



# Obama Administration Refuses to Protect Doctors-in-Training From Dangerous Work Shifts

In 2010, Public Citizen and other groups filed a petition calling on the Occupational Safety and Health Administration (OSHA) to fulfill its legal obligation and protect 110,000 resident physicians from working extremely long shifts that have been shown to harm not only them, but also their patients. In September 2011, the Obama administration denied the petition, despite clearly acknowledging that OSHA had a legal obligation to protect residents from hazardous work hours. OSHA instead chose to defer, as it did under the Bush administration, to the Accreditation Council for Graduate Medical Education (ACGME), the private organization that has traditionally been responsible for setting and enforcing resident work-hour guidelines.

## The resident work-hour issue

The problem is straightforward: Tired residents are a danger to themselves and to their patients. Numerous studies have confirmed that working shifts longer than 24 hours results in fatigue and more medical errors, some of which may be life threatening to patients. Furthermore, residents working longer on-call shifts suffer more motor vehicle accidents, needlestick injuries, mood disorders and obstetric complications than their more well-rested peers. Yet, the Obama administration ignored this evidence and rehashed a series of discredited Bush-era arguments to justify its inaction.

## Public Citizen’s first work-hour petition and subsequent weak enforcement

Last year’s petition was the second time Public Citizen has demanded that OSHA fulfill its legal obligation to young doctors-in-training. The first was in 2001. At that time, the Bush administration rejected the petition with the argument that the ACGME was the appropriate organization to deal with the issue. That administration placed its faith in new ACGME work-hour guidelines set to be released in 2003. The fact that the ACGME is a private organization primarily representing residents’ employers rather than residents themselves was apparently not seen as a problem by the administration.

It quickly became clear that this faith in the ACGME was misplaced. The 2003 guidelines were patently insufficient to address the dangers of long work hours, allowing residents to work up to 30 hours straight and permitting 80-hour workweek limits to be averaged over the course of a month, thereby enabling residents to work as many as 100 hours in one week.

## Institute of Medicine report on work hours

The inadequacy of the ACGME guidelines was confirmed by a 2009 Institute of Medicine (IOM, part of the National Academy of Sciences) report that called for much safer work-hour limits. In addition, ACGME enforcement of its own duty-hour rules was repeatedly shown to be deficient.

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In a nationwide, anonymous IOM survey of more than 4,000 first-year residents, 84 percent reported hours of work in violation of the 2003 ACGME standards. This number far exceeded the rates of violations reported by resident physicians and residency programs to the ACGME, indicating both that widespread underreporting exists and that the ACGME’s enforcement has been ineffective.

This inability to adequately monitor its own rules is likely due to the ACGME’s reliance on resident self-reports. Residents are inherently reluctant to report work-hour violations, as they may fear loss of their program’s residency accreditation as a result of their complaint. Thus, as long as the

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**OSHA, from page 1**

**Although it has now rejected two requests to set an actual standard to regulate the number of hours that medical residents work, OSHA already has the authority to act on the problem.**

ACGME relies on resident self-reports as its primary means of ensuring compliance with its rules, pervasive underreporting by residents, as clearly documented in the IOM report, will hinder any meaningful enforcement.

Under pressure to update its rules, the ACGME released new guidelines in June 2010, limiting medical interns — first-year residents — to 16-hour shifts but inexplicably allowing upper-level residents to work up to 28 hours straight. Contrary to detailed IOM recommendations, the ACGME made no other major changes to its inadequate 2003 guidelines.

**Obama administration denial of petition**

In our 2010 petition to OSHA under the Obama administration, Public Citizen pointed out that the new guidelines were further evidence of the need for federal oversight of the issue. Considering the ACGME's track record and the refusal of the organization to make any major changes to its guidelines, the Obama administration's refusal to act is particularly alarming. In his Sept. 14, 2011, denial letter, OSHA assistant secretary of labor Dr. David Michaels admitted that fatigue due to extended work hours can harm the health of employees in a wide range of fields, including medical residents. He also acknowledged that medical residents, as workers, fall under OSHA's jurisdiction and are entitled to all the legal protections enjoyed by any other worker.

Yet, despite this acknowledgment, OSHA chose to ignore its legal obligation to protect residents, instead justifying its denial through a series of irrelevant arguments that in no way negated this central premise: OSHA is clearly responsible for ensuring the health and safety of medical residents.

**OSHA's existing authority to give better protection**

Although it has now rejected two requests to set an actual standard to regulate the number of hours that medical residents work, OSHA already has the authority to act on the problem. Under the General Duty Clause of the Occupational Safety and Health Act of 1970, the law that created OSHA, employers are required to provide a workplace free from hazards that are likely to harm employees. This language gives OSHA the authority to limit the number of hours that medical residents work, preventing physician fatigue and medical errors — an authority it has, unfortunately, yet to use.

In our November 3 letter responding to OSHA's 2011 denial, Public Citizen called on OSHA not only to enforce existing work-hour limits through the agency's General Duty Clause, but also to protect medical residents who blow the whistle on work-hour abuses. Currently, residents who inform the ACGME of potential violations have no recourse in the event that their hospital or residency program takes retaliatory action. Unlike the ACGME, OSHA can protect these whistle-blowers, but as is the case with the General Duty Clause, there is no evidence that OSHA has ever utilized this tool to hold accountable teaching hospitals that have retaliated against residents.

By denying Public Citizen's petition, the Obama administration has opted to blindly follow the lead of the Bush administration in abdicating its responsibility to oversee resident work hours. Only by using its existing authority, and fulfilling what is clearly its legal obligation, can OSHA protect thousands of resident physicians and their patients from harm. ♦

# The Origins and Progress of Public Citizen's Health Research Group: The First 40 Years

*As Public Citizen celebrates its 40th anniversary, Dr. Sidney Wolfe, director of the Health Research Group, reflects on the group's early days and some victories over the past 40 years.*

This month — November 2011 — marks the 40th year since the start of the Health Research Group in November 1971. Our first group effort was a petition to ban the very widely used food, drug and cosmetic Red Dye No. 2, because there was evidence that it could cause cancer, genetic toxicity and other risks we deemed unacceptable for such a cosmetic, of which 1.5 million pounds were being consumed each year. After a battle lasting several years, Red Dye Number 2 was finally banned in 1976.

But the origins of the Health Research Group go back to earlier in 1971, while I was still at the National Institutes of Health (NIH). A government physician I knew called asking for help: he relayed that one-half of the intravenous (IV) fluids in the U.S. were potentially contaminated with a rare type of bacteria, a situation that had already resulted in nine deaths and 150 cases of blood infections in hospitals. Instead of recalling these contaminated products — as an agency of the Public Health Service, such as the Food and Drug Administration (FDA), should be expected to do — the FDA had been convinced by the manufacturer, Abbott Laboratories, that the resultant shortage of IV fluids would present an even greater health hazard than the deaths and infections caused by the fluids. It was not difficult for me to determine that there were more than enough IV fluids stockpiled by other manufacturers to eliminate the possibility of a shortage.

Ralph Nader and I wrote a letter to the FDA commissioner on March 21, 1971, demanding the immediate recall of all these Abbott IV fluids. Although

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**Working on these projects nights and weekends, including ... Red Dye No. 2, the group was officially launched that November [1971].**

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the FDA refused to comply with our demand hours after receiving our letter, the next day, after the news of our petition was covered by all the network news programs and in most major U.S. newspapers, the FDA announced the start of a recall. When the toll of damage was finally tallied, there were more than 100 deaths and more than 1,000 serious infections caused by the Abbott IV fluids. The government later stated that this “would later be recognized as the largest and most lethal known outbreak of nosocomial [health-care caused] infection associated with widespread distribution of a contaminated medical product in the United States.” This is still true as of now.

The publicity attendant to the recall precipitated a series of calls to me — still working at NIH — about other serious public health problems that people wanted me to work on, ranging from other dangerous drugs to mercury poisoning in workers. Working on these projects nights and weekends, including the above-mentioned Red Dye No. 2, the group was officially launched that November. Two months later, because this new work was so exciting and rewarding, I wound down my NIH research, and at the beginning of 1972, I started working full time at Public Citizen.

Whereas the majority of the Health Research Group's work during these 40 years has concerned inadequacies of FDA regulation of drugs and medical devices, we have also been involved in a large number of projects concerning worker health and safety and patient

safety. Our patient safety focus involves analysis and oversight over the inadequate job most state medical boards do in disciplining the small fraction of physicians whose records show they pose a threat to the safety of their patients. Summaries of our work in these three areas follow:

## **FDA and prescription drugs**

Since 1971, we have filed 34 petitions with the FDA to ban prescription drugs, and to date, 23 of these (68 percent) have been granted, including petitions involving widely prescribed drugs such as the painkiller Darvon; painkillers and arthritis drugs, such as Oraflex, Bextra, Suprol and Butazolidin; the weight-loss drug Meridia; diabetes drugs DBI and Rezulin; the attention deficit disorder drug Cylert; the antibiotic Trovan; and, of course, the infected Abbott IV fluids.

Seven other drugs we have petitioned to have banned are still on the market but in extremely limited use.

In the case of many of the drugs eventually taken off the market, we warned readers of our monthly publication *Worst Pills, Best Pills News* not to use them — often years before the FDA finally decided to ban the drugs. Our book, *Worst Pills, Best Pills*, the predecessor to *Worst Pills, Best Pills News*, sold 2.5 million copies and has thereby helped many people avoid the worst, most dangerous pills.

Aiding our efforts to affect decisions on drug approvals or withdrawals, litigation against the FDA by the Public Citizen Litigation Group has forced the agency to update its website, at least two days in advance of an advisory committee meeting, with all of its internal reviews of drugs. These procedures allow the Health Research Group to participate in meetings and be meaningfully informed about the safety and efficacy issues of the particular drug.

[see ANNIVERSARY, page 4](#)

But there is still much work to be done regarding abuses by pharmaceutical companies (see page 12). This is evidenced by our 2010 study reviewing the last 20 years of payments by drug companies to the federal government or state governments for illegal (criminal or civil) activities. Half of the \$20 billion in penalties drugmakers have paid was in the last five years, and the drug industry has now greatly eclipsed the defense industry as the number one defrauder of the federal government. The two largest criminal penalties in the history of this country were both levied within the past three years and were both against drug companies: Eli Lilly paid a criminal penalty of \$515 million in January 2009, only to be “beaten” by Pfizer, which paid \$1.2 billion in September of the same year.

### Occupational health

We have filed 19 petitions with the Occupational Safety and Health Administration (OSHA), and 13 of these (68 percent again) have been granted — in each case, the Public Citizen Litigation Group had to file suit against OSHA. Successful petitions have included benzene, ethylene oxide, cadmium, workplace smoking and chromium VI (hexavalent chromium). We recently petitioned OSHA, for the second time, to regulate the number of hours medical residents are allowed to work, because the current 80 hours for most of them is both a threat to their own health and that of patients they care for (see article on page 1).

### Patient safety and health care access

As mentioned above, the Health Research Group has been carefully monitoring the performance of state medical boards’ discipline of those physicians who threaten the health of their patients. Each year since 1999, we have ranked the rate of serious disciplinary actions per 1,000 doctors in

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each state. It is usually the case that the states doing the best job of protecting the public — perennially Kentucky, Arizona, Ohio, Colorado, Oklahoma and Alaska — discipline doctors about five times more often (per 1,000 doctors) than the states at the bottom of the rankings.

We also issued a report highlighting that almost 50 percent of U.S. hospitals have never seriously disciplined even one of their doctors with admitting privileges in the more than 20 years since reports of such activity have been filed with the federal National Practitioner Data Bank. Another Health Research Group report found that there were 220 U.S. physicians, with serious restrictions or revocations of their hospital admitting privileges, found by hospitals to present an “immediate threat to the health or safety” of hospital patients but never disciplined in any way by a state medical board.

Other studies concerning patient safety include several reports naming the hospitals in this country that illegally “dumped” very sick patients from their emergency rooms without having properly diagnosed, treated and stabilized them. We have also done three reports listing those hospitals that are performing dangerously large numbers of cesarean sections along with the hospitals doing reasonable, much lower numbers of cesareans.

Two of our reports have ranked state Medicaid programs from best to worst

regarding their provision of adequate coverage and state-specific control over this increasingly important program for people with reduced ability to afford currently unaffordable private health insurance. We have continued to support a single-payer (Medicare for All) health insurance plan without the innumerable weaknesses of so-called “Obamacare.”

### The Health Research Group as a team

We describe our work as research-based health advocacy, and we now have three full-time physicians as well as a former FDA pharmacologist, a former member of the Department of Health and Human Services Office of Inspector General’s Office and a lawyer with a degree in public health on our staff. The impact of our work is enormously magnified by the frequent support of colleagues, including the threat of litigation against the government by the Public Citizen Litigation Group as well as our collaboration with Public Citizen’s Congress Watch division when good legislation needs to be supported or — as in the past many years especially — when dangerous legislation needs to be stopped. Readers of our two publications (*Health Letter* and *Worst Pills, Best Pills News*) and Public Citizen members, along with generous donors, also push our work forward and are much appreciated.

The Health Research Group has helped to train more than 20 medical students and even more medical residents in our type of advocacy, and happily, many of them have gone on to work that incorporates these principles.

After my first year was over, in 1972, I said this would probably be the last job I would ever have. I am thankful to Public Citizen for having provided the opportunity to do this exciting public health work and hope I will still be here when we celebrate our 50th anniversary.

*\* Most of the full reports referred to above (from 1992 to 2011) can be found at [www.citizen.org/hrpublications](http://www.citizen.org/hrpublications). ♦*

# Product Recalls

## October 1, 2011 – October 31, 2011

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](http://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

**Male Enhancer Capsules**, 60-capsule bottles. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: FDA lab analysis found product contained tadalafil, an FDA-approved drug used to treat erectile dysfunction, making this product an unapproved new drug. Lot #s: All lots. U.S.A. Far Ocean Group LLC.

**Slim Xtreme Herbal Slimming Capsule**, 30-capsule bottles. Volume of product in commerce: 39,700 bottles. Marketed without an approved NDA/ANDA: Product tested positive for sibutramine, an appetite suppressant that was withdrawn from the U.S. market in October 2010 for safety reasons, making this product an unapproved new drug. Lot #s: All lots. Globe All Wellness LLC.

**Via Xtreme Ultimate Sexual Enhancer Dietary Supplement for Men**, 6-count bottles. Volume of product in commerce: 13,273 bottles. Marketed without an approved NDA/ANDA: Product found to contain sulfoildenafil methanesulfonate, sulfosildenafil and dimethylsildenafil, all of which are analogues of sildenafil, the active ingredient in an FDA-approved drug used to treat erectile dysfunction. Lot #s: 809013, 806030, A032111. Globe All Wellness LLC.

**X-Hero Capsules** 1) with English label, 1-capsule pack, 10-capsule bottles and 2) with Chinese and/or English Label, 8-capsule bottles. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: FDA lab analysis found product contained tadalafil, an FDA-approved drug used to treat erectile dysfunction, making this product an unapproved new drug. Lot #s: All lots. U.S.A. Far Ocean Group 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

**Aminophylline Tablets**, USP, 1) 100-mg tablet and 2) 1,000-mg tablet. Volume of product in commerce: 44,127 bottles. Stability data does not support exp: Failed assay and content uniformity results at 24-month test interval. Lot #s: 1) 66383B, expiration date 02/2013; 66557A, expiration date 05/2013; 67297B, expiration date 01/2014; 67921A, expiration date 01/2014. 2) 66382A, expiration date 02/2013; 66383A, expiration date 02/2013; 66557B, expiration date 05/2013; 67296A, expiration date 01/2014; 67297A, expiration date 01/2014; 67921B, expiration date 06/2014; 67922A, expiration date 06/2014. Westward Pharmaceutical Corp.

**Cyclobenzaprine HCl Tablets**, USP, 10 mg, 1) 100-count bottle, 2) 500-count bottle, and 3) 1,000-count bottle. Volume of product in commerce: 46,589 bottles. Labeling: Labeled with wrong or incorrect expiration date. Lot #s: 1) 702863, expiration date 06/2012. 2) 702830, expiration date 06/2012; 702864, expiration date 07/2012. 3) 702831, expiration date 07/2012. Teva Pharmaceuticals USA Inc.

**Extended Phenytoin Sodium Capsules**, USP, 100-mg, 1) 100 UD (10 x 10-count blisters) per carton; 2) 100 UD (100 bags of 1 capsule each). Volume of product in commerce: 11,384 blister packs. Unit dose mispackaging: Blister packs may contain more than one capsule

in the individual blister-pack cavities. Lot #s: 1) 102144, 102145, expiration date 03/2012; 102740, 102862, 102859, expiration date 05/2012. 2) 102470RP, 990163, expiration date 05/2012. American Health Packaging.

**Fluoxetine Capsules**, USP, 20-mg, 1,000-count bottle. Volume of product in commerce: 1,900 bottles. Adulterated presence of foreign tablet: A capsule of fluoxetine 40 mg was found in a bottle of fluoxetine 20 mg. Lot #: 1A14009MA, expiration date 12/2012. Alembic Ltd.

**Gabapentin** 1) 100-mg caplets and 2) 800-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Galantamine HBR ER**, 8- and 24-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

## DRUGS AND DIETARY SUPPLEMENTS (continued)

**Galantamine Hydrobromide**, 4-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Gemfibrozil**, 600-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glimepiride**, 1- and 2-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glipizide**, 5-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glipizide ER**, 2.5-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glucosamine/Chondroitin**, 500/400 mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glucosamine/Chondroitin DS**, 500/400-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glucosamine Sulfate**, 166.667- and 500-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glyburide**, 1.25-, 2.5- and 5-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glyburide/Metformin HCL**, 500-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glyburide Micronized**, 1.5- and 3-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Glycopyrrolate**, 1- and 2-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Griseofulvin Microsize**, 500-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Guaifenesin**, 200-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Guaifenesin ER**, 600-mg bi-layer tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Guanfacine**, 1- and 2-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Guanfacine ER**, 1-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Haloperidol**, 20-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Hydralazine HCL**, 10-, 25-, 50- and 100-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Hydrochlorothiazide**, 12.5-, 25- and 50-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Hydrochlorothiazide/Triamterene**, 25/37.5-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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**Hydrocodone Bitartrate and Acetaminophen**, 5/325-mg and 10/325-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

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## DRUGS AND DIETARY SUPPLEMENTS (continued)

**Hydrocortisone**, 5-, 10- and 20-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hydroxychloroquine Sulfate**, 200-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hydroxyurea**, 500-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hydroxyzine HCL**, 10- and 25-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hydroxyzine Pamoate**, 25-, 50- and 100-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hyoscyamine Sulfate**, 0.125- and 0.375-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hyoscyamine Sulfate SL**, 0.125-mg chewable/oral tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Hyoscy/atro/scopo/phenobarb**, 0.1037/0.0194/0.0065/16.2-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Ibuprofen**, 100-mg chewable tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Ibuprofen**, 200-, 400-, 600- and 800-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Imatinib Mesylate**, 100- and 400-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contami-

nation. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Imipramine HCL**, 10-, 25- and 50-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Indapamide**, 2.5-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Indinavir Sulfate**, 400-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Indomethacin**, 25-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Irbesartan**, 150-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Isosorbide Dinitrate**, 30-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Isosorbide Dinitrate ER**, 40-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Isosorbide Dinitrate SL**, 2.5-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Isosorbide Mononitrate**, 10- and 20-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Isosorbide Mononitrate ER**, 30-, 60- and 120-mg tablets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

## DRUGS AND DIETARY SUPPLEMENTS (continued)

**Isradipine**, 2.5-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Itraconazole**, 100-mg caplets. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Tylenol 8 HR Caplets**, 650-mg, 150-count bottle. Volume of product in commerce: 34,056 bottles. Chemical contamination: Presence of trace amounts of a chemical called 2,4,6-tribromoanisole (TBA). Lot #: ADM074, expiration date 03/31/2012. McNeil Consumer Healthcare.

**Tylenol(R) Cold Multi-Symptom Nighttime Rapid Release Gels 24 RR Gelcaps**. Volume of product in commerce: Unknown. Impurities/degradation products: The level of chlorpheniramine ammonio acetate was slightly higher than expected in some gelcaps. Lot #: AMA277, expiration date 08/31/2011; APA059, expiration date 08/31/2011; APA162, expiration date 08/31/2011; ASA025, expiration date 08/31/2011; APA237, expiration date 09/30/2011; ASA072, expiration date 09/30/2011; ASA208, expiration date 09/30/2011; BAA008, expiration date 10/31/2011. McNeil Consumer Healthcare.

**Tylenol(R) Cold Multi-Symptom Rapid Release Gels Day/Night 12+8 RR Gelcaps**. Volume of product in commerce: Unknown. Impurities/degradation products: The level of chlorpheniramine ammonio acetate was slightly higher than expected in some gelcaps. Lot #: AMF034, expiration date 08/31/2011; BAF005, expiration date 09/30/2011; BAF027, expiration date 10/31/2011; BCF080, expiration date 10/31/2011. McNeil Consumer Healthcare.

**Tylenol(R) Cold Multi-Symptom Rapid Release Gels Day/Night 36+24 RR Gelcaps**. Volume of product in commerce: Unknown. Impurities/degradation products: The level of chlorpheniramine ammonio acetate was slightly higher than expected in some gelcaps. Lot #: BBF001, expiration date 10/31/2011; BCF060, expiration date 10/31/2011; BCF079, expiration date 2011. McNeil Consumer Healthcare.

**Valacyclovir**, 1-g tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Valacyclovir HCL**, 500-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Valganciclovir HCL**, 450-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Valsartan**, 40-, 80, 160- and 320-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Varenicline**, 0.5- and 1-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Venlafaxine HCL**, 25-, 50- and 100-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Venlafaxine HCL ER**, 37.5-, 75-, 150- and 225-mg tablet; 37.5-, 75- and 150-mg capsule. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Verapamil HCL**, 40-, 80- and 120-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Verapamil HCL ER**, 100- and 240-mg capsule; 180-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vertigoheel**, 300-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vinate One Prenatal Multivitamin**, tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Viramune**, 200-mg table. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vitamin A**, 10,000-IU softgel. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vitamin B1**, 100-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

## DRUGS AND DIETARY SUPPLEMENTS (continued)

**Vitamin B-6**, 50-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vitamin D**, 1,000-IU tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vitamin D3**, 1,000 IU-tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vitamin E**, 100-, 200- and 400-IU softgel. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Vol-Tab RX**, tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Voriconazole**, 50- and 200-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Warfarin**, 1-, 2.5-, 3-, 5- and 7.5-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Zafirlukast**, 10- and 20-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Zidovudine**, 100-mg capsule and 300-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Zinc Gluconate**, 50-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Zinc Sulfate**, 110- and 220-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Zolpidem Tartrate**, 5- and 10-mg tablet. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

**Zonisamide**, 50- and 100-mg capsule. Volume of product in commerce: Unknown. There is a potential for penicillin cross-contamination. Lot #s: Multiple lots affected. Contact your pharmacist. Aidapak Services LLC.

## CONSUMER PRODUCTS

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

### Name of Product; Problem; Recall Information

**Bad Boy Buggies Off-Road Utility Vehicles.** The steering-assembly arm can break and cause the driver to lose control, posing a crash hazard. BB Buggies Inc., at (855) 738-3711 or [www.badboybuggies.com](http://www.badboybuggies.com).

**Ballard Designs Stafford Step Stools.** Plastic tabs on the feet of the step stools can cause the stools to be unstable, posing a fall hazard to consumers. Ballard Designs Inc., at (888) 606-2627 or [www.ballarddesigns.com](http://www.ballarddesigns.com).

**Bird Brain Firepot Fuel Gel, Bird Brain Firepot Citronella Fuel Gel and Bird Brain BioFuel Fuel Gel.** The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose potentially fatal fire and burn risks to consumers. Bird Brain Inc., at (877) 414-0842 or [www.birdbrainrecall.com](http://www.birdbrainrecall.com).

**B.O.B. Single and Double Strollers.** The stroller canopy's embroidered logo's backing patch can detach, posing a choking hazard to

## CONSUMER PRODUCTS (continued)

babies and young children. B.O.B. Trailers Inc., at (855) 242-2245 or [www.bobnotices.com](http://www.bobnotices.com).

**BUSA Children's Folding Tent.** The steel wire frame of the tent can break, producing sharp wire ends that can protrude through the tent fabric, posing a laceration or puncture hazard. IKEA North America Service, at (888) 966-4532 or [www.ikea-usa.com](http://www.ikea-usa.com).

**Chefmate 6-Speed Blender.** While in operation, the plastic pitcher can separate from the blade assembly, leaving the blade assembly in the base and exposing the rotating blades. This poses a laceration hazard to consumers. Select Brands, at (800) 440-0680 or [www.target.com](http://www.target.com).

**Children's Frog Masks.** The plush frog mask lacks proper ventilation. When secured in place across a child's face, it presents a suffocation hazard to the child. Target Corp., at (800) 440-0680 or [www.target.com](http://www.target.com).

**Chloe, Sophie and Audrey Soft Dolls.** The hair on the Chloe and Sophie dolls may contain loops that are large enough to fit around a child's head and neck, and the headband on the Audrey doll, if loosened, can form a loop that fits around a child's head and neck. These loops can pose a strangulation hazard. Pottery Barn Kids, a division of Williams-Sonoma Inc., at (855) 880-4504 or [www.potterybarnkids.com](http://www.potterybarnkids.com).

**CO 1224T Carbon Monoxide (CO) Detectors.** When the CO detector reaches the end of its useful life, it should send a signal to make a sound in the home alarm panel alerting consumers it is time to replace it and a signal to ADT's alarm-monitoring center. Some of the detectors were not wired properly to the ADT alarm system, resulting in the sound not going off in the home alarm panel and no signal to the ADT alarm-monitoring center. Not replacing a CO detector at the end of its useful life poses a CO poisoning hazard to consumers. Sensor System, at (800) 238-2727 or [www.us.adt.com](http://www.us.adt.com).

**D100 Lawn Tractors.** Hardware used to hold the brake assembly to the transmission housing can break. This can cause the brakes to fail, posing an injury hazard due to loss of control. Deere & Co., at (800) 537-8233 or [www.johndeere.com](http://www.johndeere.com).

**Drop-Side Cribs.** The drop-side rail hardware on the cribs can break or fail, allowing the drop side to detach from the crib. When the drop side detaches, a hazardous gap is created between the drop-side rail and the crib mattress in which infants and toddlers can become wedged or entrapped, posing risks of suffocation and strangulation. In addition, children can fall out of the crib when the drop-side rail falls unexpectedly or detaches from the crib. Drop-side rail failures can also occur due to incorrect assembly or with age-related wear and tear. Shermag Inc., at (800) 567-3419 or [www.shermag.com](http://www.shermag.com).

**Drop-Side Cribs.** The drop-side rails on the crib can malfunction, detach or unexpectedly fall down, causing part of the drop side to fall out of position. When this happens, a space is created into which an infant or toddler can roll and become wedged or entrapped, which can lead to strangulation or suffocation. A child can also fall out of the crib. Drop-side incidents can also occur due to incorrect assembly and due to age-related wear and tear. Yu Wei Co. Ltd., at (877) 806-8190 or [www.yuweicribrecalls.com](http://www.yuweicribrecalls.com).

**Ecotech EZ Variable Speed Pool Pump Motors.** The pump cover is not properly grounded, posing an electrical shock hazard. Nidec Motor Corp., at (866) 278-6920 or [www.nidec-motor.com](http://www.nidec-motor.com).

**Embark Resistance Cords and Cord Kits.** A black, plastic ball attached to the resistance cord's door anchor can unexpectedly release and strike the user, posing an injury hazard. Target Corp., at (800) 440-0680 or [www.target.com](http://www.target.com).

**Fireside Gel Fuel Bottles.** The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose potentially fatal fire and burn risks to consumers. 2 Burn Inc., at (877) 558-1511 or [www.myeverygreen.com](http://www.myeverygreen.com).

**GE Monogram Pro Rangetop With Grill.** Burners on rangetops operating on liquefied petroleum ("LP" or propane) may fail to ignite or light if the gas control knob is left in a position between "Off" and "Lite," posing a risk of delayed ignition or explosion. Leiser, at (866) 645-3956 or [www.geappliances.com/products/recall](http://www.geappliances.com/products/recall).

**Hand Trucks.** When the tires are overinflated, they can explode, causing the wheel hub to separate or break and ejecting pieces of the hub. This poses an injury hazard to bystanders. Harper Trucks Inc., at (800) 835-4099 or [www.harpertrucks.com](http://www.harpertrucks.com).

**Innovations and At Home With Meijer Roman Shades and Roll-Up Blinds.** Roman shades: Strangulation can occur when a child places his/her neck between the exposed inner cord and the fabric on the back side of the blind or when a child pulls the cord out and wraps it around his/her neck. Roll-up blinds: Strangulation can occur if the lifting loops slide off the side of the blind and a child's neck becomes entangled on the free-standing loop or if a child places his/her neck between the lifting loop and the roll-up blind material. Whole Space Industries Ltd., at (800) 927-8699 or [www.meijer.com](http://www.meijer.com).

**John Deere X300, X300R and X304 Series Tractors.** The cooling fan installed on top of the front-mounted Kawasaki engine in the lawn tractor can break. If the cooling fan is not operational, the engine can overheat, causing the surrounding plastic to melt and creating a risk of fire and serious injury. Deere & Co., at (800) 537-8233 or [www.johndeere.com](http://www.johndeere.com).

## CONSUMER PRODUCTS (continued)

**LittleLife Discoverer Child Carriers.** The carriers were sold without bolts that attach the carrier's main frame to the metal stand. Missing bolts cause the carrier to disconnect from the stand and fall backward, posing a fall hazard to a child in the carrier. Lifemarque, at (877) 922-5462 or [www.littlelife.com](http://www.littlelife.com).

**Losi NiMH Start-Up Combo Charger.** The charger and battery can emit excessive heat, posing a burn and fire hazard. Horizon Hobby Inc., at (877) 504-0233 or [www.horizonhobby.com/losicombo](http://www.horizonhobby.com/losicombo).

**Marshall Gardens PatioGlo Bio-Fuel Gel.** The pourable gel fuel can ignite unexpectedly and expel onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that expels and ignites can pose potentially fatal fire and burn risks to consumers. Marshall Group, at (855) 270-8482 or [www.marshallgroupcorp.com](http://www.marshallgroupcorp.com).

**Microfiber Glider Recliners with Ottomans and Leather Glider Recliners With Ottomans.** An exposed gap between the moving parts of the chair and the base framework can allow access to toddlers and infants, posing an entrapment hazard. In addition, other exposed moving parts on the chair and the ottoman can pose finger pinching and crushing hazards to older children and adults. Big Lots, at (866) 244-5687 or [www.biglots.com](http://www.biglots.com).

**OZOfire Pourable Gel Fuel (Formula 4) and SUREFIRE Pourable Gel Fuel (Formula 4) Bottles.** The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose possibly fatal fire and burn risks. Fuel Barons Inc., at (877) 469-6347 or [www.fuelbarons.com](http://www.fuelbarons.com).

**Pacific Flame Pourable Gel Fuel Bottles.** The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose possibly fatal fire and burn risks. Pacific Décor Ltd., at (425) 949-7878 or [www.PacificDecorLtd.com](http://www.PacificDecorLtd.com).

**Real Flame Pourable Gel Fuel Bottles.** The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose possibly fatal fire and burn risks. Real Flame, at (866) 918-8766 or [www.realflamerecall.com](http://www.realflamerecall.com).

**Rechargeable Lithium-Poly Battery.** The battery can overheat and catch fire. Electric Motion Systems LLC, at (877) 824-5339 or [www.epluselectricbike.com](http://www.epluselectricbike.com).

**RedMax Brushcutter/Trimmer.** Some fuel tanks allow leakage at the fuel cap, posing a fire hazard to consumers. Husqvarna Zenoah Co. Ltd., at (877) 257-6921 or [recalls@husqvarna.com](mailto:recalls@husqvarna.com).

**Smart Jel Gel Fuel Bottles.** The pourable gel fuel can ignite unexpectedly and splatter onto people and objects nearby when it is poured into a firepot that is still burning. This hazard can occur if the consumer does not see the flame or is not aware that the firepot is still ignited. Gel fuel that splatters and ignites can pose possibly fatal fire and burn risks. Smart Solar Inc., at (813) 343-5770 or [www.smartsolar.com](http://www.smartsolar.com).

**Toy Cars.** Surface paint on the toy cars contains excessive levels of lead, a violation of the federal lead paint standard. LM Import & Export, at (305) 622-7122.

**Trek 2012 FX and District Bicycles.** The bolt that secures the seat saddle clamp to the seat post can break, posing a fall hazard. Trek Bicycle Corp., at (800) 373-4594 or [www.trekbikes.com](http://www.trekbikes.com).

**Twist and Sort Toys.** The small pegs on three of the four posts can detach, posing a choking hazard to young children. Guidecraft Inc., at (888) 824-1308 or [www.guidecraft.com](http://www.guidecraft.com).

**Weehoo iGo Bicycle Pedal Trailers.** The receiver on the trailer's seat post hitch can crack and cause the trailer to detach, posing fall and crash hazards to the child in the seat. Weehoo Inc., at (800) 538-6950 or [www.weehoobicycletrailer.com](http://www.weehoobicycletrailer.com).

**Wood Twin Bunk Beds and Loft Bunk Beds.** The guard rails on upper bunks can crack and cause the mattress and its support rails to collapse, posing a fall hazard. American Woodcrafters, at (888) 429-7265 or [www.american-woodcrafters.com](http://www.american-woodcrafters.com).



## Outrage of the Month! For Big Pharma, Crime Pays

**O**n Nov. 3, 2011, GlaxoSmith-Kline (GSK), the world's fourth largest pharmaceutical company, announced that it had tentatively reached a \$3 billion settlement — the largest ever — with the federal government to conclude an investigation into illegal activity going back at least seven years.

GSK allegedly promoted multiple drugs, including the dangerous diabetes drug rosiglitazone (Avandia), for uses for which they were not approved, going so far as to pay kickbacks to get doctors to prescribe the medications. The purported settlement breaks the previous \$2.3 billion settlement record set in 2009 by Pfizer.

GSK has repeatedly been fined for unlawful conduct. A 2010 Public Citizen report ("Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010," at [www.citizen.org/hrg1924](http://www.citizen.org/hrg1924)) found that, over the past 20 years, GSK racked up \$4.5 billion — more than any other company — in fines levied by the federal government and state governments for a plethora of illegal activities.

The pharmaceutical industry has paid more in penalties to the federal government as a result of these settlements than any other industry.

**GSK allegedly promoted multiple drugs, including the dangerous diabetes drug rosiglitazone (Avandia), for uses for which they were not approved, going so far as to pay kickbacks to get doctors to prescribe the medications.**

The profits generated by such activities are massive, and when companies are caught, CEOs get off scot-free, while the penalties handed down barely put a dent in the drugmakers' bottom lines.

The \$3 billion settlement may seem like a sizeable sum, but consider that, according to *The New York Times*, GSK reaped profits of \$5 billion on \$43 billion worth of sales in just this past year alone. And by announcing the settlement in advance of its official conclusion, GSK put an end to years of investor uncertainty. The company's stock rose 3 percent following the announcement, confirming yet again that for Big Pharma, at least, crime does indeed pay. ♦

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