PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR APRIL 2011 – VOL. 27, No. 4

Experts Who Write Highly Influential Clinical Practice Guidelines Have Significant Conflicts of Interest

A research study published in the March 28, 2011, issue of the *Archives of Internal Medicine* revealed that the majority of the medical experts involved in the development of highly influential clinical practice guidelines for the prevention and treatment of heart disease and strokes had significant conflicts of interest involving financial and professional relationships with drug and device companies. The findings of this important study reaffirm our long-standing concerns that guidelines regarding the management and treatment of patients — rather than being based solely on an objective analysis of the available research data in the medical literature — are tainted by bias due to the inappropriate influence of the drug and device industry.

Why are clinical practice guidelines important and how are they developed?

For many medical conditions, physicians base their decisions and recommendations regarding diagnostic testing and treatment on standard rules called clinical practice guidelines. These guidelines, which are taught in medical schools, residency training programs and continuing medical education courses, routinely play a significant role in doctors' decisions regarding what medical tests should be ordered, when and what drugs should be prescribed, and when surgery should be performed.

Because these guidelines typically are adopted widely across the medical profession, they can have a huge impact on medical care, as well as on the sale and use of prescription drugs and medical devices.

Clinical practice guidelines usually are developed by panels of medical experts convened by medical specialty and disease advocacy organizations. For example, many important guidelines regarding the prevention, diagnosis and treatment of heart disease and strokes are developed by experts on advisory panels set up by the American College of Cardiology and the American Heart Association. All too often, the experts appointed to these panels have close professional and financial ties to drug and device companies that have a direct interest in the recommendations made in the guidelines.

Key results of the recent Archives of Internal Medicine study

In their study in the *Archives of Internal Medicine*, Dr. Todd Mendelson and his co-authors from the University of Pennsylvania School of Medicine, the Thomas Jefferson University Department of Medicine, and Harvard Medical School looked at the conflicts of interests reported by experts who served on 17 panels that wrote the most recently issued clinical practice guidelines from the American College of Cardiology and the American Heart Association. These guidelines provided recommendations for the prevention and/or treatment of atrial fibrillation (a type of heart arrhythmia), congestive heart failure, heart attacks, valvular heart disease and stroke.

They found that, overall, a total of 277 of 498 experts (56 percent) who served on these panels had reported one or more financial conflicts of interest involving drug and device companies. Moreover, 81 percent of the individuals who served as panel chairs or co-chairs or as first authors for the guidelines reported one or more conflicts of interest. This latter finding is particularly important because panel chairs and first authors have significant say in the final content of the clinical practice guidelines being developed by the panel.

The types of conflicts of interest for these panel experts included serving as a paid consultant or member of an advisory board to a drug or device company, receiving a research grant or speaking honoraria from a company, or holding stock or other ownership in a company.

A common refrain offered by individuals who defend the inclusion of experts having conflicts of interest on panels charged with developing clinical practice guidelines is that it is difficult to identify experts without conflicts of

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Many Patients Undergo Unnecessary Invasive Cardiac Procedures

Modern-day cardiology offers a variety of advanced medical technologies and procedures for the diagnosis and treatment of patients with heart disease. Among the most common invasive cardiac procedures today are cardiac catheterization with coronary angiography, which is used to definitively diagnose narrowed or blocked heart arteries (known as coronary artery disease), and percutaneous coronary interventions, such as coronary artery balloon angioplasty and stent placement procedures, which are used to mechanically open narrowed or blocked coronary arteries.

About one-third of the patients were found to have clinically significant blockages in their coronary arteries, which is dramatically lower than the 70 to 90 percent undergoing elective cardiac catheterizations in the 1990s found to have significant obstruction of their coronary arteries.

While these procedures have led to remarkable improvements in the care of heart disease, such procedures also involve significant risk of harm to patients. They are also very expensive. Therefore, use of these invasive cardiac procedures should be limited to those patients who have a reasonable chance of receiving significant clinical benefits from the procedures.

However, the results of two recent research studies, one published in the *New England Journal of Medicine* and the second in the *Annals of Internal Medicine*, raise concern that a significant number of patients are undergoing unnecessary cardiac catheterization and percutaneous coronary intervention procedures. As a result, patients are being exposed to the significant risks of these procedures without a reasonable probability of offsetting benefits, and substantial amounts of health care dollars are being wasted. For many years, Public Citizen has raised concerns about unnecessary heart procedures.

Too many elective coronary angiography procedures

Cardiac catheterization with coronary angiography is a diagnostic procedure that involves inserting a long, thin tube called a catheter into an artery in the leg or arm and moving the tip of the catheter up to the ascending aorta, the large artery that comes directly out of the left side of the heart. A contrast agent that will show up on X-rays is then injected from the tip of this catheter into the coronary arteries, which originate from the ascending aorta and provide the blood supply to the heart itself. Pictures are then taken of the coronary arteries using X-rays to identify blockages in these arteries.

Patients are referred for this procedure for a variety of justified reasons including evidence of an acute myocardial infarction (commonly referred to as a heart attack) angina (chest pain or pressure due to inadequate blood flow to the heart) and new onset congestive heart failure.

In their study in the March 11, 2010, *New England Journal of Medicine*, Dr. Manesh Patel and his co-authors from the Duke Clinical Research Institute, the University of California at San Francisco and the University of Texas Health Science Center carefully analyzed data on a total of 398,978 patients from 663 hospitals who had no prior known history of coronary artery disease and underwent elective cardiac catheterization with coronary angiography between January 2004 and April 2008.

A key finding from this study was that only about one-third (37.6 percent) of

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the patients were found to have clinically significant blockages in their coronary arteries. This percentage is dramatically lower than the 70 to 90 percent of patients undergoing elective cardiac catheterizations in the 1990s who were found to have significant obstruction of their coronary arteries. The implication is that far more unnecessary coronary angiography studies are being done now than in the 1990s.

A second key finding of this study was that 30 percent of patients had no symptoms, including angina, at the time they underwent cardiac catheterization and angiography. This result is particularly important because, as Patel and his co-authors note, research has shown that main benefits of angiography and subsequent invasive percutaneous coronary interventions, such as angioplasty or stent placement, or cardiac bypass surgery are for symptomatic patients found to have obstructed coronary arteries during angiography. Asymptomatic patients, even if found to have obstructed coronary arteries, are less likely to benefit from subsequent percutaneous coronary interventions or bypass surgery.

These study results indicate that a significant number of patients are probably undergoing cardiac catheterization unnecessarily. Patel and his co-authors conclude that better strategies are needed to identify those patients who are most at risk for coronary artery disease and therefore most likely to benefit from undergoing cardiac catheterization. In particular, they believe that the threshold for performing an elective cardiac catheterization with coronary angiography may need to be higher in asymptomatic patients.

Too many percutaneous coronary interventions

At many hospitals, patients who are scheduled for a cardiac catheterization routinely are asked to provide consent to undergo a percutaneous coronary intervention, such as angioplasty or stent placement, on the same day and as part of the same procedure, in the event a treatable obstructed coronary artery is identified on the cardiac catheterization. Thus, once a decision is made to perform a diagnostic cardiac catheterization, it opens the door to another potentially unnecessary invasive cardiac procedure. Indeed, many cardiologists believe that narrowed coronary arteries, once identified, should be opened if the procedure is technically feasible and low-risk.

For patients found to have clinically significant blockage in the coronary arteries, a variety of treatment options are available. These treatment options include drug therapy, percutaneous coronary intervention procedures and coronary artery bypass surgery. Selecting the appropriate treatment option depends on the degree and location of the blockage, the symptoms of the patient and a determination of whether the patient, is stable or unstable (e.g., presenting with unstable angina or an acute myocardial infarction).

An important study published in 2007, known as the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Treatment) trial, showed that there was no difference between optimal drug therapy and percutaneous coronary intervention for preventing heart attacks or death in patients who have stable coronary artery disease. The COURAGE study did show that percutaneous coronary interventions were more successful than optimal drug therapy in decreasing angina symptoms in such patients.

In a Sept. 7, 2010, article published in the *Annals of Internal Medicine*, Dr. Michael Rothberg and his co-authors from the Baystate Medical Center in Springfield, Mass., and the Tufts Medical Center in Boston provided data indicating that patients with stable coronary artery disease who are offered percutaneous coronary interventions frequently have significant misunderstandings about the actual benefits of these interventions. This study, conducted at Baystate Medical Center, involved asking 153 patients with stable coronary artery disease who consented to elective coronary catheterization and possible percutaneous coronary interventions about their beliefs regarding the benefits of these interventions.

The study found that 88 percent of the 153 patients incorrectly believed that percutaneous coronary intervention would reduce their risk of a myocardial infarction and 82 percent mistakenly thought it would reduce their risk of a fatal myocardial infarction. These results suggest that by overestimating the benefits of percutaneous coronary interventions when their informed consent is sought, many patients may agree to undergo such interventions when they otherwise would not consent if they had an accurate understanding of the benefits.

The practice of asking patients to consent to undergo a percutaneous coronary intervention procedure on the same day on which they are scheduled for a cardiac catheterization likely contributes to a lack of adequate informed consent by patients. Such a consent process generally does not allow for sufficient time to have meaningful doctor-patient discussion about the results of the cardiac catheterization and the likelihood of any benefits from percutaneous cardiac intervention given those individual results.

In conclusion, cardiologists need to ensure that patients selected to undergo cardiac catheterization and percutaneous coronary interventions are appropriately selected so that the potential benefits are justified by the likelihood of benefits. Furthermore, cardiologists must take additional steps to ensure that patients are informed about, and adequately understand, the indications for cardiac catheterization and percutaneous cardiac interventions, the expected benefits and risks of these procedures, and the complete range of treatment options — including drug treatment — that may be appropriate depending on individual patient characteristics, the results of the cardiac catheterization and the goals of treatment. ✦

10 Best Funded and 10 Worst Funded States in Providing Government Health Insurance Assistance

Where People Live Has Big Impact on Government Health Coverage Received — California, Arizona and Georgia Ranked Least Generous

The following article is from the Foundation for Health Coverage Education (FHCE), a non-profit organization based in San Jose, California. It complements and updates a study we did entitled "Unsettling Scores, A Ranking of State Medicaid Programs," published in 2007 and available at: http://www.citizen.org/medicaid.

Although debate continues in regard to the federal government taking on a stronger role in health coverage, Americans who need help paying for gap health care coverage — due to unemployment or inability to afford private insurance — should be aware that Medicaid, the well-known government health insurance assistance program, has varying covered services, eligibility requirements and funding levels depending on the state, according to the Foundation for Health Coverage Education (FHCE) www.CoverageForAll.org.

"With 1 in 5 Americans on Medicaid at any given time, it's important to understand that the state where you live has a big impact on if and when assistance will be available if you need it," said Phil Lebherz, FHCE founder and executive director.

The FHCE, a nonprofit organization with a mission to educate Americans about available public and private coverage options, has ranked the states to show how Medicaid differs from state to state. The data is provided by the Kaiser Family Foundation whose website's database at www.statehealthfacts.org includes extensive financial information on the expenditures per Medicaid enrollee of the 50 states and the District of Columbia. From this listing, the FHCE has culled out the 10 highest-funded and the 10 least-funded state Medicaid programs.

Table 1. The 10 states with the highest Medicaid enrollee funding are as follows:

State	Medicaid Enrollees*	Medicaid Payment Per Enrollee*	Total Federal Medicaid Payment**
1. Rhode Island	195,400	$8,796	$1,834,227,212
2. New York	4,954,600	$8,450	$47,618,463,035
3. District of Columbia	164,900	$7,932	$1,445,734,028
4. Alaska	120,800	$7,815	$890,169,313
5. New Jersey	954,000	$7,814	$9,425,126,545
6. Minnesota	785,600	$7,700	$6,977,657,315
7. Massachusetts	1,402,500	$7,490	$10,821,588,261
8. Connecticut	530,300	$7,357	$4,543,549,844
9. North Dakota	69,400	$7,288	$534,431,274
10. Pennsylvania	2,090,200	$7,159	$16,299,966,377

Table 2. The 10 states with the least Medicaid enrollee funding are as follows:

State	Medicaid Enrollees*	Medicaid Payment Per Enrollee*	Total Federal Medicaid Payment**
1. California	10,511,100	$2,701	$38,747,885,430
2. Arizona	1,455,800	$3,066	$7,506,329,319
3. Georgia	1,685,000	$3,560	$7,337,801,478
4. Oklahoma	719,200	$3,571	$3,538,913,312
5. Texas	4,170,100	$3,598	$21,461,296,293
6. Arkansas	692,300	$3,617	$3,287,326,144
7. Louisiana	1,096,500	$3,823	$6,067,665,948
8. Hawaii	216,600	$4,051	$1,206,716,133
9. South Carolina	891,600	$4,260	$4,436,586,247
10. Michigan	1,855,500	$4,348	$9,846,978,779

**Kaiser State Health Facts Medicaid Payment Per Enrollee 2007*
***Kaiser State Health Facts Total Federal Medicaid Payment 2008*

"How well a state funds its own programs and how much matching funding it receives from the federal government determines the number of physicians willing to treat Medicaid patients, the ability of hospital emergency rooms to stay open, and the waiting periods Americans must endure when enrolling. There's a direct link between how a state is funded and the quality of its overall health care delivery system," said Lebherz.

"What's surprising is that states like California, as an example, with the highest cost of living, actually spend and receive the least funding from the federal government for Medicaid at $2,701 total funding per enrollee per year," said Lebherz. "Meanwhile, states where the cost of living is much lower, such as Rhode Island and North Dakota, provide two to three times that amount, at $8,796 and $7,288 respectively per enrollee. When Medicaid falls short of paying health care providers what

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The Few, The Proud, The Thin

The following article, by Martha Rosenberg, originally appeared on OpEdNews.com. It has been reprinted with permission.

Creeping obesity illustration by Martha Rosenberg

In a report released last fall by the Organization for Economic Co-Operation and Development (OECD), the United States is the fattest of 33 countries. Mexico and New Zealand are next runners up with India and Indonesia the thinnest.

Luckily the report didn't break U.S. obesity down state by state or we'd have further shame.

Seventy percent of Americans are now overweight, says the report, a number which will balloon into 75 percent by 2020, pun intended. And ten years after that? By 2030, 86 percent of Americans could be overweight, says an article in the journal *Obesity*.

Food researchers indict the couch and mouse lifestyle with its ubiquitous commercials for high-cal foods for expanding haunches, especially in kids. After all, it's been decades since moms locked kids outside with a bottle of water and the instructions "don't come back until dinner." Nor did kids have [cell phones]. One grandmother says she took the grandkids to the seashore only to find they wouldn't leave the motel room because of their electronic priorities. But the demise of the family dinner is also a factor, says the *Star-Tribune* [of Minnesota]. Structured, please-pass-the-peas family meals — anybody remember? — gave a sense of safety and security to children at the same time they modeled normal eating. When someone's dinner date is the TV, they often scarf and scarf the wrong food because they lose track or no one is watching.

In fact, the National Center on Addiction and Substance Abuse found that substance abuse itself is lower in families that eat together three times a week, food being many people's preferred substance.

Of course there are other reasons for the national glut.

Food deserts (not "desserts," though related) make it hard for people to stay thin. A 2010 study by the University of California, Berkeley and Columbia University found 9th graders whose schools are close to fast food restaurants are fatter. And *The New York Times* found that both adults and children who ride public transit are thinner. "Walk a lot but not to Wendy's" seems to be the message.

Size inflation also contributes to obesity — and its denial. Women's size fives are now size zeros and stretchy leggings always "fit." And how about hip hop looks that aren't supposed to fit anyway?

There are also more food [opportunities] today with snacks available in banks, bookstores, body shops and hospitals and of course many eating more as they try to quit smoking. At least they get to be indoors. ✦

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they need in order to keep their doors open, providers have to charge private patients more and this impacts everyone in that state."

Launched in 2004, FHCE's website, CoverageForAll.org, is America's first public health insurance search engine, helping over two million Americans discover their free and low-cost public and private health insurance options. Every month an average of 80,000 people visit the website, download FHCE's free iPhone application, Got Coverage, or call the toll-free 24/7 multilingual U.S. Uninsured Help Line (800-234-1317) to take the simple 5 Question Eligibility Quiz that connects them with a personalized list of public and private health coverage options.

The Foundation for Health Coverage Education (FHCE) is a nonprofit 501(c)3 public organization based in San Jose, California. For the latest information regarding health care reform changes, including information for people with private health insurance, coverage for those 64 and under, or changes to small businesses, please visit www.CoverageForAll.org. In addition to its website and toll-free 24/7 U.S. Uninsured Help Line (800) 234-1317, FHCE offers free resources and guides, such as the Health Care Options Matrix™, which is customized for all 50 states. ✦

Inadequate NJBME Action Against Physicians Disciplined by Hospitals

The following is excerpted from a testimony given on April 11 of this year by Sidney M. Wolfe, M.D., before the New Jersey Senate Health, Human Services and Senior Citizens Committee at its hearing on disciplinary actions by the New Jersey Board of Medical Examiners (NJBME).

Too many hospitals are, unfortunately, reluctant to discipline physicians even when such action is merited. As of three years ago, according to data from the federal National Practitioner Data Bank (NPDB), a repository of all state disciplinary actions, hospital actions and malpractice payouts against physicians, barely over one-half of American hospitals had taken even a single action against physicians with admitting privileges at that hospital at any time during the almost 20 years that the NPDB had been in operation (since Sept. 1, 1990).

Of an estimated 900,000 or more physicians who have practiced in the U.S. at some time between 1990 until 2009, only 10,672 — barely more than one percent — have ever had a hospital action reported to the NPDB. Thus, when hospitals finally do take action against physicians, the basis for the action and the type of action are usually quite serious.

Based on our analysis of the public use file from the NPDB, during the past 19+ years, from Sept. 1, 1990, through the end of 2009, New Jersey hospitals have taken disciplinary actions against 320 New Jersey physicians. Although 43 percent of them have also had a disciplinary action by the NJBME, 57 percent — 183 — have never had any board disciplinary action despite the seriousness of what they were found to have done and the usually serious actions meted out against them by New Jersey hospitals.

- 129 of these 183 physicians had one hospital action, 39 had two actions and the remaining 15 physicians had between three and eight actions against them— but none had a licensure action.
- Of 183 physicians with New Jersey hospital actions but no NJBME actions, 97 — more than one-half — had the most serious kinds of hospital actions, either terminating or restricting their admitting privileges permanently or for one year or more.
- For 41 of these 97 physicians, the code stating the reasons for these serious hospital actions was "other, non-specified" and we could therefore not determine the precise reason for the hospital action. For the 56 physicians for whom this information was given, the reasons stated by the hospital were as follows:

- 29 physicians: unable to practice safely, incompetence, negligence, or substandard/inadequate care or skill level
- 17 physicians: unprofessional conduct
- 2 physicians: fraud
- 1 physician: criminal conviction

Thus, 49 of the 56 physicians (88%), for whom information was available about the exact cause of these serious hospital actions, were disciplined by the hospitals because of serious problems, which in almost all cases would adversely affect patient care. As a result, hospitals terminated or restricted their admitting privileges permanently or for one year or more. Yet, as mentioned at the outset, none of these physicians has ever been disciplined in any way by the NJBME.

Examples of four New Jersey physicians with hospital actions but no board actions include the following (their identities and those of the hospitals have been deleted in the NPDB public use file):

New Jersey physician 165597

In 2004, this physician had two different hospital actions, each resulting in a one-year restriction on admitting privileges. One was for substandard or inadequate skill level, the other for substandard or inadequate level of care. In 2006 and again in 2008 there were large malpractice payments made against the physician for $970,000 and $940,000 respectively. The reasons were both surgery-related, the first due to the failure to order the appropriate test, the second, because of improper performance of surgery, each resulting in "significant permanent injury" to the two patients involved.

New Jersey physician 210390

In 2009, a New Jersey hospital permanently revoked this physician's admitting privileges for a reason listed as "other" in the public use file of the NPDB. Between 2004 and 2006, there were eight malpractice payments made against this physician totaling $2.7 million. The reasons for the payouts, seven surgery-related, one treatment related, included: four instances of improper performance, one delay in treatment and failure to recognize complication, one failure to obtain informed consent or lack of consent, and one instance of improper management, the patient in this case suffering significant permanent injury.

As the medical board saw this avalanche of eight malpractice payouts against their licensed physician, why did it take no action? The hospital finally did.

New Jersey physician 212829

In 2004, this physician surrendered admitting privileges at a New Jersey

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hospital for reasons not specified. Between 2006 and 2007, there were three malpractice payouts against this physician totaling $190,000 for improper conduct and failure to recognize a surgical complication, resulting in the death of a patient, improper performance of surgery and failure to obtain informed consent or a lack of informed consent. Again, why was the strong signal of a physician surrendering admitting privileges, combined with several subsequent malpractice payouts, not enough to activate the board to take some kind of action?

New Jersey physician 55701

This physician had two clinical privilege reports, one in 1994 (denial of privileges) and one in 1999 (suspension of privileges); both for an indefinite penalty length. The 1999 action was for incompetence. This practitioner also had seven medical malpractice reports totaling $1.3 million for the period 1996-2007. The reasons for the malpractice payouts included: three cases of improper performance (surgery-related), one case of improper technique (surgery-related) and a case of wrong diagnosis. Two patients had significant permanent injuries.

Of an estimated 900,000 or more physicians who have practiced in the U.S. at some time between 1990 until 2009, only 10,672 — barely more than one percent — have ever had a hospital action reported to the NPDB. Thus, when hospitals finally do take action against physicians, the basis for the action and the type of action are usually quite serious.

In summary, the NJBME has failed to take any action, even placing these physicians on probation, against a large number of its licensed physicians who have been found by New Jersey hospitals to have been unable to practice safely, to have exhibited incompetence, negligence, or substandard/inadequate care or skill levels, or to have engaged in professional misconduct.

Perhaps as important as any means of improving board function, in New Jersey or any other state, is ongoing oversight by committees such as yours. There are many recent examples, such as in Arizona, North Carolina and the District of Columbia, wherein serious oversight hearings by state legislature committees resulted in actions, such as increased funding, that led to rapid and dramatic effects on the performance of those boards. ✦

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interest. However, Mendelson's study identified a total of 221 of 498 experts (44 percent) who reported having no conflict of interest, thus demonstrating that it should be possible to create panels composed only of experts who do not have conflicts of interest.

A case example: guidelines for chronic congestive heart failure

In 2005, the American College of Cardiology and the American Heart Association issued updated guidelines on the diagnosis and management of chronic heart failure in adults.

Of the 15 experts appointed to the committee that updated these guidelines, 11 experts (73 percent) had financial ties to one or more drug and device companies, many of which had an interest in the final recommendations made in the guidelines (one expert had ties to 18 companies).

For example, these guidelines included recommendations for using a class of medicines called angiotensin receptor blockers. Eight experts on the panel that wrote the guidelines had ties to one or more drug companies that make angiotensin receptor blockers. While there are studies suggesting that these drugs may be useful for treating congestive heart failure, the fact that a majority of the experts had ties to drug companies that benefited from the recommendations to use these drugs raises suspicion that the process for developing the guidelines was tainted by bias.

The process for writing clinical practice guidelines must be reformed

In a commentary that accompanied the article by Mendelson and his colleagues, Dr. Steven Nissen, a cardiologist at the Cleveland Clinic, clearly explained why the process for developing clinical practice guidelines must be reformed to exclude experts with ties to industry:

> ...Mendelson et al raise disturbing questions about the independence and reliability of [clinical practice guidelines] in cardiovascular medicine. ... The depth and breadth of industry relationships reported in this article is extraordinary. Unexpectedly, financial ties between companies and [the clinical practice guideline] authors include relationships extending far beyond scientific collaboration ... To allow such individuals to write [clinical practice guidelines] defies logic. ... If we fail as a profession to police our [clinical practice guideline] process, the credibility of evidence-based medicine will suffer irreparable harm.

We agree! ✦

Product Recalls

March 23, 2011 – April 14, 2011

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

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

DURO EXTEND capsules, 500mg; 1-count blisters displayed in 12-count and 24-count trays; 3-count bottles; and 10-count bottles. Volume of product in commerce: 1,066,020 capsules. Marketed Without an Approved NDA/ANDA: Laboratory analysis of this product found the presence of sulfoaildenafil an analogue of sildenafil which is an FDA approved drug used in the treatment of male erectile dysfunction making DURO EXTEND an unapproved new drug. Lot #s: All lots, exp. dates 03/11 to 06/12. Metaugus Inc.

Reversitol Dietary Supplement Capsules, 624mg, 60 capsules/bottle. Volume of product in commerce: 29,758 bottles. Marketed Without an Approved NDA/ANDA; product contains 6-Etioallochol-1, 4-Diene-3, 17-Dione which is a synonym of ATD. ATD is classified as an aromatase inhibitor. Lot #s: All lot/codes mfr through 12/09. Tribravus Enterprises, LLC.

REVIVEXXX Herbal Supplement, Extra Strength Sexual Enhancer for Men, sublingual (under tongue), 1 tablet. Volume of product in commerce: 3,864 blister packs. Marketed Without an Approved NDA/ANDA: Product found to contain undeclared tadalafil. Tadalafil is an FDA-approved drug for the treatment of male Erectile Dysfunction (ED), making REVIVEXXX an unapproved drug. Lots #s: All lots, exp. dates including and prior to August 2013. Changsha Foreign Economic Relations and Trade Corp. and Velocity Pharma LLC.

Rock Hard Extreme and Passion Coffee Capsules Dietary Supplement, 1-count blister pack and 10-count bottle; single packets. Volume of product in commerce: 3749 (3446 blister packs, 14 x 10 ea bottles, 93 packets, 7 x 10 packs). Marketed Without an Approved NDA/ANDA: product found to contain sulfoaildenafil, an analogue of sildenafil, an FDA-approved drug used in the treatment of male Erectile Dysfunction (ED), making this product an unapproved new drug. Lots #s: 1152010, exp. date: 01/13; UPC only. Colman Botanicals, 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

Arthrotec 75, 75 mg/200 mcg, 60-tablet count bottle, Rx only. Volume of product in commerce: 138,608 bottles. Tablet Separation: Recalled lots may contain broken tablets. Lot #s: C091403, exp. date: 06/13; C091600, exp date: 07/13. Pfizer Us Pharmaceutical Group.

Carbamazepine Tablets, 200mg; 100 Unit-dose Tablets (10x10s); and individual blister pack, Rx only. Volume of product in commerce: 16,869 units. Failed USP Dissolution Test Requirements: may not meet dissolution specifications over product shelf life. Lots #s: 092246A, exp. date: 2/11; 092571A, exp. date: 4/11; 092926A, exp. date: 5/11; 092931A, exp. date 7/11; exp. date: 7/11; 094039A, exp. date: 10/11; 094899A, exp. date: 1/12. Taro Pharmaceutical Industries, Ltd.

Flexeril, 10 mg, bottles of 100. Volume of product in commerce: 52,406 units. Product is being recalled due to cGMP deviations. Review of past production records found instances were equipment cleaning procedures were insufficient or that cleaning was not adequately documented. Lot #s: SBC0548, exp. date: 01/31/2011; SDC0149, exp. date: 3/2011. McNeil Consumer Healthcare.

Lisinopril Tablets, 30 mg, 100-count plastic bottles, Rx only. Volume of product in commerce: 14,256 bottles. Adulterated Presence of Foreign Tablets: Product may contain foreign tablets. Lot #s: 3104749, exp. date: 10/13. Lupin Limited, Verna, Salcette.

Methylprednisolone Tablets, 8 mg, 25 tablets/bottle, Rx only. Volume of product in commerce: 8,724 bottles. Adulterated Presence of Foreign Tablets: A foreign yellow oblong Meclizine 25 mg tablet was found in a 25-count bottle of white oblong Methylprednisolone 8 mg tablets. Lot #s: 9P370, exp date: 07/11. Cadista Pharmaceuticals Inc.

Minipress, 2 mg, 250 capsules bottle, Rx only. Volume of product in commerce: 18,210 bottles. Marketed Without an Approved NDA/ANDA: Material sourced from a manufacturer that has not been

DRUGS AND DIETARY SUPPLEMENTS (continued)

registered as a supplier for the U.S. Lot #s: V090952, exp date: 03/14; V100373, exp date: 03/14; V100541, exp date: 03/14. Pfizer Pharmaceuticals LLC.

Pancrelipase (CREON) Delayed Release Capsules, 6000 USP units in 12-count professional sample bottles only. Volume of product in commerce: 20,377 12-count bottles. Subpotent; 12 month, 18 month and 24 month stability time-points. Lot #s: 44840, 45114 and 45398. Solvay Pharmaceuticals Inc.

Triamterene and Hydrochlorothiazide Tablets, 75mg/50mg, Rx only 500 Tablets. Volume of product in commerce: 5427 / 500 count bottles. cGMP Deviations: the firm states that the root cause is related to an event that occurred during the compression process for the batch. Lot #: 192733, exp. date: 02/13. Sandoz Inc.

Tizanidine hydrochloride (Zanaflex), 4 mg, 2 mg, bottles of 150 capsules and 150 tablet bottles, Rx only. Volume of product in commerce: 21,922 bottles. Subpotent; empty capsules were found in certain lots. Lot #s: 9P445, exp. date: 8/2014; 9M227, exp. date: 5/2014; 0L371, no exp. date. Elan Pharma Ltd. and Elan Holdings, Inc.

Topiramate Tablets, 25 mg, 1000 count bottle, Rx only. Volume of product in commerce: 7,770 bottles. cGMP Deviations; Firm's laboratory investigations were not performed in accordance with the "FDA Guidance for Industry - Investigating Out-of-Specification Test Results for Pharmaceutical Production." Lot #s: 28T033 and 28T034. Teva Pharmaceutical Industries.

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 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

Active Leisure Folding Canopy Tents. The tents do not meet the flammability label claim on the unit, posing a fire hazard to consumers. Active Leisure Inc., (877) 730-1583.

ADP FOA Series Unit Heaters. Some heaters were manufactured without a required flame rollout switch, which is a back-up device that shuts down the heater in the event of a heater failure. This poses a fire hazard. Advanced Distributor Products (ADP) LLC., (866) 303-8634 or www.adpnow.com.

Box Fans. An electrical failure in the fan's motor poses a fire hazard to consumers. Lasko Products Inc., (877) 445-131 or www.laskoproducts.com.

Cub Cadet Riding Lawn Mowers. A fuel leak can occur near the rear mounting screws on the bottom of the fuel tank, posing a fire hazard. Cub Cadet, (888) 848-6038 or www.cubcadet.com.

Exmark Pioneer S-Series Riding Mowers. Welds on the motion control linkage can fail and cause the driver to lose control of the machine, resulting in a crash hazard. Exmark Manufacturing Company, (800) 667-5296 or www.exmark.com.

Garage Heaters. Some heaters were manufactured without a required flame rollout switch, which is a back-up device that shuts down the heater in the event of a heater failure. This poses a fire hazard. Lennox Industries Inc., (888) 584-2353 or www.lennox.com.

Gas Fireplaces. Delayed ignition can cause the fireplace's propane gas to explode and break or shatter the glass door. This poses a laceration hazard to consumers nearby. Kingsman Fireplaces, (855) 593-3304 or www.marquisfireplaces.net.

Gerber® Gator® Combo Axe. The knife in the axe handle can come out when the axe is used for chopping or hammering, posing a laceration hazard to the user. Gerber Legendary Blades, (877) 314-9130 or www.gerbergear.com.

Girl's Tops. The jewelry and decorative trim attached to the girl's garments contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. My Michelle, (800) 960-8791 or www.mymichellerecall.com.

Hot Chocolate Pots. The handle of the hot chocolate pot can break off during use, posing burn and laceration hazards. Williams-Sonoma Inc., (855) 643-4206 or www.williams-sonoma.com.

CONSUMER PRODUCTS (continued)

Infant Bed-Side Sleepers. When the fabric liner is not used or is not securely attached, infants can fall from the raised mattress into the loose fabric at the bottom of the bed-side sleeper or can become entrapped between the edge of the mattress and the side of the sleeper, posing risks of suffocation. Arm's Reach Concepts Inc., (800) 954-9353 or www.armsreach.com.

Pampers® Natural Stages Infant Ortho and Bulb Pacifiers. The pacifiers fail to meet federal safety standards and pose a choking hazard to young children. Key Baby LLC, (800) 447-1224 or www.key-baby.com.

P.Jamas Children's Sleepwear. The garments fail to meet federal flammability standards for children's sleepwear, posing a risk of burn injury to children. P.Jamas, (888) 554-6495 or www.p-jamas.com.

Rogue Fitness Barbell Brackets. The weld between the bracket and the pin that holds the barbell bracket in place on a weightlifting rack can break, causing the weights to fall, and posing an injury hazard to consumers. Ventures LLC dba Rogue Fitness, (888) 454-6925 or www.roguefitness.com.

Soldering Irons. The power cord can break at the flex point where the cord attaches to the handle, posing a burn hazard to consumers. Cooper Tools LLC, (800) 476-3030 or www.cooperhandtools.com.

Spray Mousse Foam Cans. The aerosol container's liner can corrode over time, posing a risk of the cans rupturing and expelling its contents. Redken 5th Avenue NYC, (888) 241-9504 or www.redken.com.

Toro Z Master ZRT Mowers. Mowers with the optional deluxe seat have an operator presence switch built into the seat that may activate the mower when the operator vacates the seat, posing an injury hazard from the blade to the operator and anyone in the vicinity of the mower. The Toro Company, (866) 946-3109 or www.toro.com.

Troy the Activity Truck. The plastic beads on the activity truck's bead runs can detach, posing a choking hazard to young children. Infantino LLC, (888) 808-3111 or http://service.infantino.com.

Wrist Rattles and Baby Booties. The pom-poms attached to the wrist rattles and booties can detach, posing a choking hazard. Midwest-CBK Inc., (800) 394-4225.

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She concludes that such funding undermines the important independence of such groups and ends by stating: "A consumer group funded by telephone companies would not be trusted to judge the best mobile phone package, nor to be a public advocate on telecommunications policy. Is health less important?" ✦

National Cancer Institute's Helpline: A Valuable, Underused Resource

The following article was written by Erin N. Marcus, M.D., and originally appeared on the website of New America Media. It has been reprinted with permission.

Brenda Bryant learned she had breast cancer while she was sitting alone in her car in the parking lot of her grandson's day care center. It was early evening on a Friday two years ago, and her surgeon called to tell her the results of a biopsy. "He just gave me my results and that was it," says Bryant, who lives in Northern Virginia. "It was like there was this big knot in my throat. I was lost, and I didn't know who to go to. I just started going crazy."

Searching on the Internet for more information about the disease, Bryant found the telephone number of the National Cancer Institute's Cancer Information Service (1 800-4-CANCER, or 1-800-422-6237). The woman who answered told her about local support groups and medical specialists in her area and shared her own story of having breast cancer. "The person on the other line was really comforting," Bryant says. "It made me feel like I might have some hope."

Despite its 35-year history, the NCI's free service remains under the radar to many. The helpline handles about 78,000 calls a year, in English as well as in Spanish, from patients, family members, and others who have questions about different types of cancer. By contrast, in 2007, some 11.7 million Americans were living with the disease.

The service is especially underused in ethnic minority communities, according to Dr. Nancy Burke, a researcher at the University of California, San Francisco. "There's an issue of awareness, and there's also the comfort issue of seeking information over the phone," she says. "But once we introduce people to it, they love it. Cancer patients are often overwhelmed by information, and the line can help them sort through it."

The cancer line fields a wide variety of queries, including what to expect after different diagnoses; what to ask doctors; where to get help with financial, legal and transportation problems that might interfere with treatment; the benefits and side effects of different treatment options; and what clinical trials are available for different diagnoses.

Callers are encouraged to share as many details as possible about the exact type and stage of their cancer, so that the staff can tailor the information they provide. "But if they don't know this, we can help them formulate questions they can take to their doctor," says Mary Anne Bright, a former oncology nurse who directs the program. "We will spend as much time with somebody as they need."

Unlike many other toll-free helplines, "we're not a pharmaceutical company, and we're not collecting donations," Bright adds. "We're all about reporting the most accurate and up-to-date information about cancer and the results of research in a way that people can understand."

The phone line is open Monday through Friday, from 8 a.m. to 8 p.m. Eastern time. Callers aren't asked for their name, unless they want to receive printed material in the mail, and only their area codes are collected. They are asked some basic demographic questions at the end of the call, but can choose not to answer, and "it won't have an impact on how we deliver our service," Bright says.

The Cancer Information Service also handles questions by email and by instant messaging. Recently, the line has been answering more questions about where to get financial help, how to pay for treatment, and where to get free or low-cost screening tests, such as mammograms.

"We're not a pharmaceutical company, and we're not collecting donations. We're all about reporting the most accurate and up-to-date information about cancer and the results of research in a way that people can understand."

— Mary Ann Bright

Burke says one unexpected benefit of the call line is the confidence it instills in patients navigating the medical system. "Many people don't feel entitled to getting good service," she says. "It was empowering for people to feel they were going into their appointment with questions to ask and information to discuss with their doctor."

Brenda Bryant called the line a second time, a month after her initial breast cancer diagnosis. Even though she had insurance, she was worried that she wouldn't be able to afford her treatment, and she also wanted information about a clinical trial that her cancer specialist was pushing. She ended up deciding to go with the standard treatment for her type of cancer, and she reports that she is now doing well.

"They just gave me a lot of information on different services, and they didn't promote any treatment or trial," she says. "I just felt that it was a good resource." ✦

PUBLICCITIZEN
Health Letter, Public Citizen Health Research Group
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PUBLICCITIZEN Health Letter

Outrage of the Month! Patient Advocacy Groups and Drug Company Funding

Are disease-specific patient advocacy groups affected by taking money from drug companies that make products to treat these diseases? Examples of groups that have received such funding include the American Diabetes Association, March of Dimes, Cystic Fibrosis Foundation, Leukemia and Lymphoma Society, National Kidney Foundation, National Osteoporosis Foundation, Y-Me National Breast Cancer Organization, National Alliance on Mental Illness and many others.

In a debate in the *British Medical Journal*, arguing there is nothing improper with such groups taking drug company money, a representative of the British Genetic Interest Group stated that "There is nothing inherently wrong with patient groups taking money from the drug industry provided that it does not put them under pressure to adopt a position that they would otherwise not choose to take up." He goes on to say that "Patient groups are not naïve. They value their independence fiercely and are quite capable of spotting the strings that may be attached to funding — whatever the source." Other sources reveal that this group is funded by, among others, GlaxoSmithKline, Merck, Novartis, Pfizer, Schering Plough, AstraZeneca, Genzyme Therapeutics and GE Healthcare.

Contrary to this claim of immunity from such influences and on the other side of this debate is Dr. Barbara Mintzes, a Canadian researcher who has investigated this issue thoroughly. She agrees that "Patient groups provide information, advice, and support; represent patients on governmental committees; and speak in the media on behalf of patients. They can be a voice for someone who faces pain, invasive procedures, isolation, disability, and at times discrimination and poor medical care." But she then quotes the drug industry itself, from a publication entitled *Pharmaceutical Executive*, stating that:

> "Product managers see advocacy groups as allies to help advance brand objectives, like increasing disease awareness, building demand for new treatments and helping facilitate FDA clearance of their drug." Mintzes discusses the risks to patients of such drug company funding as including:

- "Disguised promotion channeled through a seemingly neutral third party"; and
- "Confusion between patients' and sponsors' interests in policy of patient groups."

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