng Extract 5 mg, Cistanche 45 mg. Other Ingredients: Cassia Extract, Asian Ginseng Extract, Rice Flour and Gelatin. Volume of Product in Commerce: 150,000 capsules. Made in The USA. Marketed Without an NDA/ANDA: product contains sildenafil (Viagra), the active ingredient in an FDA approved drug used in the treatment of erectile dysfunction, making the product an unapproved new drug. Lot # 060607-01 060108-01, exp. date 06/2013. Kanec USA, Inc.

Bodybuilding.com has recalled 48,890 bottles of 62 individual products that have been sold without an approved NDA/ANDA. Although they were marketed as dietary supplements, these products have been found to contain steroid or steroid-like substances, making them unapproved new drugs. All lots of the following products have been recalled: D-DROL capsules, D-Drol Complex; DIENE DRONE capsules; Liquid drone UTT anabolic suspension; HYPERDROL X2 capsules; MASTAVOL capsules; REVAMP capsules; ULTRA MASS STACK capsules; ULTRA RIPPED STACK capsules; Finadex capsules; STRAIGHT DROL capsules; STRAIGHT PHLEXED capsules; TESTRA FLEX capsules; METHYLDROSTANOLONE tablets; EPITREN capsules; Magna Drol capsules; Epivol capsules; Pheravol-V capsules; M-DROL capsules; P-PLEX capsules; X-TREN capsules; EPIO-PLEX capsules; FINABOLIC 50 capsules; REVENGE capsules; MethAnstane capsules; Susto-Test Depot capsules; ON CYCLE II HARDCORE capsules; SUS500 softgels; TREN-250 softgels; T-ROID capsules; 1,4 AD BOLD 200 capsules; 17a PheraFLEX capsules; DYMETHAZINE capsules; 2a,17a Methadrol capsules; BROMODROL tablets, Bromodrol Growth Complex; GROW TABS capsules; MASS TABS capsules; OXODROL PRO tablets; RIPPED TABS TR capsules; Massdrol capsules; Phera-Mass capsules; Trenadrol capsules; MONSTER CAPS capsules; Spawn capsules; D-STiANOZOL tablets; H-DROL tablets; MD1T capsules; Nutracoastal S-Drol tablets; TRENA tablets; 2a, 17a METHASTADROL capsules; TRI-METHYL X capsules; e-pol capsules; Nasty mass capsules; RAGE RV2 capsules; RAGE RV3 capsules; RAGE RV4 capsules; RAGE RV5 capsules; FINAFLEX 550-XD capsules; FINAFLEX RIPPED capsules; FORGED EXTREME MASS capsules; FORGED LEAN MASS capsules;RIPPED TABS TR tablets; IForce Dymethazine/Reversitol Combo Pack.

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

Glumetza, metformin hydrochloride, Extended Release Tablets, 500 mg, physician samples and 100 count bottles. Volume of Product in Commerce: 50,679 bottles/100 tablets per bottle. Chemical contamination; TBA (2,4,6 tribomoanisole). Multiple lots. Patheon Puerto Rico, Inc.

Ibudone (hydrocodone bitartrate and ibuprofen tablets), 5 mg/200 mg, 100 count bottles, Rx only. Volume of Product in Commerce: 6,372 units. Subpotent (Multiple Ingredient Drug): Below specification for the assay at the room temperature 3-month stability time-point for Ibuprofen and Hydrocodone Bitartrate. Lot # T036K09A, exp. date 11/2011. Vintage Pharmaceuticals LLC.

Isosorbide Mononitrate Extended-Release Tablets, 30 mg, Rx only, 100 and 1,000 count bottles. Volume of Product in Commerce: 28,543 bottles (100 count tablets); and 1,082 bottles (1,000 count tablets). Tablet Thickness; presence of thicker, overweight tablets due to presence of start-up waste in acceptable product. Lot #s: 0913001 (100) and 0913002 (1,000). Schwarz Pharma Manufacturing, Inc.

Liothyronine Sodium Tablets, USP 5 mcg, RX only, Net contents 100 tablets, NDC0574-0220-01, UPC code (01) 00305740220016. Volume of Product in Commerce: 11,064 bottles. The recall is being conducted due to a stability failure at the 12 month timepoint; the assay value of this lot was found to be sub-potent. Lot # 9C548. Metrics Inc.

Motrin IB (Ibuprofen) Caplets USP, 200mg, Pain Reliever/Fever Reducer (NSAID), 24 Coated Caplets. Volume of Product in Commerce: 555,696. Failed Dissolution Specification. Lot # SDA149, exp. date 10/2010. McNeil Healthcare, LLC.

Nifediac CC (Nifedipine) Extended Release Tables, 60 mg 100 count bottle, Rx only, NDC 0093-1022-01. Volume of Product in Commerce: 18,923 bottles. Does Not Meet Sustained Release Specifications: Active ingredient may release slightly faster than required by product release rate specification. Lot #s: 0804T28 exp. date 04/2010 and 0807T25 exp. date 05/2010. Biovail Pharmaceuticals.

Red Yeast Rice 0.4%, powder in 25kg cardboard drum. Volume of Product in Commerce: 5700 Kg. Product contains an unapproved new drug, marketed without an NDA/ANDA (contains higher than naturally occurring amounts of Lovastatin). All production lots and codes sold during the period of 01/2008 to 01/2010. Pacific Rainbow International Inc.

Spectrum Kanamycin Sulfate, USP, (Kanamycin Monosulfate), Catalog #K1390, Sizes: 25g, 100g & 6 x 100g bottles. Volume of Product in Commerce: 10,000g. Presence of foreign substance; trimethoprin detected. Lot #s: YI0763 (Mfr. Lot #: 90803) & YK0432 (Mfr. Lot #: 90803). Spectrum Chemicals and Laboratory Products.

Sertraline Hydrochloride Tablets, 100 mg, 1000 count bottles, Rx only, NDC 16714-613-06. Volume of Product in Commerce: 948 bottles. Adulterated Presence of Foreign Tablets: One foreign tablet of Zolpidem Tartrate Tablets, 10 mg, was found in a bottle of 100 count Sertraline HCL Tablets, 100 mg. Lot #: SR1009068-A, exp. date 07/2011. Aurobindo Pharma Limited.

Zolpidem Tartrate Tablets, 10 mg, CIV, 500 count bottle, Rx only, NDC 16714-622-02. Volume of Product in Commerce: 6,755 bottles. Tablet Thickness: oversize tablet was found in two lots of Zolpidem Tartrate, 10 mg, 500 count. Lot #s: ZT1009034-A, exp. date 07/2011; ZT1009036-A, exp. date 07/2011. Aurobindo Pharma Limited.

Ultram ER (tramadol HCl) Extended-Release Tablets, 100 mg, a) 30 count bottle, NDC 0062-0653-30, b) Physician samples 4 count blister pack, NDC 0062-0653-01, Rx only. Volume of Product in Commerce: 245,941 bottles; 368,760 physician samples. Does Not Meet Sustained Release Specifications: Certain lot numbers may release the active ingredient at a slightly faster rate than required by the products release specification at the 8 hour and 10 hour time points. a) Lot #s: P08H006, exp. date 06/2010; P08I008, exp. date 06/2010; P08I009, exp. date 06/2010; P08J012, exp. date 07/2010; P08J014, exp. date 07/2010; P08K017, exp. date 08/ 2010; P08K019, exp. date 08/2010; P09B017, exp. date 08/2010; P09B018, exp. date 08/2010; 09A006P, exp. date 11/2010; 09A007P, exp. date 11/2010; 09A008P, exp. date 11/2010; 09A013P, exp. date 11/2010; 09A014P, exp. date 11/2010; b) Lot #s: 9AA3276, exp. date 09/2010; 9AA3276P1, exp. date 09/2010. Ortho-McNeil Pharmaceutical, 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 Consumer Product Safety Commission, call its hotline at (800) 638-2772. The CPSC Web site 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

2009 Felt Model B12, B16 and S32 Road Bicycles. The bicycle's fork steer tube can break, causing the rider to lose control, fall and suffer injuries. Felt Bicycles, (866) 433-5887 or www.feltracing.com.

2009 Muddy Outdoors Tree Climbing Sticks. Bolts that secure the cam locks to the frame of these climbing sticks that retains the rope around the tree can break, allowing the cam locks to detach from the frame. This causes the retaining rope to detach and the climbing stick to release from the tree, posing a fall hazard to the user. Muddy Outdoors, (877) 366-8339 or www.gomuddy.com.

2010 Redline Conquest Cyclocross Bicycles and Framesets. The bicycle fork's legs can separate from the fork crown and cause the rider to lose control, posing a fall hazard and risk of injury. Seattle Bike Supply, (800) 283-2453 or www.redlinebicycles.com.

Baby Walkers. The recalled walkers can fit through a standard doorway and fail to have sufficient stair-fall protection to prevent falls down stairs. Babies using these walkers can be seriously i njured or killed if they fall down stairs. Suntech Enterprises Inc., (888) 268-8139.

Baja Motorsports Mini Bikes and Go-Carts. The gas cap can leak or detach from the fuel tank on the recalled mini bikes and go-carts, posing a fire and burn hazard to consumers. In addition, the throttle can stick due to an improperly positioned fuel line and throttle cable, posing a sudden acceleration hazard to consumers. Baja Inc., d/b/a Baja Motorsports, (888) 863-2252 or www.bajamotorsports.net.

Bamboo Torches. The fuel canister that holds the wick of the torch has a sharp edge inside the lip of the opening that poses a laceration hazard when consumers try to remove the wick. Atico International USA Inc., (866) 448-7856 or www.aticousa.com.

Bonavita, Babi Italia and ISSI Drop-Side Cribs. The cribs' drop sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop-side incidents can also occur due to incorrect assembly and with age-related wear and tear. LaJobi Inc., (888) 738-5676 or www.lajobi.com.

Child Craft Brand Drop-Side Cribs. The drop-side hardware can fail, causing the drop-side to detach from the crib or fall to the dropped position. When the drop side detaches, even partially, it creates a space in which an infant or toddler can become entrapped and suffocate or strangle. Drop side incidents can also occur due to incorrect assembly and with age related wear and tear. Additionally, when drop-side hardware fails and/or disengages, an infant or toddler can be injured by falling out of the crib. Child Craft Industries, Inc., (866) 614-0557 or www.cribsafetyinfo.com.

Children's Coin Purse and Jewelry. The surface paint on the zippers of the coin purses and the clasps on the jewelry contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Daiso California LLC, (888) 580-8841 or www.daisorecall.com.

Children's Happy Charm Bracelets and Football Rings. The metal substrate in the jewelry contains high levels of cadmium. Cadmium is toxic if ingested by young children and can cause adverse health effects. SmileMakers Inc., (877) 390-5470 or www.smilemakers.com.

Dayton Electric Baseboard Heaters. The baseboard heaters are labeled for 240 or 208 volt use. However, some of the heaters have an internal heater built for a maximum of 120 volts. If the heater is connected to a 240 or 208 volt electrical circuit as directed, the unit could catch fire. Marley Engineered Products LLC, (800) 642-4328 or www.marleymep.com.

Delta Cribs. Drop-Side Hazard: The cribs' drop sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Incidents can also occur due to incorrect assembly and with age-related wear and tear. Mattress Support Hazard: In addition, the wooden stabilizer bars on some Delta drop-side and fixed-side cribs can be installed upside down, which puts extra stress on the crib and can cause the mattress platform to collapse, creating a gap in which an infant or toddler can become entrapped and posing a risk of strangulation or suffocation. Delta Enterprise, (877) 342-3418 or www.cribrecallcenter.com.

Drop-Side Cribs Sold Under the Brand Names Million Dollar Baby, Baby Mod and Da Vinci. The cribs' drop-sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop side incidents can also occur due to incorrect assembly and with age-related wear and tear. Bexco Enterprises, Inc., d.b.a. Million Dollar Baby of Montebello, (888) 673-6488 or www.themdbfamily.com/safety.

Eastside Fix Bicycle Forks. The bicycle's front fork can crack or break, causing a sudden loss of steering control and posing a fall hazard to bicyclists. Campus Cruisers LLC, (877) 260-2721 or www.campuscruisers.com.

External Laptop Battery. The battery cell can short-circuit and overheat, posing a fire hazard to consumers. Tekkeon Inc., (888) 787-5888 or http://www.tekkeon.com/recall.

Jardine Drop-Side Cribs. The cribs' drop sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop-side incidents can also occur due to incorrect assembly and with age-related wear and tear. Jardine Enterprise Ltd., (800) 295-1980 or www.jdservice.biz.

Jenny Lind Cribs. The cribs' drop sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop-side incidents can also occur due to incorrect assembly and with age-related wear and tear. Evenflo Inc., (800) 356-2229 or http://safety.evenflo.com.

CONSUMER PRODUCTS

Kariño Baby Pacifiers. The pacifier fails to meet federal safety standards. The nipple can separate from the base easily, the pacifier handle is too long, the mouth guard is too small and there are no ventilation holes on the mouth guard. The pacifier could pose a choking and aspiration hazard to young children. Antonio Flores, (619) 395-4543.

Metal Necklaces, Bracelets and Earrings. The children's metal jewelry contains high levels of cadmium. Cadmium is toxic if ingested by children and can cause adverse health effects. Tween Brands Inc., (800) 934-4497 or www.shopjustice.com.

Pottery Barn Kids Drop-Side Cribs. The cribs' drop-sides can detach when hardware breaks, creating space into which a child can become entrapped, which can lead to suffocation. A child can also fall out of the crib. Drop side incidents also occur due to incorrect assembly and age-related wear and tear. Pottery Barn Kids, a division of Williams-Sonoma, Inc., (877) 804-3877 or www.potterybarnkids.com.

Power Adapters for Heated Pet Beds. When the metal connector is removed from the bed, it can cause arcing between the coil spring and the connector, posing a fire and burn hazard to consumers. Radio Systems Corporation, (800) 732-2677 or www.petsafe.net.

Power Clear 180 Single Stage Snow Blowers. Exposure to ethanol in gasoline can cause the carburetor needle to become corroded. A corroded needle can stick in the open position and allow fuel to leak from the carburetor, posing a fire hazard to consumers. The Toro Company, (877) 738-4440 or www.toro.com.

Power Inflator. The oral inflator button is not properly bonded to the oral stem and can fall off during use, posing a leak of the buoyancy compensator contents. This poses a drowning hazard. Aqua Lung America, (877) 253-3483 or www.aqualung.com.

Powertec Drill Presses. Wires in the motor housing can be pinched, posing a risk of electrical shock to the consumer. Southern Technologies, (877) 393-7121 or www.southerntechllc.com.

Salomon "Quest Touring Pads" and Salomon "Quest Pro Pebax" and "Quest Pro" Touring-Style Ski Boots. The toe portion of the boot pad may unexpectedly release from the touring-style ski binding on a ski, posing a fall or injury hazard to the user. Salomon USA, (877) 789-5111 or www.salomon.com.

Scope® Original Mint Mouthwash, 1 Liter Size. The mouthwash contains ethyl alcohol and certain bottles have malfunctioning child-resistant closures. Ethyl alcohol is toxic and can cause serious injury or death if ingested by children. The Procter & Gamble Co., (877) 340-8825 or www.scopemouthwash.com.

Simmons Drop-Side Cribs. The cribs' drop sides can malfunction, detach or otherwise fail, causing part of the drop side to fall out of position, creating a space into which an infant or toddler can roll and become wedged, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop-side incidents can also occur due to incorrect assembly and with age-related wear and tear. Simmons Juvenile Products, (877) 342-3439 or www.cribrecallcenter.com.

Sony VAIO Notebook Computers. The computers can overheat, posing a burn hazard to the consumer. Sony Electronics Inc., (866) 496-7669 or http://esupport.sony.com/US/f1cw2update.

Super Lightning Rockets. The rockets are overloaded with pyrotechnic composition, violating the federal regulatory standard for this product. This could result in a greater than expected explosion, posing a risk of burns and bodily harm to nearby consumers. Big Fireworks, (866) 514-6225 or www.bigfireworks.com.

Suzuki QuadSport ATVs. The flame arrester screen can become detached from its mounting ring, preventing the throttle valve from returning to the idle position when the throttle lever is released and causing the rider to lose control of the ATV. This poses a serious hazard of injury or death. American Suzuki Motor Corp., (800) 444-5077 or www.suzukicycles.com.

Television Sets. A capacitor on the television's power supply board can fail, posing a fire hazard. (800) 992-7734 or www.pdiarm.com.

Whitco Company LP Poles 70 Feet Tall or Higher. The poles can fracture or crack and fall over, posing a risk of serious injury or death to patrons and bystanders from being hit or crushed. The poles range from 1 to 4 tons increasing the risk of death if the pole falls toward a crowded stadium or onto a building. Whitco Company LP, (800) 638-2772 or info@cpsc.gov.

Wire Feed Welders. The wire welder's torch does not have a cold contactor as erroneously stated on the packaging and instruction manual. Without this feature, the welder generates an electrical arc immediately upon contact with the welding material, posing a burn hazard to consumers. Star Asia USA, LLC, (800) 386-0191.

Women's Bathrobes. The bathrobes fail to meet the federal flammability standard for clothing textiles and pose a risk of burn injury. Christy, (800) 261-6326 or www.bloomingdales.com.

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PUBLICCITIZEN Health Letter

Outrage! Don't Get Sick in July

For those of you who are planning to go to the hospital for diagnosis or treatment but have not yet gone, breathe more easily, now that July is over.

A study just published in the *Journal of General Internal Medicine* (JGIM) examined death certificates of 244,000 people who had died in the U.S. between 1979 and 2006 because of medication errors. The authors found that inside medical institutions such as hospitals, in counties containing teaching hospitals, fatal medication errors spiked significantly, over what was expected, by 10 percent in July and in no other month. In contrast, there was no July spike in counties without teaching hospitals. These findings held only for medication errors, not for other causes of death such as surgical errors.

Why is this happening? Each July more than ten thousand new doctors begin medical residencies in teaching hospitals, thereby having more responsibility for treating patients. Although it has been suggested for a long time that these new medical residents may make more mistakes resulting in worse patient outcomes, often referred to as the "July Effect," there has previously been no U.S. evidence documenting this.

In an accompanying editorial, JGIM Co-Editor Dr. Richard Kravitz wrote:

The accumulated evidence on the "July spike" is probably convincing enough to prompt action: for example, having attendings or senior residents "in house" during extended hours, conducting rounds twice a day (as pediatrics has done for decades), or just making sure adequate help is available at the point of care. Academic general internal medicine doesn't shut down during the dog days of summer. Our resolve to improve the quality of hospital care shouldn't shut down either.

We couldn't agree more! ✦