PUBLIC CITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR OCTOBER 2012 – Vol. 28, No. 10

To Nap or Not to Nap

It is quite likely that if you are older than 60, you have made an effort not to fall asleep during the day, feeling that doing so might interfere with your nighttime sleep. You probably have heard the popular notion that napping during the day will prevent you from sleeping at night. Now there is evidence that for many older people, a nap during the day can not only increase your total daily sleep time but will also make you a better functioning individual while you are awake.

A carefully researched study from the Weill Cornell Medical College published in February 2011 has provided evidence that for healthy older adults, one daily nap, taken no later than 6 p.m. at least five days per week, could increase both total sleep time and mental ability.

Early and inconsistent sleep-disorder research

The topic of sleep disorders began to receive increased scientific attention in 2006. It was then that the Institute of Medicine (IOM), the nonprofit health arm of the National Academy of Sciences, published *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem*, a report highlighting the need for training, research and awareness of these issues. The IOM report estimated that between 50 million and 70 million Americans suffered chronically from a disorder of sleep and wakefulness "associated with a wide range of health consequences." These consequences included hypertension, diabetes, obesity and an estimated 20 percent of serious car crash injuries resulting from driver sleepiness.

However, the IOM report was sponsored by several privately funded groups — the American Academy of Sleep Medicine (AASM), the National Sleep Foundation and the Sleep Research Society — as well as the National Institute of Aging, a government agency. The authors of the report stated that the opinions are their own and "do not necessarily reflect the views of the organizations or agencies that provided support for the project." Yet the report's "Advertise With Us" page (filled with solicitations to advertise in various journals) and the page containing links to 15 affiliated websites and items available from the AASM shop lead one to doubt that the authors could be completely neutral.

Nevertheless, in 2007, as a result of the IOM's report, a group of "thought leaders," along with sleep experts and clinicians representing 13 unidentified national organizations, attended a conference to begin collaboration. The results, published in 2009 and titled *Evidence-Based Recommendations for the Assessment and Management of Sleep Disorders in Older Persons*, provided checklists for the detection and treatment of sleep problems, as well as a list defining recognized sleep disorders. The report offered no information about the financial ties of its authors.

To improve nighttime sleep, the report recommended that older adults "[a]void daytime napping," although it goes on to say, "If you do nap during the day, limit it to 30 minutes and do not nap, if possible, after 2 pm." The advice to "avoid daytime napping" has been widely circulated and has become part of health lore.

For healthy older adults, one daily nap, taken no later than 6 p.m. at least five days per week, could increase both total sleep time and mental ability.

Subsequently, in 2010, the journal *Sleep Medicine Reviews* published a review of medical literature regarding sleep. No methods were provided, but the paper included a section on "napping, sleep and health in older adults." The authors (one of whom worked on the earlier-referenced 2009 report) noted studies that produced both positive and negative results on the napping issue. However, data from many of the studies reviewed appeared to rely on self-reported questionnaires rather than laboratory-condition measurements.

Concluding that napping increases with age — and even that brief, planned naps may be beneficial — the researchers reported:

> Frequent, unplanned, longer daytime naps in older adults have the

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potential to negatively impact nighttime sleep quality and may be associated with significant negative health consequences such as increased risk of morbidity, cardiovascular illness, falls and cognitive impairment.

Recent rigorous sleep studies

The group at Weill Cornell Medical College has made an impressive effort to address these confusing research results and has come up with some very useful information. Its first study in 2005 evaluated sleep in a group of healthy men and women (16 in each category) with a mean age of 69 years. That study had participants spend an initial three nights and three days in the laboratory. Subjects would nap for two hours and have their cognitive skills subsequently tested. Researchers electronically monitored sleep and used closed-circuit video and continuous electroencephalography (EEG, to measure brain waves and eye movements during sleep) monitoring to determine when participants were, in fact, sleeping. Participants visited the laboratory a second time after a week or so at home.

The group's second study, published in 2011, went further in both the duration studied (about one month) and the methods used to monitor their subjects. Again, these participants were healthy older individuals (11 men and 11 women aged 50 to 88, with a mean age of 70). The protocol involved a baseline laboratory stay of three consecutive nights and two intervening days, followed by a four-week-long in-home phase. Participants were randomly assigned to a 45-minute or two-hour nap to be completed by 6 p.m. at least five days a week.

After the initial laboratory session, there were two subsequent sessions — one after two weeks and another after four weeks — that lasted two nights and the intervening day. At-home monitoring included sleep logs (completed by the subjects twice a day) as well as the continuous wearing of "Actiwatches," watch-shaped devices worn on the nondominant arm that continuously monitored rest-activity cycles and recorded movements. The data were automatically sent to a computer and analyzed.

> The [Weill Cornell Medical College's] research results ... put to rest the notion that naps should be avoided.

Researchers employed the same monitoring as in the first study, via EEG and closed-circuit television. Subjects' mental performance was measured every two hours using four parts of a Performance Assessment Battery. These tests are a subset "designed to assess performance changes in sustained operations and sleep deprivation" and are the product of 30 years of Department of Defense research. The tests chosen for the sleep study measured proficiency in logical reasoning, mathematical processing, six-letter memory search and reaction time.

The researchers concluded that "a daytime nap may improve neurobehavioral functioning in healthy older adults without negatively affecting subsequent nighttime sleep," with participants showing significant improvements in performance from baseline. Both long (two-hour) and short (45-minute) naps significantly increased participants' 24-hour sleep amounts, and neither had a negative effect on nighttime sleep.

Given the rigorous methods used in its studies, the Weill Cornell Medical College research appears more sound than the privately funded IOM evidence and recommendations. The medical college's research results thus put to rest the notion that naps should be avoided. Indeed, they should be encouraged, as they have also proven beneficial to seniors. ✦

Dangerous Lack of Evidence Characterizes Prescription Drug Use in Children

Doctors know that from a medical perspective, children are not merely "little adults." They have their own unique biology, and this extends to the way they process and respond to medications. Despite this fact, most drugs currently on the market, and those frequently administered to children, have not been tested in this population.

Although off-label use of medications in children (that is, using a drug to treat a disease for which the Food and Drug Administration [FDA] has not approved the drug) is legal, it can undoubtedly be dangerous. In 1999, researchers estimated that 81 percent of all medications used in children had neither sufficient trial data nor adequate labeling regarding pediatric use. A more recent study from 2009 estimated that 62 percent of all outpatient visits to a pediatrician result in a prescription for an off-label use.

There are several reasons for the relative lack of pediatric data with respect to pharmaceuticals. Pediatric clinical trials are generally more difficult to conduct than those in adults. For one, parents are generally reluctant to enroll children in a risky clinical trial with no guarantee of benefit. This understandable hesitation is exacerbated for trials involving medications developed primarily to benefit adults, such as those for heart disease and other chronic conditions of older age. Even if recruitment were not a challenge — the prevalence of these diseases is lower in children — it takes longer to find enough children to ensure that a trial will detect some benefit with the drug.

Perhaps a more fundamental reason for the dearth of pediatric drug data is simple dollars and cents. Children, as a smaller and healthier population, are generally not as lucrative a market for drug companies as adults are. This is compounded by the increasing reliance by the pharmaceutical industry on "lifestyle" medications (such as those for heartburn and depression) for middle-aged and older adults, who will take the drugs throughout their lives. Healthier children do not fit neatly into this business model (drugs for attention deficit-hyperactivity disorder, or ADHD, being a notable exception).

> [Children] have their own unique biology, and this extends to the way they process and respond to medications.

Congress responds

Ostensibly to remedy the disparity between adult and child drug data, Congress enacted two laws: the Best Pharmaceuticals for Children Act (BPCA) in 2002 and the Pediatric Research Equity Act (PREA) in 2003. The BPCA (based on an earlier, 1997 law) is a provision that rewards companies by granting a six-month extension on the patent exclusivity period of a drug if the company, at the FDA's request, conducts clinical trials of the medication in children.

The PREA, on the other hand, grants the FDA the authority to require pediatric clinical trials for certain drugs, including those off-patent, when the agency determines that such studies are necessary. Both the BPCA and the PREA were permanently reauthorized in the July 2012 FDA Safety and Innovation Act.

Proponents of the laws say that together they create a "carrot and stick" approach, with the BPCA and its granting of additional monopoly time being the "carrot" and the PREA's compulsory provisions the "stick." But critics have argued that this is a case of a carrot with few strings attached and a stick that is rarely wielded.

Impact of the laws: The IOM weighs in

The Institute of Medicine (IOM) released a report this year evaluating the impact of both the BPCA and the PREA (and their predecessor regulations) over the past 14 years. The IOM confirmed that the studies spurred by these two laws have generated much useful information, leading to hundreds of labeling changes such as pediatric dosing instructions or safety information. The report also unequivocally showed that the current system is rife with gaps and that companies that don't comply are not held accountable.

Specifically, the report identified a series of gaps along the regulatory pathway that prevent completion of pediatric drug studies. First, many studies are never undertaken or are delayed until long after a drug is approved. The PREA requires pediatric "assessments" of all drugs and supplements at the time of approval, unless the FDA grants a deferral or a full waiver of this requirement on a case-by-case basis. An internal FDA analysis noted that, of 1,129 new drug and supplement approvals from 2004 through September 2007, most had been granted either deferrals (338) or full waivers (524). In addition, approximately a third of the waivers had been granted for reasons other than those specified in the PREA or that represented an incorrect interpretation of the law.

Compliance regarding deferred studies has not fared much better. Under the PREA, companies do not

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have any financial incentive to complete pediatric studies on already-approved drugs in a timely manner, as with the BPCA. Not surprisingly, the proportion of deferred studies that were officially considered by the FDA to be delayed tripled from 5 percent to 15 percent from 2007 to 2010. Another 65 percent had been required but had not started at any given point during the time period.

[Understandably], parents are generally reluctant to enroll children in a risky clinical trial with no guarantee of benefit.

Many of the studies that do get completed, whether at the time of approval or later, are of poor quality. The IOM cited numerous cases of weak study design and uninterpretable or missing information. The report also revealed multiple instances where tests were conducted on the wrong patient populations and drugs were administered to the wrong study groups. In one case, a trial on a risky medication for severe asthma was conducted in children with normal lung function who had not tried and failed other, safer therapies first, raising a clear ethical red flag (see shaded box on this page).

Whatever rigor the studies lack, once the pediatric trials are completed, the results do not consistently reach the physicians who must ultimately use the study information to guide their practice. The IOM report acknowledged that most doctors likely do not refer to the FDA-approved drug labels prior to prescribing a drug. Nor, it seems, are they reliably informed of the pediatric trials' findings from more traditional sources, such as medical journals. A 2006 *Journal of the American Medical Association* study found that, of the 253 clinical trials undertaken for pediatric exclusivity up to that time, fewer than half (45 percent) were published in a peer-reviewed medical journal. Not surprisingly, those that yielded a finding favorable to the drug were published more frequently (54 percent of studies published) than studies that cast the drug in an unfavorable light (36 percent of studies published).

The ethics of drug experimentation on children

Under the Best Pharmaceuticals for Children Act (BPCA), an obvious ethical quandary arises when children are subjected to risky drug trials. In many of these studies, the primary beneficiaries are not the children but the companies' bottom lines. According to the Institute of Medicine (IOM), "the health benefit expected from requested studies [under the BPCA] is … rarely described or justified [by the Food and Drug Administration (FDA)]." The problem of ethics is further exacerbated by the outsourcing (at least in part) of the majority of pediatric trials to companies operating in foreign countries. In many cases, the studies involve poor children whose families will likely never be able to afford the medication under investigation.

Beyond the ethical question of the trials' lack of benefits for the subjects is the issue of unethical study design of some of the trials. Perhaps the most concerning finding in the 2012 IOM report on the effectiveness of laws regarding pediatric drug trials was that many companies conducted placebo-controlled trials when there was an effective treatment available, thus denying half of the children in the trials safe and effective therapies, even for life-threatening conditions such as asthma and hypertension. The IOM, while stopping short of calling such trials unethical, was clearly alarmed and urged the FDA to strengthen its ethical oversight of the trials.

These studies fly in the face of the long-standing principle that children, as a vulnerable population, should be granted more, not fewer, protections from human research abuses than adults.

Fundamental questions related to the two laws

It is undeniable that some beneficial research has been generated as a result of the BPCA and the PREA. But fundamental questions arise as to the laws' underlying assumptions (and implementation) and whether they are the optimal way to foster more useful evidence on the safety and effectiveness of drugs in children.

Since its enactment, the BPCA in particular has been a focus of controversy. The law allows a company to reap the profits from extra market protection but requires little in return. The IOM has demonstrated the poor quality of some of the studies that have resulted in exclusivity grants. Critical to the root of this problem, a trial does not have to show that a drug is safe and effective in children for the company to receive the six-month patent extension. Although a trial that shows no benefit of the drug can also be helpful if it leads to greater restrictions on its pediatric use, it is often the case that the trial is of such poor quality that it yields no definitive answer and thus no action either way.

The BPCA also creates misaligned interests. The public's interest is in testing the drugs that will be used most often and that will confer the most potential benefit in children, while that of the company is to test the most profitable drugs in its arsenal, regardless of their potential use in children. Although the BPCA specifies that the FDA can only request such studies if they might produce some health benefit in the pediatric population, this vague provision has rarely been translated into practice. According to the IOM, "the health benefit expected from requested studies [under the BPCA] is … rarely described or justified [by the FDA]."

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As a result, the list of 192 drugs for which companies have received the six-month exclusivity bonus through July 2012 is replete with medications for conditions, such as congestive heart failure and high cholesterol, that are exceedingly rare in the pediatric population but are among the top-selling drugs in the adult population. A 2007 analysis of the drugs granted pediatric exclusivity confirmed that the drug classes with the most pediatric exclusivity grants closely matched drug sale patterns in the adult, not pediatric, market.

This is not to say that pediatric data are not necessary for these drugs, including those that will only be used on a few children with rare diseases. They are. But the current system prompts a follow-up question: What is an appropriate reward for a company that produces such data? Six months of patent exclusivity can mean billions in returns for companies that conduct these studies, which often don't cost more than a few million dollars. A 2007 estimate put the average net economic returns on individual drugs at $134 million, with one drug projected to generate an additional $515 million in sales for a pediatric trial that cost $7 million.

Another issue to consider is whether all studies should be considered equal when it comes to that reward. Are studies that are poorly conducted or largely irrelevant to the population studied (children) worth subjecting the majority of adult users of that drug — and taxpayers, through Medicare and Medicaid — to six more months of monopoly pricing privileges?

Finally, critics also question whether pediatric trials should be rewarded, as opposed to being required, in the first place, for companies that arguably have a responsibility to ensure their drugs are safe and effective in all patients who will predictably use them. This is where stronger enforcement of the PREA comes into play, to ensure that pediatric trials are carried out in cases where the FDA deems pediatric studies to be crucial (which is particularly the case for off-patent medicines, for which further studies are naturally of little interest to the manufacturers).

The public's interest is in testing the drugs that will be used most often and that will confer the most potential benefit in children, while that of the company is to test the most profitable drugs in its arsenal, regardless of their potential use in children.

However, the FDA lacks either the authority or the will to hold companies accountable for the many delayed studies documented by the IOM. The FDA's main enforcement tool in these cases is to require a "misbranding" label on the drug involved, a criminal offense that can result in the drug's removal from the market. Of course, this is often an undesirable outcome for the federal government, which relies on these medications for Medicare and other federal health programs. PREA lacks any language on financial penalties in cases of noncompliance, with the exception of deferred studies requested after a drug is approved. It is unclear whether the FDA has ever punished a company, through either a misbranding prosecution or financial penalties, for not completing a required pediatric study on time. The IOM report authors stressed the need for Congress to grant the FDA the authority to impose financial penalties for study delays, but efforts to do so through this year's FDA Safety and Innovation Act failed.

Laws fail to address fundamental cause of lack of child drug data

Over the past decade, the BPCA and the PREA have advanced the production of useful pediatric research. However, the reality remains that a large number of drugs on the market still have no evidence of safety or effectiveness in children. This is an entirely predictable outcome of the current system of incentives for for-profit pharmaceutical research. Studying children is simply not a good return on investment for an industry that relies on government-granted monopolies for its drugs, regardless of their public health benefit.

Policymakers will not find the solution by granting even longer monopolies with few strings attached (as the BPCA does through the six-month market exclusivity period), but by mandating pediatric studies, whenever necessary, as a condition of existing monopolies. Strengthening and enforcing the PREA would require the industry to generate more ethical, timely and useful data to guide the safe use of prescription drugs in this most vulnerable population and would actually hold accountable companies that fail to follow through on this obligation.✦

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2. Recent worsening of the rate of serious state medical board disciplinary actions in Texas compared to that of other states (Report p. 9)

Each year, Public Citizen ranks state medical boards based on their rate of serious disciplinary actions per 1,000 physicians. Texas had initially, in our 1995 and 1996 rankings, stood among the top one-half of states, at numbers 25 and 23, respectively. Since 1997, however, Texas has consistently been among the bottom one-half of states in the rate of seriously disciplining doctors.

B. Causes of dangerously inadequate discipline by the Texas Medical Board (Report pp. 11-16)

1. Serious funding and staffing problems

Currently, the Medical Board brings in about $60 million from licensing and renewal fees over a two-year budget period. Because of a state legislature policy decision, the Medical Board gets to keep only one-third, $20 million, of the licensing and renewal fees over the two-year period, while two-thirds, or $40 million, is turned over to the state general revenue fund. (Report p. 12)

From 2006 to 2011, there has been a 57 percent increase in the number of complaints to the board. But during this interval, the board's budget, adjusted for inflation, increased only 12 percent, and the number of staff increased by only 16 percent. (Report p. 12)

2. Predictable backlog of complaints because of staffing shortages

As of Aug. 31, 2011, 454 physician investigations in the agency had been open for at least one year, including cases going back as far as 2007, 2006 and 2005. Moreover, the Medical Board resolves only about one-third of documented complaints within the 180-day statutory time frame for resolving complaints. Furthermore, the Medical Board acknowledges that because of staff shortages, it has not been able to do complete investigations on 87 doctors who have been sanctioned by hospital or managed care peer review committees. (Report pp. 14-15)

3. Adverse impact of backlog and staffing deficiencies on board actions and Texas patients' risks

Fourteen percent of complaints that originate with the Medical Board itself include the statutory requirement to review the medical competency of a physician against whom three or more malpractice suits have been filed within five years. (Report p. 15)

Given the length of time it is taking to complete complaint investigations, many Texans should be concerned that they may be at risk for substandard care in cases involving quality concerns about doctors who should have been but were not disciplined by the board. (Report p. 15)

In response to our inquiry of the board about inaction concerning doctors with clinical privilege actions but no board action against them (discussed in section A. 1. of this letter), we were told that the Medical Board does not have the resources to determine why it could find no record of its own action for 59 percent (87) of doctors with hospital peer review reports, or why the Medical Board never received the hospital report. (Report p. 15-16)

C. Recommendations for a more effective Texas Medical Board (Report pp. 16-17)

1. Allow the Medical Board to keep a greater share than the current one-third, ideally all, of the revenue it generates. (Report p. 16)
2. Appoint an independent Medical Board enforcement monitor, similar to that used to address problems involving the Medical Board of California's performance. The monitor could: (a) advocate for the Medical Board; (b) review the impaired physician program to ensure that impaired practitioners are properly monitored, tested, counseled, etc.; (c) monitor enforcement policies and practices to ensure that disciplinary actions and consent orders are commensurate with violations of the Texas Medical Practice Act; and (d) oversee investigation caseloads to ensure that investigations lasting for long periods of time do not compromise the safety of Texas patients. (Report p. 16)
3. Consider instituting random practice audits of physicians as a proactive quality assurance mechanism. The Office of Inspector General (OIG), U.S. Department of Health and Human Services, has highlighted the use of random practice audits. The OIG has also noted the College of Physicians and Surgeons of Ontario experience in making the most extensive use of random practice audits. (Report p. 17)

In summary, this report provides evidence concerning the inadequate capacity of the Texas Medical Board to protect Texas patients from preventable medical harm. We hope that you will take these findings and suggestions seriously and implement the proposed changes as soon as possible.

To view the entire Public Citizen report on the Texas Medical Board, visit http://www.citizen.org/hrg2063 ✦

HRG Works for You!

Our latest work involves: brain stents, superbug infections and Alzheimer's treatment

The work of Public Citizen's Health Research Group (HRG) doesn't end with its *Health Letter* and *Worst Pills, Best Pills News* publications. HRG uses current academic research, government data and information from whistleblowers to advocate for consumers by:

- petitioning the government to remove unsafe drugs or medical devices from the market, and to require warnings of dangerous side effects on other drugs;
- testifying before government committees and arguing against approval of unsafe or ineffective drugs and medical devices;
- writing letters to government agencies about the adverse effects of drugs and medical devices; and
- lobbying Congress to strengthen the regulatory oversight of drugs and medical devices.

Our latest consumer advocacy includes:

- **FDA Rejects Petition against Brain Stent System — 8/8/2012 —** The Food and Drug Administration (FDA) rejected Public Citizen's Dec. 21, 2011, petition to ban the Wingspan brain stent system. The agency took this action despite evidence from a randomized controlled study showing that for every 11 patients treated with the Wingspan system, one additional patient dies or suffers a stroke within 30 days, compared to patients treated with aggressive medical therapy alone. (This study was stopped because of the high stroke and death rate.) Public Citizen's Health Research Group continues to insist this device be taken off the market because the risks clearly outweigh the benefits.

- **NIH Failed to Meet Ethical Obligations — 8/24/2012 —** In a letter to the editor published by *The Washington Post*, HRG Deputy Director Dr. Michael Carome and Director Dr. Sidney Wolfe called out the National Institutes of Health's Clinical Center for not alerting the public and state and local health officials sooner regarding an outbreak of multidrug-resistant Klebsiella that began in June 2011 and lasted until December 2011. Carome and Wolfe asserted that by not issuing a timely alert, the Clinical Center denied patients considering inpatient care at the hospital the opportunity to weigh the risk of exposure to the superbug against the benefits of being hospitalized there. Of the 17 patients who suffered the infection, 11 died.

- **Lawsuit to Prevent Dangerous Alzheimer's Treatment — 9/5/2012 —** Having petitioned the FDA to ban the 23-milligram dose of Alzheimer's drug Aricept, Public Citizen filed a lawsuit against the FDA to finally act on HRG's petition, which states that this dosage of Aricept causes severe — potentially fatal — side effects. The adverse events associated with Aricept 23, and reported in the original petition of May 18, 2011, include higher incidence of vomiting, slow pulse rate and nausea.

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

Product Recalls

August 9, 2012 – September 5, 2012

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

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

V Maxx Rx, All Natural Male Enhancement, 10-count bottle. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: Samples tested by the FDA were found to contain sulfoaildenafil (an analogue of sildenafil, an FDA-approved drug used in the treatment of male erectile dysfunction), making these products unapproved new drugs. Lot #s: 301000 and 301001. The Menz Club LLC.

V Maxx Rx, All Natural Male Enhancement, five-count blister pack. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: Samples tested by the FDA were found to contain sulfoaildenafil (an analogue of sildenafil, an FDA-approved drug used in the treatment of male erectile dysfunction), making these products unapproved new drugs. Lot #s: 101108, 101109 and 101110. The Menz Club LLC.

V Maxx Rx, All Natural Male Enhancement, one-count blister pack. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: Samples tested by the FDA were found to contain sulfoaildenafil (an analogue of sildenafil, an FDA-approved drug used in the treatment of male erectile dysfunction), making these products unapproved new drugs. Lot #s: 101108, 101009, 101010 and 101011. The Menz Club LLC.

Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Daytrana (Methylphenidate) Transdermal System Patch, 15 mg over nine hours (1.6 mg/hour), one patch per pouch, packaged in 30-count boxes. Volume of product in commerce: 231,270 patches. Miscalibrated and/or defective delivery system: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #: 53823, expiration date 08/2012. Noven Pharmaceuticals Inc.

Daytrana (Methylphenidate) Transdermal System Patch, 20 mg over nine hours (2.2 mg/hour), one patch per pouch, packaged in 30-count boxes. Volume of product in commerce: 177,900 patches. Miscalibrated and/or defective delivery system: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #: 55302, expiration date 12/2012. Noven Pharmaceuticals Inc.

Daytrana (Methylphenidate) Transdermal System Patch, 30 mg over nine hours (3.3 mg/hour), one patch per pouch, packaged in 30-count boxes. Volume of product in commerce: 121,530 patches. Miscalibrated and/or defective delivery system: Out-of-specification results for mechanical peel force and/or the z-statistic value, which relates to the patient's ability to remove the release liner from the patch adhesive prior to administration. Lot #: 56506, expiration date 12/2012. Noven Pharmaceuticals Inc.

Leflunomide Tablets, 10 mg, 30-count bottle. Volume of product in commerce: Unknown. Subpotent (single-ingredient drug): Product did not meet specifications. Lot #: GY4197, expiration date 11/2007. Apotex Corp.

Leflunomide Tablets, 10 mg, 1,000-count bottle. Volume of product in commerce: Unknown. Subpotent (single-ingredient drug): Product did not meet specifications. Lot #: GZ1273, expiration date 11/2007. Apotex Corp.

Leflunomide Tablets, 20 mg, 1,000-count bottle. Volume of product in commerce: 31. Subpotent (single-ingredient drug): Product did not meet specifications. Lot #: GZ1274, expiration date 11/2007. Apotex Corp.

Meloxicam Tablets, USP, 15 mg, 100 tablets per bottle. Volume of product in commerce: 1,749 bottles. Tablet thickness: Recall was initiated due to the presence of one slightly oversized tablet in a bottle of the identified lot. Lot #: 7212558, expiration date 12/2012. Apotex Corp.

Mercaptopurine Tablets, 50 mg, packaged in 60-count bottles. Volume of product in commerce: 25,516 bottles. Failed USP dissolution test requirements: The recalled lots do not meet the specification for dissolution. Lot #s: 11A003, 11A004 and 11A005, expiration date 01/2013; 11L071 and 11L072, expiration date 10/2013. Prometheus Laboratories Inc.

Mercaptopurine Tablets, 50 mg, 250-count bottle. Volume of product in commerce: 2,569 bottles. Failed USP dissolution test requirements: The recalled lots do not meet the specification for dissolution. Lot #s: 11B009, expiration date 01/2013; 11L073, expiration date 10/2013. Prometheus Laboratories Inc.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

Acrylic Bathtubs, Whirlpools and Air Massage Bathtubs. The grab bars used on the products can loosen and break, posing a fall hazard to consumers. Mansfield Plumbing Products LLC, at (800) 999-1459 or www.mansfieldplumbing.com.

Air Compressors. The air compressor motor can overheat, posing a fire hazard. DeVilbiss Air Power Co., at (866) 885-1877 or www.porter-cable.com.

Animal Snap Bracelet. The metal snap band can wear through the fabric covering, resulting in exposed sharp edges and posing a laceration hazard. Toysmith of Sumner, at (800) 356-0474 or www.toysmith.com.

Beadboard Bunk Beds. The front upper horizontal panel on the bunk beds can crack or break, posing a risk of injury to the consumer. PBteen, a division of Williams-Sonoma Inc., at (855) 217-5223.

Bicycle Brakes. The bridge of the brakes can crack, posing a fall hazard to riders. Eecycleworks LLC, at (855) 838-6924 or www.eecycleworks.com.

Bicycle Brake Levers. The adjuster cap and brake cable can slide out of position and make the brakes nonoperational. This can cause a rider to lose control of the bicycle and crash. Specialized Bicycle Components Inc., at (877) 808-8154 or www.specialized.com.

Bumbo Baby Seats. Babies can maneuver out of or fall from the Bumbo seat, posing a risk of serious injuries. Bumbo International Trust, at (866) 898-4999 or www.recall.BumboUSA.com.

CareBears Pacifiers. The pacifiers fail to meet federal safety standards. The nipples can separate from the base, posing a choking hazard to young children. Yi Wu Jiangyi Plastic Co., at (212) 686-5221 or www.pacifierrecall.net.

Crib Fringe. The narrow fabric strip connecting individual fabric triangles presents a strangulation hazard to young children. Babylicious Products Inc., at (855) 684-8399 or www.babylicious.ca/recall.

Dupli-Color Perfect Match Automotive Paint. The aerosol paint canister can leak, posing a fire hazard to consumers if the paint can is stored near a source of ignition. Sherwin-Williams Co., at (888) 304-3769 or www.sherwin-williams.com.

Emerson Corsair Ceiling Fans. The ceiling fan's hanger bracket can spread apart due to heat from the motor and/or out-of-balance operation, causing the fan to fall from the ceiling. This poses a risk of injury to bystanders. Air Comfort Products, a division of Emerson Electric Co., at (866) 994-8759 or www.emersonfans.com.

Energizer Rotating Night-Lights. The night-lights can overheat and smoke, posing a burn hazard to consumers. Ningbo Sun-alps Industry Develop Co. Ltd., at (800) 383-7323 or www.energizer.com.

EOS Rebel T4i Digital SLR Cameras. A chemical used in the camera's rubber grips can result in a reaction that changes the grips from black to white and poses a risk of skin irritation to the consumer. Canon U.S.A. Inc., at (855) 902-3277 or www.usa.canon.com.

Gerber Bear Grylls Parang Machetes. A weakness in the area where the handle meets the blade can cause the handle or the blade to break during use, posing a laceration hazard. Gerber Legendary Blades, at (877) 314-9130 or www.gerbergear.com.

Indoor Pet Heating Comfort Pad Mats. The heated mats have poor wiring and construction, posing fire and electrical shock hazards to consumers. Fuzhou Senhor Leisure Products Co. Ltd., at (888) 941-5079 or gsiamazon@gmail.com.

Krylon Triple Thick Crystal Clear Glaze and Krylon Indoor/Outdoor Crystal Clear Acrylic Paint. The aerosol canister can leak, posing a fire hazard to consumers if the can is stored near a source of ignition. Sherwin-Williams Co., at (888) 304-3769 or www.sherwin-williams.com.

Legrand Under-Cabinet Power and Lighting Four-Outlet Power Strip. The electrical wires are reversed on the receptacles on the power strips, posing a risk of electrical shock. Legrand Wiremold, at (800) 617-1768 or www.legrand.us.

LG Electronics and Kenmore Elite Gas Dryers. The gas valve in the recalled dryers can fail to shut off properly, continuing to heat the dryer and its contents after the drying cycle is complete. High temperatures inside and on the exterior surface of the dryers can scorch the drum and burn or damage the dryer contents, posing a risk of burn, fire and smoke inhalation. LG Electronics Inc., at (866) 223-5355 and www.lg.com/us (LG consumers) or (888) 375-9741, www.sears.com (Sears consumers).

Mother's Touch/Deluxe Baby Bathers. When the bather is lifted and/or carried with an infant in it, its folding wire frame can suddenly disengage from the side hinge, dropping the baby out of the bather. This poses a fall hazard and a risk of serious head injury to infants. Summer Infant Inc., at (800) 426-8627 or www.summerinfant.com/batherrepairkit.

Mr. Coffee Single-Cup Brewing System. A build-up of steam in the water reservoir can force the brewing chamber open and expel hot coffee grounds and water, posing a burn hazard. Sunbeam Products Inc., at (800) 993-8609 or www.mrcoffeerecall.com.

CONSUMER PRODUCTS (continued)

PRO VIBE Carbon Bicycle Handlebars. The recalled handlebars can break during riding, posing a fall hazard. Great Go Cycles Inc., at (800) 353-4719 or www.shimano.com.

Rayovac NI-CD and Rayovac NI-MH Cordless Tool Battery Packs. The replacement battery pack can explode unexpectedly, posing a risk of injury to consumers. BatteriesPlus LLC, at (877) 856-3232 or www.batteriesplus.com.

Recycled Silk Floor Mats. The recalled silk mats can have a tack or staple woven into the fabric strips. The tack or staple can cut consumers, posing a laceration hazard. Cost Plus Inc., at (877) 967-5362 or www.worldmarket.com.

Scooter. The one-piece plastic platform that covers the front wheel base can break, posing a laceration hazard to children. Micro-Mobility Ltd., at (888) 236-5657 or http://www.kickboardusa.com.

Shower Light Trim. The shower light's trim and glass lens can fall from the ceiling fixture, posing an impact and laceration hazard to consumers. Cooper Lighting LLC, at (800) 954-7228 or www.cooperlighting.com.

Snowpulse Avalanche Airbags. A leak in the airbag's cartridge can result in the airbag not deploying, posing a risk of death and injury in the event of an avalanche. Snowpulse SA, at (800) 451-5127 or www.snowpulse.com.

Teryx4 Recreational Off-Highway Vehicles. The steering gear assembly and front brakes can fail, resulting in the loss of steering and braking. This poses a risk of injury or death. Kawasaki Motors Corp. USA, at (866) 802-9381 or www.kawasaki.com.

Traveller Recreational Tubes. Contact with the inflatable tube can result in severe skin irritation or burns. Tractor Supply Co., at (877) 872-7721 or www.tractorsupply.com/TravellerTireRecall.

Tree House Studio Clear Acrylic Matte Coating. The aerosol canister can leak, posing a fire hazard to consumers if the can is stored near a source of ignition. Sherwin-Williams Co., at (888) 304-3769 or www.sherwin-williams.com.

Various Models of Huffy, Iron Horse, Mongoose, Northwoods, Pacific, Razor and Schwinn Bicycles. Pedals on the bicycles can loosen or detach during use, posing a fall hazard to the rider. Meijer Inc., at (800) 927-8699 or www.meijer.com.

Wilson and Fisher White Cast Bistro Table and Chairs Set. The chairs can break during normal use, posing a fall hazard to consumers. Zest Garden, at (800) 893-3006 or www.biglots.com.

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

Outrage of the Month!

Deficiencies of the Texas Medical Board

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

The following letter accompanied the Aug. 22, 2012, report of Public Citizen's Health Research Group regarding disciplinary actions taken against physicians by the Texas Medical Board.

Dear Governor Perry:

The attached report documents why you need to initiate immediate action to improve the performance of the Texas Medical Board (hereafter referred to as "Medical Board") and thereby protect patients in Texas from physicians who should have been, but were not, disciplined.

The report contains three sections (summarized below, with specific references to pages in the full report where the points are discussed in more detail):

A. Evidence of dangerously inadequate discipline by the Texas Medical Board

B. Causes of dangerously inadequate discipline by the Texas Medical Board

C. Recommendations for a more effective Texas Medical Board

A. Evidence of dangerously inadequate discipline by the Texas Medical Board (Report pp. 4-11)

1. 459 physicians with Texas clinical privilege sanctions — 75 percent by hospitals — but not disciplined by the Texas Medical Board

The reasons for these sanctions included immediate threat to health or safety of patients, incompetence/negligence/malpractice, substandard care, sexual misconduct, and inability to practice safely/alcohol/substance abuse/physical impairment.

The seriousness of the actions taken for the above offenses includes summary/emergency suspension of clinical privileges, summary/emergency limitation/restriction/reduction of clinical privileges, revocation of clinical privileges, suspension of clinical privileges, and denial of clinical privileges for a large proportion of these physicians.

Malpractice payouts against these physicians. Almost one-half (47 percent) of these physicians (216 physicians) had one or more malpractice payouts for a total of 473 payouts, an average of more than two for each of these 216 physicians, one of whom had 22 malpractice payouts.

see OUTRAGE, page 6