PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR MARCH 2011 – VOL. 27, No. 3

Patients at Risk: Medical Boards Fail to Discipline Almost 6,000 Physicians With Hospital Sanctions

Public Citizen released a report on March 15, 2011, involving an analysis of the National Practitioner Data Bank (NPDB) Public Use File that found a total of 10,672 physicians in the NPDB with one or more clinical privilege actions. Fifty-five percent, or 5,887, of these physicians had no state licensing actions. (See the table on page 4 for a state-by-state analysis of this). The report is an analysis of violations by and the privileging actions taken against these physicians who, despite having clinical privilege actions, escaped any state licensing action.

Clinical privilege action refers to a peer review-based disciplinary action that is taken by a hospital or managed care organization or other health care entity against a physician because of performance or conduct reasons, such as incompetence or violations of patient foundries. If a physician's privileges to practice in the health care organization are limited or revoked for a period of more than 30 days, the action must be reported to the NPDB, which is a national clearinghouse of doctor disciplinary and medical malpractice information operated by the Department of Health and Human Services (HHS) and available to only health care organizations and state medical boards.

In terms of public safety, state medical board action against a physician's license, if warranted, provides a greater assurance than a hospital privilege action alone that (a) the practitioner's medical practice would be monitored, limited or curtailed by a medical board order and (b) other state medical boards and future employers will have a more complete account of a practitioner's practice history.

We analyzed the NPDB Public Use File and extracted information about 5,887 physicians (identified in this file only by a coded number) who had at least one clinical privilege action report in the NPDB but no medical board licensure action report in the NPDB.

For the purposes of our analysis, these physicians were assigned to a state based on the state in which the last clinical privilege action occurred.

Types of violations causing clinical privileging actions

The reasons for the actions against these 5,887 physicians included:

- 220 physicians disciplined because they were an "Immediate Threat to Health or Safety"
- 1,119 physicians disciplined because of incompetence, negligence or malpractice
- 605 physicians disciplined because of substandard care

Other categories of serious deviations of physician behavior/performance that resulted in clinical privilege revocation or restrictions included sexual misconduct; unable to practice safely; fraud, including insurance fraud, fraud obtaining a license and fraud against health care programs; and narcotics violations.

Thus, a total of 2,071 physicians (35 percent of those physicians with clinical privilege actions but no medical board actions) had one or more of the above most serious categories of violations.

Types of clinical privileging actions taken against the 5,887 physicians

According to our study, 3,218 physicians lost their clinical privileges permanently, and an additional 389 physicians lost privileges for more than one year.

Thus, 3,607 physicians, representing 61 percent of those with one or more clinical privilege reports but no state disciplinary action, had either a permanent clinical privilege penalty or a penalty of one year or more.

In addition, many of the 5,887 physicians who had been disciplined by hospitals, but had no state medical board action, had a history of medical malpractice payments (as reported to the NPDB). A physician in New Mexico had 26 malpractice cases while a physician in Indiana had 20. Fourteen states had a physician with at least

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Beware of Fraudulent 'Dietary Supplements'

The following article appeared on March 15, 2011, on the Food and Drug Administration's website, www.fda.gov.

Federal regulators continue to warn consumers about tainted, dangerous products that are marketed as dietary supplements. These fraudulent products can cause serious injury or even death.

The Food and Drug Administration (FDA) has found nearly 300 fraudulent products — promoted mainly for weight loss, sexual enhancement and bodybuilding — that contain hidden or deceptively labeled ingredients, such as:

- The active ingredients in FDA-approved drugs or their analogs (closely related drugs);
- Other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients.
- Products claiming to be alternatives to FDA-approved drugs or to have effects similar to prescription drugs;
- Products claiming to be a legal alternative to anabolic steroids
- Products that are marketed primarily in a foreign language or those that are marketed through mass e-mails;
- Sexual enhancement products promising rapid effects, such as working in minutes to hours, or long-lasting effects, such as working for 24 to 72 hours;
- Product labels warning that you may test positive in performance enhancement drug tests.

"These products are masquerading as dietary supplements — they may look like dietary supplements but they are not legal dietary supplements," says Michael Levy, director of FDA's Division of New Drugs and Labeling Compliance. "Some of these products contain hidden prescription ingredients at levels much higher than those found in an approved drug product and are dangerous."

FDA has received numerous reports of harm associated with the use of these products, including stroke, liver injury, kidney failure, heart palpitations, and death.

Advice for consumers

"We need consumers to be aware of these dangerous products and to learn how to identify and avoid them," says Levy. Consumers should look for potential warning signs of tainted products marketed as dietary supplements, such as:

Generally, if you are using or considering using any product marketed as a dietary supplement, FDA suggests that you

- Check with your health care professional or a registered dietician about any nutrients you may need in addition to your regular diet;
- Ask your health care professional for help distinguishing between reliable and questionable information;
- Ask yourself if it sounds too good to be true;
  - Be cautious if the claims for the product seem exaggerated or unrealistic;
  - Watch out for extreme claims — for example, "quick and effective," "cure-all," "can treat or cure diseases" or "totally safe";
  - Be skeptical about anecdotal information from personal "testimonials" about incredible benefits or results obtained from using a product;
  - See FDA's website to help recognize fraudulent weight-loss products and claims.

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Proud, Safe Gun Owners Want Their Right to Bear Arms Privately

The following article was written by Martha Rosenberg. Ms. Rosenberg frequently writes about the impact of the pharmaceutical, food and gun industries on public health. Her work has appeared in The Boston Globe, San Francisco Chronicle, Chicago Tribune *and other outlets. This article originally appeared on OpEdNews.com on March 8, 2011. It has been reprinted with permission.*

Illustration by Martha Rosenberg

Owning firearms is supposed to make you safe. Except when it doesn't.

Illinois Attorney General Lisa Madigan's ruling [March 1, 2011], that the names of the 1.3 million people with Firearm Owners Identification cards (FOID) in the state be published has gun owners up in arms, pun intended.

The same groups that declare no one would put a sign in front of their home saying NO GUN now fear the opposite. They're no longer worried about their right to bear arms, they're worried about their right to bear arms anonymously. Their right to privacy.

If the Illinois State Police release the names of FOID holders per Madigan's ruling which it has so far refused to do and which would not include FOID holders' addresses, phone numbers of photos, gun activists' fears include:

- Fear that criminals will break in their houses and steal their weapons;
- Fear that their jobs will be at risk thanks to anti-gun employers;
- Fear that gun control groups will use the information to harass them;
- And fear that they will be singled out and shamed in their communities.

"It's bad enough that private citizens are not allowed to defend themselves when they walk our dangerous streets," says Illinois State Rifle Association Executive Director Richard Pearson in preparation for a huge pro-gun rally in Springfield on Friday. "But now Attorney General Madigan willfully sets citizens up as targets for crime by releasing their personal information to anyone who asks for it."

Pro-gun Illinois politicians say the public has no right to the information, which the Illinois State Police have kept sealed for 40 years, and have introduced counter legislation to Madigan's.

But pro-disclosure activists say knowing whether a neighbor, daycare worker or the college kid sitting next your son or daughter is armed is very much their business!

Two years ago, a similar flap occurred when the *Memphis Commercial Appeal* decided to publish a searchable base of state firearm permit holders, despite gun owner identity protection laws in states like Florida, Ohio and South Dakota that sealed names. The *Appeal* had found that 70 of 154 state permit holders had criminal records, including Bernard Avery (arrested 25 times with a murder charge dismissed on mental competency) and Reginald Miller (a felon with 11 arrests). Who wouldn't want to know that? Even before Tucson?

But Chris Cox, then executive director of Illinois' NRA, wrote the newspaper and called the decision "dangerous" — as if gun safety advocates and employers were armed instead of gun-owners. Hello?

In fact, gun owners are so worried that Madigan's ruling will cause criminals to break in their homes and steal their weapons, you have to wonder if the weapons make them safe or unsafe. Maybe they need to buy more weapons to defend their weapons.

Here in Illinois, millions get to work every day without the help of a firearm, including women, night shift workers and people on public transportation. They attend church, college classes and state parks in cars and on foot without feeling the need to carry lethal weapons. Yet gun extremists see danger in all these activities and even in unarmed citizens knowing they're armed. They're so proud and safe as gun owners, they don't want anyone to know. ✦

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one clinical privilege report, no state licensure action, and at least 10 medical malpractice payments.

Public Citizen identified 33 state medical boards where more than half of the physicians with clinical privilege reports in their states did not have any reported medical board licensure action. Letters were sent to each of these 33 medical boards asking them to work with the Health Resources and Services Administration, which operates the NPDB for HHS, on identifying the physicians and determining why no action was taken.

Public Citizen identified 33 state medical boards where more than half of the physicians with clinical privilege reports in their states did not have any reported medical board licensure action.

Table 1 shows large differences between states in what percentage of those doctors with hospital actions did not have any state disciplinary action. At the more successful end of the spectrum, Kentucky, Colorado, Vermont and Massachusetts all have fewer than 40 percent of doctors with hospital disciplinary actions who have not been disciplined by the state medical board. It is of interest that two of those states, Kentucky and Colorado, have been consistently among the top 10 states in their overall rate of serious disciplinary actions for all of the past 10 years, according to our annual ranking.

At the other end of the spectrum are those states with the poorest record in disciplining those physicians who have hospital disciplinary actions. In eight states — Delaware, Hawaii, Indiana, Nevada, New Mexico, Pennsylvania, South Dakota and Tennessee — more than 70 percent of those doctors with hospital disciplinary actions have never

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Table 1. Percentage of Physicians With Clinical Privilege Actions Who Have No Licensure Actions, By State of Last Clinical Privileges Action

(National Practitioner Data Bank Public Use Data File, Sept. 1, 1990 - Dec. 31, 2009)

State of Last Clinical Privilege Action	Number of Physicians with One or More Clinical Privilege Actions	Number of Physicians with One or More Clinical Privilege Actions but No Licensure Actions	Percent of Physicians Who Have One or More Clinical Privilege Actions but No Licensure Actions
AK	30	16	53.33%
AL	137	69	50.36%
AR	114	65	57.02%
AZ	276	117	42.39%
CA	1312	710	54.12%
CO	196	62	31.63%
CT	82	36	43.90%
DC	42	25	59.52%
DE	30	22	73.33%
FL	572	361	63.11%
GA	334	204	61.08%
GU	5	3	60.00%
HI	48	37	77.08%
IA	109	47	43.12%
ID	49	26	53.06%
IL	328	215	65.55%
IN	230	170	73.91%
KS	152	82	53.95%
KY	163	63	38.65%
LA	143	59	41.26%
MA	302	115	38.08%
MD	238	102	42.86%
ME	62	28	45.16%
MI	374	220	58.82%
MN	151	74	49.01%
MO	181	96	53.04%
MS	72	35	48.61%
MT	46	30	65.22%
NC	220	130	59.09%
ND	33	15	45.45%
NE	81	56	69.14%
NH	51	28	54.90%
NJ	320	183	57.19%
NM	72	52	72.22%
NV	121	85	70.25%
NY	802	400	49.88%
OH	439	249	56.72%
OK	183	99	54.10%
OR	135	56	41.48%
PA	393	276	70.23%
PR	17	17	100.00%
RI	51	23	45.10%
SC	137	75	54.74%

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If you suspect a dietary supplement sold online may be illegal, FDA urges you report that information online. In addition, you or your health care professional can also report an illness or injury you believe to be related to the use of a dietary supplement by phone at 1-800-FDA-1088.

Dietary supplements and FDA

Dietary supplements, in general, are not FDA-approved. Under the law (Dietary Supplement Health and Education Act of 1994), dietary supplement firms do not need FDA approval prior to marketing their products. It is the company's responsibility to make sure its products are safe and that any claims are true.

Just because you see a supplement product on a store shelf does NOT mean it is safe or effective. When safety issues are suspected, FDA must investigate and, when warranted, take steps to have the product removed from the market. However, it is much easier for a firm to get a product on the market than it is for FDA to take a product off the market.

FDA has worked with industry to recall numerous products with potentially harmful ingredients including:

- More than 40 products marketed for weight loss;
- More than 70 products marketed for sexual enhancement;
- More than 80 products marketed for bodybuilding.

FDA last alerted the public to tainted products in December 2010, and will continue to issue consumer alerts and press announcements about these products. The agency has issued warning letters, seized products, and conducted criminal prosecutions. In December 2010, a woman pleaded guilty to an 18-count indictment charging her with the illegal importation and distribution of more than 4 million diet pills that contained a controlled substance, unapproved drugs and a possible cancer-causing agent.

Remember, FDA cannot test all products on the market to identify those that contain potentially harmful hidden ingredients. Consumers must also be aware of these dangerous products and learn how to identify and avoid them using the warning signs described above. ✦

Keep Up-to-Date on Tainted Products

Get the latest news on tainted products by using FDA's "widget" and "RSS feed." Both of these online tools contain alerts, health information and FDA actions on tainted products marketed as dietary supplements.

A widget is a portable application that displays featured content directly on a Web page. Bloggers or owners of websites can embed this content into their sites. Once FDA's widget is added, there's no technical maintenance — FDA will automatically provide updates to content displayed on the widget.

The RSS (Really Simple Syndication) feed, like the widget, includes updated content published on FDA's website. RSS is usually used for news and blog websites and requires an RSS news reader to pick up the content in the feed. Organizations and bloggers can subscribe to the RSS feed to receive updates automatically and put together their own customized lists of news and information.

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been disciplined by the state medical boards.

We also wrote to HHS Secretary Kathleen Sebelius asking that the Office of Inspector General (OIG) re-initiate reviews of state medical boards. Such investigations were stopped in OIG because of a questionable legal opinion from OIG lawyers. The last OIG review of medical boards took place 18 years ago. ✦

Table 1. ***(continued)***

State of Last Clinical Privilege Action	Number of Physicians with One or More Clinical Privilege Actions	Number of Physicians with One or More Clinical Privilege Actions but No Licensure Actions	Percent of Physicians Who Have One or More Clinical Privilege Actions but No Licensure Actions
SD	27	19	70.37%
TN	214	150	70.09%
TX	725	438	60.41%
UT	82	44	53.66%
VA	253	113	44.66%
VI	6	6	100.00%
VT	26	11	42.31%
WA	238	124	52.10%
WI	163	98	60.12%
WV	78	36	46.15%
WY	21	10	47.62%
Total	10672	5887	55.16%

Our Unsafe Health Care System Is the Issue, Not Caps on Tort Settlements

The following article was originally published on Huffington Post *on Feb. 22, 2011. It was written by Pearl Korn, a former journalist and longtime advocate for health care reform. It has been published with permission.*

A little-noticed proposal in the president's budget managed to squeak by without a ripple in the media or comment from savvy political pundits and progressive activists. The president is offering $250 million dollars over four years to the states to test ways to curb medical malpractice tort, further denying the rights of victims to seek justice and redress for medical malpractice. Our president appears to have bought into the conservative flim-flam of frivolous lawsuits and lottery-sized payouts, both of which are non-existent. Even though this issue has been buried for decades, what better time to resurrect it than now, since the budget and deficit are on the minds of all those newly minted deficit "hawks" in D.C.?

If we're going to have one of those "adult conversations" on this issue, Mr. President, then we need to look at what is the real contributor to the impact medical costs have on the deficit. Congress and the medical community are in denial when it comes to the great harm and costs medical malpractice and in-hospital adverse events from drug reactions, infections, surgery, unnecessary procedures, etc. impose on our health care system, while also inflicting pain and suffering on a generally unsuspecting public. Millions of victims have been invisible and voiceless for too long, with no massive protests in the streets and few advocacy organizations speaking for them, with one notable exception: Public Citizen and its Health Research Group, which has been fighting for patient safety for decades, researching the system's failures and offering up solutions. Public Citizen has been instrumental in removing some of the most dangerous drugs from the market, and their book "Worst Pills, Best Pills" (www.worstpills.org) by Dr. Sidney Wolfe, director of their Health Research Group, is an invaluable resource for all who care about their own health and safety.

So why has there been no massive outcry for change? One reason is that I believe the victims of malpractice suffer from post-traumatic stress disorder. The betrayal of trust by a doctor leaves mental and emotional scars that do not fade, and the trauma of an avoidable injury, maiming or death of a loved one can sap the strength and resolve of the most resolute among us. The victims' minds are unfocused and unable to organize into a fighting body that can take on the system. Flashbacks can linger for years, even decades.

So what has tort reform to do with our health delivery system? Nothing. It has been a diversion that prevents us from dealing with the terrible truth that when we see a doctor or enter a hospital, there is nothing in place to protect us. Recently, ABC World News reported about hip, knee and heart valve replacements leaking dangerous chemicals into the bodies of their recipients, including cobalt — yet another example of the FDA failing to protect us and another of the near-daily health care horror stories we hear about.

It is our health care delivery system that needs an overhaul, not just tort. We must change from a "sick-care" system to a real health care system. The "free market" of healt h care delivery fails us on every level. For heaven's sake, even Justin Bieber refers to our health care system as "evil," due in part to its being unaffordable. He is Canadian, so he knows what a health care system can deliver, noting that in Canada, if you're sick, you just go see the doctor. How simple.

To truly deal with this crisis, there are three main issues that must be addressed:

1. How health care is financed and payment is delivered to doctors, hospitals and other providers
2. Tort reform that focuses on overhauling the legal system that addresses medical malpractice
3. Regulation

As Public Citizen recently noted to its membership, "(P)reventable medical errors hurt millions of Americans every year. Many suffer unspeakable pain, become disabled, lose their livelihoods, sometimes even lose their lives, because of these medical errors." Two hundred and fifty thousand Americans die each year due to those errors, and close to 900,000 deaths in total per year come as the result of unnecessary surgery, hospital-acquired infections, adverse drug reactions, medical errors, even bedsores. From adverse drug reactions and medical malpractice alone, the number of deaths was 420,000 in 1997, as reported by Dr. Lucien Leape of Harvard. If this isn't a crisis, I don't know what is. The pain and suffering is enormous, and so is the financial cost. It would be reasonable to assume that at least $200 billion or more per year is added onto our national health care costs as a result of these errors, and we can anticipate these numbers will continue to rise yearly unless there is intervention and some serious changes begin to take place. Safety must become the major priority, instead of profits. A priority shift is imperative.

Addressing this crisis is one way, Mr. President, of cutting back on the cost of health care in America. Your health care reform bill will be delivering another 32 million people into the same bloated, unsafe system that exists today. Can any of us recall

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the last time we read an article about patient safety? This is forbidden fruit to a humongous industry that, according to 2008 statistics from the Bureau of Labor Statistics within the Department of Labor, provides 14.3 million jobs for wage and salaried workers among 595,800 establishments that make up the health industry. Between 2008 and 2018, 3.2 million jobs will be added to this industry, which is one of the fastest growing, thanks in part to those aging boomers. With these numbers, we can understand why the status quo and special interests hold reign. If any other industry had such appalling safety records, they would be shut down. When was the last time we heard "FIRST, DO NO HARM?" Hippocrates must be rolling in his grave.

In truth, the real impact of litigations on our total health care costs is a mere 0.55 percent ("Medical Malpractice Claims Negligible," by J. Robert Hunter, Consumer Federation of America, in "Dispatches" in the September 15, 2009 issue of *The Progressive Populist*) with very few victims even bringing suits against doctors or hospitals. And if there is a settlement, it averages about $42,000 — hardly hitting the lottery, especially with legal counsel collecting 1/3 plus expenses and the insurers (including Medicare) also seeking their share of any legal settlement to cover the costs of care for the injury caused by the malpractice in the first place. The litigation process can drag on for years, which also makes lawyers reluctant to take these cases to begin with.

How much could be accomplished if doctors and hospitals would step up to the plate and meet with the injured party or family of a deceased loved one, explain what went wrong and apologize? Chances are litigation could be avoided, which is what those few hospitals that offer this kind of doctor-patient sharing have discovered. It works. Unfortunately, many doctors find it too hard to admit making mistakes and displaying fallibility. Image-control is everything, and admitting health care providers can make mistakes appears to be too much to risk just to do what's right. But mandating doctors come clean would go a long way to resolving so much pain and suffering. This is something that must be addressed in medical school, instead of perpetrating a culture of "catch me if you can."

In 1999, the Institute of Medicine estimated that medical errors cost an estimated $17 billion-$29 billion annually for lost income, lost household production, disability and health care. Adjusted for inflation, those numbers become $22.1 billion-$37.7 billion today. The Department of Health and Human Services estimates the cost to Medicare at $4.4 billion per year for medical errors. It is abundantly clear that if we are to finally have a safe health care system — after decades of evasion, deaths and injury — we must overhaul the way care is delivered, which will create safer health care and, in turn, less malpractice, helping to reduce costs. After all, haven't we a right to expect safety and responsibility in the best health care system in the world?

Right now, the Judiciary Committee in the House is working on the tort issue, and a leading voice on the committee is Rep. Phil Gingrey (R-Ga.), a former obstetrician who was sued four times for medical malpractice. He actually ran for Congress in 2002 and won while he was being sued. One suit was dropped, and the others settled. This man is writing key legislation that would severely cap malpractice settlements — little more than the fox building the henhouse. Apparently there is no such thing as recusing oneself due to a personal agenda in a congressional committee. But, hey, since when is it news to mention a conflict of interest in Congress?

In 1999, the IOM's landmark study "TO ERR IS HUMAN" reported up to 98,000 deaths each year in the U.S. from "doctors' errors." The study shook the nation. Today those numbers are considerably greater. It would seem that it is time for the IOM to revisit the numbers and also come up with positive solutions, joined by the agency that addresses quality in health care, the Agency for Healthcare Research and Quality (AHRQ). One of its missions should be to code every possible kind of medical error and other adverse events in hospitals and medical facilities, along with mandating the reporting of such events. Hospital accreditation is based on GOOD performance, so do we really know how much may be underreported? Bring in leading academic voices for safety, like Dr. Leape and Dr. Sidney Wolfe from Public Citizen, who has spent decades on this problem.

Additional ways to address this crisis could be the creation of a NATIONAL MEDICAL SAFETY BOARD (NMSB), an independent entity modeled on the NTSB, with an advocate similar to Elizabeth Warren at its helm. We must also develop a new paradigm for the states' OPMCs (Office of Professional Medical Conduct), which currently monitors doctors' performances and renders disciplinary action, but only after a complaint is registered. OPMCs are monitoring and reporting doctor misdeeds less and less, ineffective and reactive rather than being the preventive and proactive agencies they should be. An NMSB could chart regional doctors' errors in medical outcomes and then act as a consulting party to the states OPMCs and make recommendations to implement safety measures — a federal/state dialogue and a unique partnership supporting patient safety. Another good start for the overhaul of all state OPMCs would be to recruit all of their commissioners from the professional medical ranks, and not have them appointed by the governors, which politicizes the post and contributes to their inaction and tendency to cover up and shut down cases following complaints.

Real solutions to all of the above could be addressed with the passage of H.R. 676, reintroduced last week in Congress by Rep. John Conyers (D-Mich.), an Expanded and Improved Medicare for All Act delivered by a single payer.

Mr. President, if you are serious

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Product Recalls

March 1, 2011 – March 22, 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

Mr. Magic Male Enhancer Capsules, 480 mg; 3, 6, 12 and 20-count bottles; 1-count foil cards; and a display box containing 24 x 1-count foil cards. Volume of product in commerce: 251,473 capsules. Marketed without an approved new drug application: FDA sample analyses determined that the product contains hydroxythiohomosildenafil and sulfoaildenafil, analogues of the FDA-approved drug sildenafil. Lot #s: 8121904, exp. date 12/2011; 9041401, exp. date 01/2012 or 04/2012; 251209, exp. date 01/2013. GT Pro Nutrition and Biogenixs.

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

Arixtra Patient Starter Kits, "Looking Ahead with ARIXTRA." Kit contains an education booklet, a puncture-proof container, alcohol wipes and prescribing information for ARIXTRA. Volume of product in commerce: 185,390 units. Microbial contamination of non-sterile product: The kits are being recalled because the alcohol prep pads have the potential to be contaminated with Bacillus cereus. Kit #s: XRA698R0, XRA582R0, XRA582R1, XRA381R0, XRA381R1. GlaxoSmithKline, Inc.

Campral Delayed-Release Tablets, 333 mg, 100-count dose packs, 180-count dose packs, Rx only. Volume of product in commerce: 5,276. Failed dissolution testing at 12-month testing interval. Lot #s: 1069782, 1066737, exp. date 02/2012. Forest Pharmaceuticals, Inc.

Caziant Tablets, 0.1/0.025mg, 0.125/0.025mg, 0.15/0.025mg, 28-tablet boxes. Volume of product in commerce: 19,268 boxes. Firm is recalling product due to impurities/degradation in products. The firm found out-of-specification result for the 3-keto desogestrel degradant at the 12-month stability time point. Lot #: 228088A, exp. date 01/2011. Watson Laboratories, Inc.

Citalopram Tablets, 20 mg, 500-tablet bottles, Rx only. Volume of product in commerce: Unknown. Label mix-up: A bottle labeled as citalopram hydrobromide 20 mg contained Torent's topiramate 100-mg tablets. Lot #s: BF710007, BF710008, BF710011, BF710012. Torrent Pharmaceuticals Ltd.

Levothyroxine Sodium Tablets, 25 mcg, 50 mcg, 100-tablet bottle, 1,000-tablet bottle, Rx only. Volume of product in commerce: 72,500 bottles. Subpotent (single-ingredient drug): Out of specification result in an assay test for the levothyroxine sodium tablets. Lot #s: 09T11270, 09T11280, 09T11290, 09T11370, 09T11380, 09T11390, exp. date 03/2011; 10T0990, 10T0980, 10T1000, 10T1010, 10T1020, 10T1170, exp. date 04/2011. Patheon Puerto Rico, Inc.

Metronidazole Tablets, 250 mg, 250-count bottle, Rx only. Volume of product in commerce: 1,434 bottles. Low tablet weight: Some tablets may not meet weight specification. Lot #: 312566, exp. date 05/2012. Pliva Krakow.

Physicians Total Care Arthrotec, 75/200mcg, 30-tablet bottles, 60-tablet bottles. Volume of product in commerce: 12 bottles. Identified lots may contain broken tablets. Lot #s: 515Q, 51B4, 51JE, exp. date 9/2012; 5H1W exp. date2/2013. Physicians Total Care, Inc.

Plavix Tablets, 75 mg, 30-count bottles. Volume of product in commerce: 210916 bottles. Firm is recalling product because of chemical contamination. The odor was confirmed for returned complaint samples received and was determined to be due to the presence of 2, 4, 6-tribromoanisole (TBA) found at very low levels in the bottles and caps for the recalled lots. The source of TBA has been determined to be associated with the use of the chemical wood preservative 2, 4, 6-tribromophenol (TBP) on wood sourced to manufacture wood pallets. Lot #s: 0G56655, 07/2013; 0H49877, 08/2013. Bristol Myers Squibb Manufacturing Co.

DRUGS AND DIETARY SUPPLEMENTS (continued)

Pravastatin Sodium Tablets, 40 mg, 90-count bottles, Rx only. Volume of product in commerce: 51,365 bottles. Tablet thickness: Some tablets may not meet weight specification. Lot #s: 33Y095, 33Y104, exp. date 03/2012. Teva Pharmaceutical Industries.

ROLAIDS Extra Strength Plus Gas Relief Softchews, tropical fruit flavor, calcium carbonate 1177 mg, simethicone 80 mg, 6-count package, 12-count package, 36-count package. Volume of product in commerce: Unknown. All lots. Best Sweet, Inc.

ROLAIDS Extra Strength Softchews, cherry flavor, 36-count bag. Volume of product in commerce: 57,120 units. The firm received complaints for a hard white substance in the product, which analysis revealed was crystallized sugar. Lot #: 0053AG2, exp. date 01/2012. Best Sweet, Inc.

ROLAIDS Extra Strength Softchews, wild cherry flavor, calcium carbonate 1,177 mg, 6-count package, 18-count package (3 packs of 6 count), 18-count bag, 36-count bag, 42-count package (7 packs of 6). Volume of product in commerce: Unknown. All lots. Best Sweet, Inc.

ROLAIDS Multi-Symptom Antacid plus Anti-Gas Softchews, calcium carbonate 1177 mg and simethicone 80 mg, 6-count package, 12-count bag, 24-count bag. Volume of product in commerce: Unknown. All lots. Best Sweet, Inc.

Simvastatin Tablets, 10 mg, 30-count bottle, 1,000-count bottle, Rx only. Volume of product in commerce: 11,590 bottles. Tablet thickness: There is the potential of some tablets not meeting the weight specification. Lot #s: 22S001, 22S002, 22S003, exp. date 03/2012; 22S022, 22S024, exp. date 07/2012. Teva Pharmaceutical Industries.

Simvastatin Tablets, 10 mg, packaged in cartons of 10 blister cards containing 10 tablets each (100 tablets), Rx only. Volume of product in commerce: 3,793 cartons. Tablet thickness: There is a potential for some of the tablets not meeting weight specification. Lot #: 0M447, exp. date 03/2012. Teva Pharmaceutical Industries.

Topiramate Tablets, 100 mg, 60-tablet bottles, Rx only. Volume of product in commerce: Unknown. Label mix-up: A bottle labeled as citalopram hydrobromide 20 mg contained Torent's topiramate 100-mg tablets. Lot #s: BF710007, BF710008, BF710011, BF710012. Torrent Pharmaceuticals Ltd.

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

6K and 7KC Series Door Locksets. The latches can fail and the door cannot be unlocked from the inside, posing an entrapment hazard. This failure could lead to the inability to vacate a location in an emergency. Stanley Security Solutions, Inc., (888) 312-8875 or www.stanleysecuritysolutions.com.

Baby Jogger Jump Seats. If the jump seat does not properly lock into place, it could disengage from the stroller allowing the child to fall out. Baby Jogger, LLC, (877) 506-2213 or www.babyjogger.com.

Camp Nod Lantern Nightlights. An electrical short circuit can occur in the nightlight's wiring, posing a risk of fire or shock hazard to consumers. The Land of Nod, (800) 933-9904 or www.landofnod.com.

Children's Hooded Sweatshirts With Drawstrings. The hooded sweatshirts have drawstrings through the hood, which can pose a strangulation or entrapment hazard to children. In February 1996, CPSC issued guidelines, which were incorporated into an industry voluntary standard in 1997, to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Sunsations, Inc., (800) 786-9044 or www.sunsationsusa.com.

Circo Beaded Door Curtains. Strangulations can occur when a child plays with the beaded strands by wrapping them around their necks or by creating loops in which they can insert their heads. Also, children can get entangled in the strands, which are prone to entangle, just by running through the doorway. Target Corp., (800) 440-0680 or www.target.com.

Colin Cowie Gel-Fuel Wood Fireplaces. Heat from the operating unit causes the plastic mounting screws to deform, making unit fall from the wall, posing a fall and fire hazard. Southern Enterprises, Inc., (877) 858-4959 or www.seidal.com/retrofit.

CONSUMER PRODUCTS (continued)

Baja Dirt Bikes. Fuel can leak from the fuel tank, posing a fire and burn hazard to consumers. Baja, Inc., (888) 863-2252 or www.bajamotorsports.com.

FÖRSTÅ Coffee/Tea Makers. Pressure from the metal pot holder against the coffee/tea maker can cause the glass to break unexpectedly, posing burn and laceration hazards. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Freestanding Steel Outdoor Fireplaces. The decorative bronze powder coat finish on the fireplace chimney can ignite during use, posing a fire hazard to consumers. Sunjoy Industries Group Ltd., (877) 343-5651 or www.sunjoydirect.com/fireplacerecall.htm.

Gasoline-Powered Backpack Blowers and Mister Dusters. The gasoline tank can split and leak fuel, posing a fire hazard to consumers. Maruyama U.S., Inc., (866) 783-7400 or www.maruyama-us.com.

Gasoline-Powered Backpack Blowers. The gasoline tank can split and leak fuel, posing a fire hazard to consumers. Kawasaki Motor Corp., (877) 364-6404 or www.kawpowr.com.

Girls' Jeans for Toddlers. Decorative rhinestones and sequins on the jeans' pockets can pose a choking hazard to young children. Parigi Group Ltd., (212) 378-1205 or www.parigigroup.com.

Girls' Chelsa Dress. The buttons can come off, posing a choking hazard. Matilda Jane, LLC, (260) 424-3511 or www.matildajaneclothing.com.

Global Workbench Power Risers, Power Aprons and Power Shelves. Misrouted wiring in the electrical outlets on the workbench risers, aprons and shelves, and reverse polarity in some workbench power cords pose an electric shock hazard. Global Equipment Co., (855) 657-0424.

Guardian Full-Face Diving Masks. The purge assembly on the diving mask can disengage from the regulator, resulting in loss of air to the diver. This poses a drowning hazard to the consumer. Undersea Systems International, Inc., (877) 270-1984 or www.otscomm.com.

Holiday Rattle Baby Slippers. The internal stuffing and rattle inside the slippers' decorative figures can be pulled out, posing a choking hazard to young children. Atico International USA, Inc., (877) 546-4835 or www.aticousa.com.

Instant Power® Toilet Bowl Restorer™. The contents can leak from the cap when the bottle is turned on its side. When this happens, the cleaner can come into contact with consumers and property, posing a risk of chemical burns and irritation to the skin and eyes. Scotch Corp., (800) 613-4242 or www.scotchcorp.com.

Lennox Shadowdance Natural Gas Log Set Burner Assemblies. A crack can develop at the gas valve connection allowing natural gas to leak while the burner is in use, posing a risk of carbon monoxide poisoning. Lennox Hearth Products, LLC, (800) 299-0027 or www.lennoxhearthproducts.com.

Liebherr Built-In 30-Inch Wide Bottom Freezer Refrigerators. The refrigerator's door can detach, posing an injury hazard to consumers. Liebherr-Canada Ltd., (877) 337-2653 or www.liebherr.us.

Little Pet Vet Costumes and Dr. Littles Costumes. The costumes are sold with a toy stethoscope accessory. The plastic ear pieces at the end of the stethoscope can be pulled off, posing a choking hazard to young children. Fun World, Inc., (800) 247-5314.

Low-Profile Power Conditioners/Surge Protectors. Improper grounding of the case and inadequate insulation for the circuit breaker poses an electrical shock hazard to consumers. Milestone AV Technologies, LLC, (877) 894-6280 or www.milestone.com/recall.

Mini-Candle Travel Sets. The candle flame can spread from the wick to the wax causing a larger than expected flame, posing a risk of burns to consumers. Tommy Bahama Group, Inc., (866) 986-8282 or www.tommybahama.com.

OBall Links & Mini Rattles™. The hard plastic C-links on both ends of the rattles' soft plastic chain can break, posing a choking hazard to young children. Rhino Toys, Inc., (888) 250-9969 or www.rhinotoys.com.

Parents® Busy Time Activity Centers™. Wooden pegs on the xylophone activity can come loose, posing a choking hazard to young children. Manhattan Group, LLC, (800) 541-1345 or www.manhattantoy.com.

Bravo Pogo Sticks. The bottom of the pogo stick's frame tube can break or come apart and a pin holding the spring in place can break, posing laceration and fall hazards to consumers. Bravo Sports, (877) 992-9905 or www.bravopogorecall.com.

CONSUMER PRODUCTS (continued)

Resistance Tubes and Resistance Tube Kits. The plastic clip that attaches the resistance tube to the handle can break during use causing the tubing, handle or fragments of the plastic clip to strike the user. This poses a contusion and laceration hazard. Dick's Sporting Goods, Inc., (866) 677-4771 or www.dickssportinggoods.com.

Rocky Mountain Bicycles. The front fork steering tube can break, posing a fall injury hazard. Procycle Group, Inc., (855) 880-9062 or www.bikes.com.

Slow Cooker. The slow cooker's control panel can overheat and melt, posing a fire hazard. Burlington Coat Factory, (888) 223-2628 or www.burlingtoncoatfactory.com.

Suzuki KingQuad ATVs. Some KingQuad ATVs' plastic fuel tanks were improperly manufactured and can develop a fuel leak, posing a fire hazard. American Suzuki Motor Corp., (800) 444-5077 or www.suzukicycles.com.

Suzuki QuadSport ATVs. The regulator/rectifier circuit board can fail and cause the engine to stall during riding due to an insufficient battery charge, increasing the risk of a crash. American Suzuki Motor Corp., (800) 444-5077 or www.suzukicycles.com.

Wine Bottle Openers. The wine bottles can break when opened with the recalled opener, posing a laceration hazard to consumers. Sunbeam Products, Inc., (888) 759-2279 or www.skybarhome.com.

Wooden Fruit Puzzles. The knobs attached to the puzzle fruits can come loose, posing a choking hazard to young children. Kid O Products, LLC, (212) 366-5858 or www.kidoproducts.com.

Wooden Playpens. The wooden playpen can break, split and/or crack at points where screws and other hardware are located. Small, broken wood pieces and hardware from the playpen can pose a risk of choking and laceration hazards to children. In addition, an unstable playpen can fall over onto a child, posing an entrapment hazard. AOSOM LLC, (877) 644-9366 or www.aosom.com.

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about this issue — and you should be — I would be glad to bring a group of malpractice victims to the White House who will offer up serious, real-world solutions to this issue. They know first hand how the system has failed them. No "Lite" beers, however; only the real deal. Our talk might even include finally establishing a coherent national health policy, which is long overdue.

For much more on these issues, please go to www.citizens-for-medical-safety.com, www.citizen.org/medical-error-stories and my *Huffington Post* story on Christina Zisa, a victim of this crisis, www.huffingtonpost.com/pearl-korn/in-memoriam-christina-zis_b_814356.html. ✦

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

Outrage of the Month! Atomic (Nuclear) Power

It should not have taken the sad, tragic recent events in Japan to increase serious worldwide concerns about the multiply awful consequences of nuclear power, an allegedly "clean" form of energy. In addition to the well-known consequences of Three Mile Island in 1979 and Chernobyl in 1986, there has been unremitting evidence for decades of routine radiation exposure of workers in many of these atomic power plants, especially older ones.

Aside from the dire health consequences to workers and to those living near these plants (or downwind from these plants in the case of a release), the true economic costs of atomic power have been maliciously understated by ignoring or underplaying, for example, the costs of decommissioning plants when they have aged enough to become more dangerous or the cost per kilowatt hour compared to other energy sources.

It is long overdue to say "no" to the licensing of any new atomic power reactors and to the relicensing of existing reactors. At a recent White House briefing, however, Deputy Energy Secretary Daniel Poneman clearly stated that nuclear power remains part of the U.S. energy policy. "Seventy percent of the carbon-free electricity in this country comes from nuclear power," Poneman said. "So we do see nuclear power as continuing to play an important role in building a low-carbon future, but be assured that we will take the safety aspect of that as of our paramount concern." In addition to being extremely misleading — since only 20 percent of U.S. energy is from atomic power — this sounds like the kind of assurances the Japanese atomic power industry used to give.

In the wake of this still-unfolding disaster, Tyson Slocum, Director of Public Citizen's Energy Program, called on the government to do the following:

1) Immediately stop activity relating to relicensing aging U.S. reactors;
2) Halt all activity geared toward building new reactors; and
3) End federal subsidies — such as loan guarantees — for commercial nuclear power, which total $500 billion to date.

Instead, the U.S. should focus on developing wind power and assisting families in the installation of rooftop solar systems.

To sign the petition, visit www.citizen.org/end-nuclear-subsidies-petition. ✦