

Health Letter

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Obama Administration Must Make Disciplinary Records of Nurses, Health Workers Available to Hospitals, Nursing Homes

More than 22 years after the federal government started tracking serious disciplinary actions against non-physician health workers, the infractions — everything from fraud and abuse to improperly prescribing drugs — are still kept secret from most hospitals and many nursing homes doing background checks of potential employees, according to a letter Public Citizen sent August 26, 2009, to the Department of Health and Human Services (HHS).

The Healthcare Integrity and Protection Data Bank contains discipline records for more than 100,000 nurses, physician assistants, pharmacists and other non-physician health workers. However, HHS has failed to finalize a regulation that would implement a 1987 law that would allow access to the records to more than 5,000 U.S. hospitals and about 700 nursing homes.

“Many of these workers would not have jobs in the health care field if their current employers knew about their checkered pasts,” said Dr. Sidney Wolfe, M.D., director of Public Citizen’s Health Research Group. “Keeping these records secret greatly increases the chance that patients will be injured or killed at the hands of their caretakers.”

The letter to HHS Secretary Kathleen Sebelius, from Dr. Wolfe and staff researcher Alan Levine, points out

that as of Dec. 31, 2007, the health care data base listed:

- More than 40,000 nurses sanctioned for health care-related violations, including unsafe practice or substandard care (23,551 reports), misconduct or abuse (10,930 reports), fraud/deception/misrepresentation (3,437 reports), and improper prescribing/dispensing/administering drugs (7,526 reports).
- More than 49,000 licensed practical nurses and nurse aides sanctioned for health care related violations such as unsafe practice or substandard care (16,110

reports), misconduct or abuse (12,197 reports), fraud/deception/misrepresentation (4,247 reports), and improper prescribing/dispensing/administering drugs (4,634 reports).

HHS and the Office of Management and Budget should immediately issue the Section 1921 regulation, which would allow hospitals and nursing homes to access the information in the health care database, Wolfe said.

Public Citizen’s August 26th letter sent to Secretary Sebelius follows on page 2.

CONTENTS

Letter Urging Secretary Sebelius to Provide Hospitals and Nursing Homes Access to Names of Disciplined Nurses and Other Health Workers	2
A Call to Action: Why We Need Medical Resident Work Hour Reform	5
Recalls July 15, 2009 - August 13, 2009	
This month, digoxin and bed steps are on the list.....	7
Are we now twice as sad? The drug industry and doctors think we are.....	11
Outrage	
Ghostly Prescriptions	12

Letter Urging Secretary Sebelius to Provide Hospitals and Nursing Homes Access to Names of Disciplined Nurses and Other Health Workers

Dear Secretary Sebelius:

This letter is to urge you to immediately implement Section 1921 of the Social Security Act. This would significantly reduce the chances that patients will be injured or killed by any of the more than 100,000 non-physician health professionals (e.g., nurses, pharmacists, physician assistants) and other health workers with disciplinary records who may be employed in hospitals or nursing homes. The adverse action reports concerning these health professionals are contained in the federally run Healthcare Integrity and Protection Data Bank (HIPDB). Federal hospitals and a few nursing homes have access to these reports. However, the failure to implement Section 1921 keeps the data from more than 5,000 U.S. hospitals and approximately 700 nursing homes. This secrecy ensures that though they have been disciplined one or more times, many in multiple states, such healthcare workers can get jobs at hospitals or nursing homes because their employers lack awareness of their previous unsatisfactory records.

As of December 31, 2007, the HIPDB contained the following data:

- Names of more than 40,000 nurses sanctioned for health care-related violations including unsafe practice or substandard care (23,551 reports), misconduct or abuse (10,930 reports), fraud/deception/misrepresentation (3,437 reports), and improper prescribing/dispensing/administering drugs (7,526 reports).
- Names of more than 49,000 licensed practical nurses (LPNs) and nurse aids sanctioned for health care-related violations such as unsafe practice or substandard care (16,110 reports), misconduct or abuse

(12,197 reports), fraud/deception/misrepresentation (4,247 reports), and improper prescribing/dispensing/administering drugs (4,634 reports).

The much-needed action to immediately make this important information available to over 5,000 hospitals and about 700 nursing homes from whom it is currently being kept secret is clearly within your authority.

Twenty-two years after Section 1921 was enacted, the Department of Health and Human Services (HHS) has still not published the final Section 1921 regulation needed to implement the legislation. Publication of the final regulation would expand the National Practitioner Data Bank (NPDB) to allow hospitals and nursing homes access to the following adverse action reports, which have already been collected by the Health Resources and Services Administration (HRSA).

Disciplinary Reports Maintained by HRSA – Not Available to Hospitals (As of December 2007)

Profession	# of Persons	# of Reports
RNs	44,070	76,771
Para-Professional Nurses (LPNs and Nurse Aides)	49,961	85,038
Pharmacists and Pharmacy Assistants	8,548	14,758
Physician Assistants	979	1,684
Respiratory Therapists	2,131	2,944
Physical Therapists	2,384	3,124

The above data are already maintained by HRSA in the HIPDB. However, the HIPDB enabling legislation, Section 221 (a) of the Health Insurance Portability Act of 1996 (Public Law 104-191), does not allow hospitals, except for federal hospitals, to have access to the HIPDB. In addition, unless nursing homes are part of a health plan, they do not have access to the HIPDB.

Implementation of Section 1921 would, for the first time, allow this data to become part of the National Practitioner Data Bank, thus permitting over 5,000 non-federal hospitals and approximately 700 nursing homes, which have registered with the NPDB, access to thousands of disciplinary records involving the type of practitioners who work in such health care facilities.

Section 1921 Regulation

In October 2008, HHS submitted the draft final Section 1921 regulation to the Office of Management & Budget (OMB) for review. However, because of the presidential transition, OMB sent the final regulation back to HHS, indicating that the regulation could be re-submitted after January 20, 2009.

Although the regulation had been previously cleared by HHS prior to being submitted to OMB, HHS staff has advised us that the regulation will now have to go through departmental clearance once again. According to current and former HHS staff, the clearance process will delay issuance of a final regulation — and hospital and nursing homes access to the crucial data — to 2010 or beyond.

Discussions about Section 1921 at meetings of the National Practitioner Data Bank Executive Committee, which Public Citizen has attended as a member, indicated that the regulation is not controversial, has considerable support and places no additional reporting burden on anyone.

In fact, since HRSA has already

done the computer programming to implement Section 1921, implementation costs would be minimal. Furthermore, HRSA is likely to get additional revenue as the number of health care entities using the NPDB increases with Section 1921 implementation because there is a query fee of \$4.25.

According to the 2006 HRSA “Program Improvement Plan” submitted to OMB as part of the OMB government-wide performance assessment process, HHS committed to doing the following:

Adopting regulations and making system changes implementing Section 1921 of the Social Security Act to minimize the program’s identified limitations and to operate at maximum efficiency.

Although the Section 1921 legislation was passed 22 years ago, HHS has not met this commitment. Only your immediate intervention will expedite issuance of the final regulation.

Importance of Section 1921 Data to Hospitals and Nursing Homes

The data on allied health professionals have been highly desired by hospitals, but as noted earlier are currently not legally available to non-federal hospitals and many nursing homes. However, the information has been legally available to state licensing boards, health plans, managed care organizations and federal hospitals. According to a recently retired HHS employee whose job required him to read many of the reports and perform statistical analysis on all of them, some of the reports involved serious lapses in performance and judgment that would be of extreme interest to hospitals considering hiring nurses and other professionals. Furthermore, some individuals had multiple reports — for instance, 10,509 nurses have more than one adverse action report, a fact that would also be of great interest to hospitals and nursing homes considering job applicants. Statutory confidentiality requirements prevent this former HHS employee

from identifying the subjects of the reports he has seen. Public Citizen notes that according to unpublished HRSA data, as of December 2007, HRSA has the following disciplinary reports on nurses in its possession that are not available to non-federal hospitals and many nursing homes:

RNs with Multiple State Licensure Disciplinary Reports (As of December 2007)

Number of Individual Nurses	Number of Reports
21,725	1 report
10,509	2 or more reports
4,213	3 reports
1,716	4 reports
883	5 reports
429	6 reports
72	9 reports
32	10 reports

Additional reports on nurses include: 517 reports involving civil judgments or criminal convictions relating to health care malfeasance; 62 reports involving “Government Administrative Actions,” which could include actions taken by Medicaid Fraud Control Units and the Center for Medicare and Medicaid Services; and 31 reports from health plans, which could involve substandard care.

Impact of Section 1921 on Hospitals and Nursing Homes

There are numerous examples of nurses with performance or conduct problems who continued to practice because of the failure of regulatory oversight. Although we do not know whether the following nurses are listed in the HIPDB, their records strongly suggest that they were and that they might not have been able to get new employment if their previous records had been known.

- Diana Kutz continued to practice despite a history of criminal offenses related to alcohol abuse convictions.
- Donna Redcross continued to practice after she had been convicted three times for petty theft, three times for driving without a license, and once each for possession of methamphetamine, drunk driving and disturbing the peace.
- Cynthia Knott continued to work as a nurse despite having served jail time for drug-related arrests. The drugs had been stolen from her job site.
- Schwam Linstead continued to work even though she was convicted of driving under the influence, forging prescription drugs and possessing controlled substances (two convictions). The nurse acknowledged that she went to work under the influence of methamphetamine.

Hospitals are not the only venues where health care is potentially compromised because of HHS and OMB’s failure to issue the Section 1921 regulation. There are currently about 700 nursing homes registered with the National Practitioner Data Bank. With Section 1921 implementation, these nursing homes would have access to over 76,000 sanction reports on nurses and over 85,000 sanction reports on para-professional nurses (e.g. LPNs, Nurse Aides).

On May 15, 2008, the Chief Counsel to the Inspector General of HHS testified before the House Subcommittee on Oversight and Investigations. In discussing nursing home screening of employees, the OIG noted:

Residents of nursing homes have a right to live in safe and secure environments, free from abuse at the hands of their caregivers. OIG has found, however, that states and nursing facilities currently depend on a patchwork of data sources to identify persons posing possible threats of elder abuse in

nursing homes ... In a July 2005 report, OIG found that although most facilities check their State nurse aide registries prior to employing an individual, they do not routinely check registries in other States, thereby potentially jeopardizing the safety of their residents. Additionally, while most States require criminal background checks, the scope of these checks varies widely ... about half of the background checks were limited to one State ... some individuals with criminal records in one State were certified in other States and therefore still able to have access to residents.

The July 2005 OIG study also noted that almost 100,000 nurse aides had registrations in multiple states, “suggesting that interstate movement of nurse aides is not uncommon.”

A February 2005 OIG report on nurse aide registries and long term care facilities noted that:

- In Texas, a nurse aide poured milk on a resident’s head, grabbed his arms and pushed him back into the wheelchair, and hit him on the head, causing multiple skin tears and bruises.
- In Alaska, a nurse aide struck a resident in the face, fracturing his nose, and breaking his glasses.
- In Virginia, a nurse aide pushed a resident, causing the resident to fall to the floor. The nurse aide later retrieved a snow shovel from the kitchen, and while the resident was still on the floor, struck the resident with the shovel and yelled that she was going to kill the resident.
- In North Carolina, a nurse aide neglected a resident by leaving them in the facility transport van. The resident was found alone in the van when he could not be located in the facility.
- In Texas, a nurse aide took a resident’s debit card without permission, got the personal identification number, and withdrew money from the

resident’s bank account totaling approximately \$1,100.

Currently Available Data Bases

The National Council of State Boards of Nursing operates the NURSYS data base, which contains licensure and disciplinary information on nurses (RNs) and LPNs. However, only 37 states plus the District of Columbia and Virgin Islands submit licensure and disciplinary data on both RNs and LPNs to NURSYS. Louisiana submits data on only RNs, while West Virginia contributes data on only LPNs. Furthermore, NURSYS does not contain information on nurse aides.

Currently, to do a thorough backgroundcheck, non-governmental hospitals and most nursing homes must query numerous individual licensing boards for disciplinary reports on nurses and other allied health professionals such as pharmacists, physical therapists and physician assistants. Many boards charge for each query. According to a senior credentialing official at the Department of Veterans Affairs, the average querying fee for allied health professional licensing boards is about \$25.

A senior credentialing official for a corporate hospital chain advised Public Citizen that implementation of Section 1921, which provides for “one-stop shopping,” would increase efficiency and reduce her hospital credentialing costs, which now average about \$300 per background check.

A performance review of the NPDB and HIPDB by the Office of Management and Budget in 2006 noted the following:

The NPDB and HIPDB are the only programs collecting and disseminating malpractice payment and adverse licensure, privileges, membership, judgment, and other adverse action information on practitioners, providers, and suppliers in the US. There are no other comparable programs, including government, private or non-profit. ... For clinical privileges

actions, professional society membership actions, malpractice payments, State exclusion actions, and adjudicated actions, information could possibly be obtained from the entity which took the action if the querying entity knows where to look and is willing to spend considerable time and effort gathering the information. ... For some professions State board organizations, such as the Federation of State Medical Boards, collect and make available information on licensure sanctions of licensed practitioners. They do this under varying circumstances and at varying cost. The amount of information available to licensing and credentialing authorities depends to a large degree on individual State laws. However, this information is limited to information on actions taken in the individual State. The Data Banks are the only source of this information on a national basis, which is necessary as health care providers today often move to, and look for work in, different States. As a practical matter there is no single alternative source to the data banks for the information they contain.

Costs Savings – Section 1921 Implementation Would Allow HIPDB to Sunset

Section 1128e of the Social Security Act requires the Healthcare Integrity and Protection Data Bank to be self-sustaining from the revenue it generates from query fees; however, according to HHS officials, HIPDB has not been self-sustaining since FY 2003. As a result, it has received a \$450,000 subsidy from the Health Care Fraud and Abuse Control Program (HCFAC). Once Section 1921 is implemented, many customers of the HIPDB, such as health plans, are likely to discontinue querying the HIPDB if they also have access to the NPDB because, according to retired HHS staff who had worked on NPDB and HIPDB issues, almost all

continued on page 5

A Call to Action: Why We Need Medical Resident Work Hour Reform

On March 4, 1984, Libby Zion, an 18-year-old college freshman with a history of depression and cocaine use, was admitted to New York Hospital with fever, chills and agitation. Two doctors-in-training (residents) evaluated her and were unable to make a definitive diagnosis, but gave her a painkiller and sedative, a plan approved on the phone by a senior clinician. Libby died eight hours after admission. Libby's father, Sidney Zion, and his wife Elsa, sued the hospital and doctors for gross negligence and later lobbied for stricter limits on

residents' work hours and supervision. (The hospital subsequently admitted it had provided inadequate care in Libby Zion's case and paid a measly \$13,000 fine to the state).

The case sparked a massive debate about errors resulting from medical residents' long hours and lack of supervision. It also led to the formation

of a commission to examine resident training in New York State, which produced a report known as the "Bell Report," named after the committee's chair, Dr. Bertrand Bell. In 1989, New York became the first (and so far only) state to regulate resident work hours, setting a still-hefty limit of 80 hours per week, averaged over four weeks.

Today, the length of U.S. residents' shifts far exceeds federal standards in other safety-sensitive industries, such as those for pilots.

Today, the length of U.S. residents' shifts far exceeds federal standards in other safety-sensitive industries such as those for pilots (no more than 8 hours of flying per day) as well as those of their medical resident

counterparts in Europe. European health care workers are limited by law to 13 consecutive hours of work and to 48-56 hours of work per week.

And the public is justifiably concerned. In a 2002 survey conducted by the National Sleep Foundation, 70 percent of respondents

to a national public opinion poll reported that they were "somewhat likely" or "very likely" to request another doctor if they learned that their doctor had been working for 24 hours. Of course, most of the time they remain in the dark about their doctor's sleeping schedule.

But the reaction to the Zion case at the national level in the U.S. was a deafening silence. Control of residents' work hours falls under the purview of the Accreditation Council for Graduate Medical Education (ACGME), a private, non-profit council that evaluates and accredits medical residency programs in the United States. As pointed out in a 2002 New York Times editorial, the ACGME is subject to an irresolvable conflict of interest: "Its board is dominated by the trade associations for hospitals, doctors, and medical schools, all of which benefit from the cheap labor provided by medical residents."

In April 2001, Public Citizen, the Committee of Interns and Residents (CIR), the American Medical Student Association (AMSA), Bertrand Bell

LETTER, from page 4

of the data in the HIPDB will be in an expanded NPDB. With the loss of querying revenue, the HIPDB would need additional financial support. An unofficial HHS estimate indicates that the HIPDB would require a subsidy of at least \$900,000 annually when Section 1921 is implemented. According to HRSA's 2009 budget justification,

with the implementation of Section 1921, the HIPDB will not be able to financially sustain its own existence. Therefore, the HIPDB will continue to require additional ... funding in order to maintain its

existence until it can be properly shut down.

The FY 2009 HRSA Performance Appendix to their budget notes "with the implementation of Section 1921 in FY 08 there will be little unique information available in the HIPDB. The FY 2009 legislative proposal would sunset HIPDB and move the unique HIPDB reports not covered by Section 1921 into the NPDB."

Twenty-two years after Section 1921 became law, HHS has failed to finalize a regulation that would make American hospitals and nursing homes safer. To provide hospitals and nursing homes a critical tool

necessary to assure patient safety, and to eliminate the expenses associated with funding the HIPDB, Public Citizen calls upon HHS to work with OMB to issue the final Section 1921 as soon as possible.

Sincerely,

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and Kingman P. Strohl, a leading sleep researcher, petitioned the Occupational Safety and Health Administration (OSHA) for regulation of residents' work hours, arguing that resident work schedules placed them at risk for depression, motor vehicle accidents and adverse pregnancy outcomes. The coalition also succeeded in getting legislation introduced in the U.S. House and Senate. These efforts, although not directly successful, kicked up quite a storm of political and public concern, and so in 2003 ACGME reluctantly revamped its voluntary work hour standards. Unfortunately, the limits provide ample room for excessive work schedules. Although there is a New York-like 80-hour work-week restriction, hours are averaged over four weeks (thus three 70-hour weeks could be followed by a 110-hour week) and "on-call" shifts can last 30 consecutive hours. The guidelines have not been enforced strongly enough, and violations are frequent. Moreover, residents are unlikely to report violations, for the ACGME might revoke the program's accreditation, placing the residents' chances of graduating from an accredited program at risk.

The ACGME's actions succeeded in putting the issue to rest politically, until the Institute of Medicine's December 2008 report, *Resident Duty Hours: Enhancing Sleep,*

Supervision, and Safety. It is the most comprehensive review of medical resident work hour practices to date. The report found that "the evidence concerning patient safety and the risk of causing errors when fatigued argues for strong and prompt action." It further recommended either not allowing residents to work more than 16 hours continuously or a mandatory 5-hour nap for residents working longer than 16 hours.

In contrast to many other potential improvements in patient safety, the area of resident fatigue is distinguished by having a gold-standard, randomized, controlled trial proving the efficacy of reduced work hours in lowering medical error rates. In this study, interns in the intensive care unit at a large academic hospital in Boston were randomly assigned to work either a traditional work schedule (77 to 81 hours per week with up to 34 hours of continuous scheduled work) or an intervention schedule (60 to 63 hours per week with no more than 16 hours of consecutive work). Over the course of the year-long study, researchers demonstrated that the intervention schedule reduced serious medical by 36 percent. Other research has found a link between extended work hours and increased risks of traffic accidents and needlestick injuries.

In response to the IOM report, the ACGME is currently conducting a

review of the 2003 reforms and the data underlying the IOM report. The ACGME has assembled a Joint Task Force to review the literature (again!) and evaluate the current regulations, a process that promises to be dragged out. The ACGME has also embarked on various data collection exercises that seek to document organized medicine's view of the problem.

In fact, the ACGME's mind is largely made up. In a February 2009 letter to the graduate medical education community explaining the review process, ACGME's CEO Thomas Nasca attempted to make the case that reducing hours for residents undermines the learning process. (What, exhaustion doesn't?) He also makes the shopworn argument that the safety of patients will be compromised by increasing the number of "hand-offs" between the outgoing and incoming residents as shifts shorten. This theory has been debunked by the randomized, controlled trial cited above in which, even with increased hand-offs, the net effect of reducing work hours on patient care was to reduce medical errors.

Overall, the ACGME's response seems like yet another exercise in administrative foot-dragging. How much longer will American patients and doctors-in-training have to wait before these abusive practices are eliminated?

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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Product Recalls

July 15, 2009 – August 13, 2009

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

DRUGS AND DIETARY SUPPLEMENTS

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

Recalls and Field Corrections: Drugs – CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Digoxin, 0.25 mg, packaged in 30 tablet bottles, NDC 57664-441-04, part #5758-0; Rx only, 670 bottles; Some of the tablets are over sized or undersized, which will result in the patient not receiving the expected dose of medication. Lot #: 9023045, 8350165, 8325065, 8294169, 8291068, 8086157, 8045070, 7334139 and 7218363; A-S Medication Solutions LLC.

Influent Jr. Severe Cold & Flu, each teaspoon (5 mL) contains Acetaminophen 162.5 mg, Dextromethorphan HCl 5 mg, Phenylephrine HCl 5 mg, 4 oz (118 mg) bottles, 2,535 bottles; Superpotent; phenylephrine HCl. Lot #: 800077; Ion Labs Inc.

Universal A.B.C. Beauty Supply International, Inc.

The following products have been recalled by Universal A.B.C. Beauty Supply International, Inc. because they contain sibutramine, an FDA-approved drug for weight loss based on FDA sampling and analysis. There are multiple lots, with an unknown number of affected units. Call your pharmacist to see if yours is one of the affected lots.

ProSlim Plus – 100% Natural – Supplement for Diet Support; 3 Days fit; Eight Factor Diet; 24hours Diet; Slim 3in1 M-18 Royal Diet; 3X Slimming Power; Extrim Plus 24 Hours Re-Burn Formula; Slim 3in1 Extra Slim Formula; Slim 3in1 Extra Slim Waist Formula; Slim Express 360 C; Slim Express 4in1; Royal Slimming Formula; Body Creator; Slim Waistline (labeling written in Chinese); Body Shaping; Perfect Slim; Perfect Slim No 1. 4 – 5X – Super Slim Power; Imelda Perfect Slim; Slim Waist Formula; Super Slimming; 2 Day Diet – Japan Lingzhi – Slimming Formula – Fat Burner; Powerful Slim – The slimming total effect – No. 1 Slim. Product of Japan; Body Shaping; Super Fat Burner;

Slimming Formula – A Scientific Breakthrough; Slim Fast 2; Slim Fast – 100% Natural Ingredients; Slim up; 7 Days Diet; Perfect Slim Up! – Royal Slimming Powerful Capsules; JM Fat Reducer – 100% Natural Herbal Essence; SlimBurn – 15 Minutes Overall Burning Fat; 21 Double Slim; Trim Plus 2 (Trim 2 Plus).

For more information, visit the Food and Drug Administration Enforcement Report online at <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

LIBIMAX All Natural Herbal Extract Capsules, 430 mg herbal blend, sold in 1-capsule individual packs and 10-capsule or 20-capsule plastic bottles, Libido Enhancer, Rev Up Your Sex Drive, Approximately 400 cases/720 individual packets per case; 1,000 bottles of 10 capsule bottle; 300 bottles of the 20 capsule bottle; Unapproved New Drug; product contained undeclared active pharmaceutical ingredient tadalafil. All codes; Nature & Health Company.

Zencore Plus, Natural Male Enhancement Dietary Supplement, 275mg proprietary blend of herbal ingredients, supplied in 2 capsule blister packs and 10 capsule blister packs, labeled... It's Natural And It Works, For Male Sexual Performance, UPC for 10 Capsule box: 8 5919700106 8; UPC Code for Individual 2 Capsule Packet: 8 5919700102 0; UPC Code for Display Box 8 5919700103 7; 1,500,000 capsules; Unapproved New Drug; product found to contain benzamidenafil which is a newly discovered PDE-5 inhibitor similar to FDA approved drugs to treat erectile dysfunction. All lot codes; Hi Tech Pharmaceuticals.

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

Name of Drug or Supplement; Problem; Recall Information

Nicomide Tablets (nicotinamide, zinc, copper, folic acid) Each tablet contains Nicotinamide USP 750 mg, Zinc Oxide USP 25 mg, Cupric Oxide 1.5 mg and Folic Acid USP 500 mcg, 60 count bottles, Rx, NDC 65880-792-60, 63,366 bottles; Failed Dissolution Specifications (zinc). Lot #s: 70973A1 (exp. date 11/1/2009); 70974A1 (exp. date 11/1/2009); 71055A1 (exp. date 12/1/2009); Dusa Pharmaceuticals, Inc.

unknown number of lots. These drugs are all part of a major recall due to the manufacturer's failure to comply with good manufacturing practices (GMP). The products involved are too numerous to list; if you have any drugs manufactured by Advantage Dose LLC, call your pharmacist to see if yours is one of the affected lots.

For more information, visit the Food and Drug Administration Enforcement Report online at <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

Advantage Dose LLC

Four large drug recalls by Advantage Dose LLC affect an

CONSUMER PRODUCTS

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

Name of Product; Problem; Recall Information

2009 Model Year Polaris All-Terrain Vehicles (ATVs). The valve assembly can fail in freezing temperatures, causing oil to leak into the exhaust system. This could pose a fire and burn hazard to the rider. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

Bay West & Hillyard Hybrid Wave N Cut Paper Towel Dispensers. The dispenser's board can overheat posing a fire hazard. Global Plastics Ltd., (888) 225-7380 or www.globalplastics.com.

2009 Polaris Ranger "Crew" and "6x6" Side-by-Side Recreational Vehicles. An electrical short can lead to overheating in the rear tail light wiring harnesses, posing a fire hazard to consumers. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

Black & Decker GH1000 Grasshog XP String Trimmer/Edgers. The trimmer/edger's spool, spool cap and pieces of trimmer string can come loose during use and become airborne projectiles, posing a serious laceration hazard to the user, as well as bystanders. The trimmer/edgers can also overheat, posing a burn hazard to consumers. Black & Decker (U.S.) Inc., (888) 742-9158 or www.blackanddecker.com.

208-Volt and 240-Volt Thermostats. The recalled thermostat's floor sensor or its cable can be damaged from cutting, drilling, or nailing. This poses a risk of electric shock to consumers if the power supply is not disconnected. OJ Electronics, (800) 380-6940 or www.ojelectronics.com.

Blue Ember Gas Grills. The hose of the gas tank can get too close to the firebox and be exposed to heat, posing a fire hazard to consumers. Fiesta Gas Grills, (866)740-7849 or www.blueembergrills.com.

Art Collection Leather Shag Rugs. The rugs fail to meet federal flammability standard, posing fire and burn hazards to consumers. Chandra Rugs, (800) 258-6614 or www.chandrarugs.com.

Boys Hooded Sweatshirts and Warm Up Sets. The sweatshirts and jackets to the warm up sets have drawstrings through the hoods, posing a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Burlington Coat Factory, (888) 223-2628 or www.burlingtoncoatfactory.com.

BabyBjörn® Babysitter Balance and BabyBjörn® Babysitter Balance Air bouncer chairs. Small, sharp metal objects found in the padded area of the bouncer chair can protrude, posing a laceration hazard to children. BabySwede LLC, (866) 424-0200 or www.babyswede.com.

Buster Brown & Co.'s Clog Children's Shoes. The shoe has decorative wheels that can detach, posing a choking hazard to young children. Brown Shoe Co. Inc., (888) 869-1044 or www.busterbrownshoes.com.

CONSUMER PRODUCTS

Circo Booster Seats. The booster seat restraint buckle can open unexpectedly, allowing a child to fall from the chair and be injured. Target, (800) 440-0680 or www.target.com.

Crosley®, Frigidaire®, Kelvinator®, Kenmore®, Wascomat®, and White-Westinghouse® clothes washers. An internal defect in the washer's drain pump can cause heat to build up, posing a fire hazard to the consumer. Frigidaire, (800) 734-4519 or www.laundrypumprecall.com; For consumers who purchased their product at Sears, (888) 549-5870 or www.sears.com.

Domestications Bed Steps. The bed steps break during use, posing a hazard to consumers. Domestications, (800) 969-4094.

Elliptical Cross Trainers. Stamina modified the warning/assembly instructions in the owner's manuals to emphasize that the elliptical pedal shafts must be securely tightened to the cranks. If not securely tightened, the pedal shafts could become loose from the cranks, which could result in serious injury to the user and/or damage to the product. Stamina Products Inc. (800) 375-7520 or www.staminaproducts.com.

Enviro-Flo Plus Fuel Containers (1 and 2 gallon container sizes). The spout's plunger cap can dislodge which can open the seal of the fuel container and allow gasoline vapors to escape. This could cause liquid gasoline to spill from the top of the container during use and result in a fire hazard. Blitz USA Inc., (888) 540-5177 or www.blitzusa.com.

H2O Mop Steam Cleaners. The power cord can unexpectedly wear down and expose the wiring, posing a shock and burn hazard to consumers. Thane International, Inc., (800) 485-0017 or www.h2omopservice.com.

Homelite, Husky and Black Max Brand Generators. The fuel gauge can leak excessive amounts of gasoline, posing a fire hazard to consumers. Homelite Consumer Products Inc., (800) 242-4672 or www.homelite.com.

Hooded Jackets. The jackets have a drawstring around the waist which can pose an entrapment hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. EMH Associates Inc., (212) 575-4311 or www.meijer.com.

Jump 'n Jive™ Doorway Jumpers. The recalled doorway jumpers include detachable toys that are attached to the jumper straps with strips of hook and loop fabric. The strips of fabric are not permanently attached to the toys and can become detached during use, posing a choking hazard. Graco Children's Products Inc., (800) 345-4109 or www.gracobaby.com.

La Siesta Yayita Baby Hammocks. The hammock can flip over, posing a serious fall hazard and strangulation hazard to infants who become entrapped in the seat's restraint straps while upside down. Kaplan Early Learning Company, (800) 334-2014 or www.kaplanco.com.

Leather Butterfly Chairs. The chair legs can detach unexpectedly causing the chair to collapse, posing a hazard to consumers. Hobby Lobby Stores, (800) 326-7931 or www.hobbylobby.com.

Little Tikes Clubhouse Swing Set. The recalled swing sets did not come with assembly directions for the swing seat harness. The swing seat harness assembly needs to be completed by the consumer. The swing seats can detach if the harness is not assembled properly, which could result in fall and injury during use. Little Tikes, (800) 321-0183 or www.littletikes.com.

Little Tikes™ Workshops Sets and Trucks. The recalled workshop sets and trucks have oversized, plastic toy nails that can pose a choking hazard to young children. Little Tikes, (800) 791-2737 or www.littletikes.com.

Marble Top Plant Stands. The marble top of the plant stand can detach from the base and fall onto consumers, posing a risk of injury. Ross Stores Inc., (800) 305-0510 or www.rossstores.com.

My Pal Scout Electronic Plush Toy Dogs. The decals on the paws of the plush toy can be removed and ingested by a child, posing a choking hazard. LeapFrog Enterprises Inc., (800) 701-5327 or www.leapfrog.com/recall.

Natural Sense Foam Blocks with Cotton Cover (Mattresses). The foam blocks with cotton covers (intended to be used as mattresses) fail to meet the mandatory federal open flame standard for mattresses, posing a fire hazard to consumers. Foamorder.com, (800) 256-6162 or www.foamorder.com.

Nautilus F3 Chin Dip Stationary Exercise Units. The footpads on the unit can break, posing a fall hazard to consumers. Nautilus Inc., (800) 935-7313 or www.nautilus.com.

Orbitrek Elite and Orbitrek Elite Magnetic Elliptical Exercise Gliders. The written instructions incorrectly identify the proper location of the spring washer. An incorrectly installed spring washer can put undue stress on bolts, causing them to loosen, which poses a fall hazard to consumers. Thane International Inc., (888) 863-4003 or www.thane.com.

Power Functions IR Remote Controls. The batteries in the remote controls can overheat, posing a burn hazard to consumers. LEGO Systems Inc., (800) 718-1858 or www.LEGO.com.

Psyclone Essentials and React Wii™ 4-Dock Battery Recharge Stations. The battery pack can overheat, posing a burn or fire hazard to the consumer. Griffin International Cos., Inc., 888-344-4702 or productsafety@psyclonegamer.com.

Purdy 2 ½" 4-Edge Scrapers. The recalled scraper's body can break away from the handle when struck against a hard object. This poses a laceration hazard to users. The Sherwin-Williams Co., (888) 304-3769 or www.sherwin-williams.com.

"Reflections of Magic" Hanging Mirrors. The metal plate used for hanging the mirror can become detached and cause the mirror to fall, posing an impact or laceration hazard. The Bradford Exchange Ltd., 866-903-2755 or www.collectiblestoday.com.

Safety 1st SmartLight Stair Gates. The hinges that hold the stair gate in place can break, posing a fall hazard to children if the gate is placed at the top of the stairs. Dorel Juvenile Group USA, (866) 690-2540 or www.djgusa.com/safety_notice/.

Sevylor® Tow Behinds with Quick Hitch Connectors. The Quick Hitch, which connects the towable to the boat, can break and project pieces of the plastic Quick Hitch back towards the boat. If this occurs, an individual can be struck and seriously injured. Shanghai Suofeng Plastic Metal Manufactures Co., Ltd., (800) 356-3612 or www.sevylor.com.

Spalding In-Ground Basketball Hoops. The bolts at the base can fail, causing the unit to fall. This poses a risk of serious injury to consumers. Russell Brands LLC, (800) 431-5827 or www.spalding.com.

SWR Natural Blonde Acoustic Bass Amplifiers. The amplifier's wiring can overheat, posing a fire hazard. Fender Musical Instruments Corp. (FMIC), (800) 856-9801 or www.swrsound.com.

Yayita Baby Hammocks. The hammock can flip over, posing a serious fall hazard and strangulation hazard to infants who become entrapped in the seat's restraint straps while upside down. Nova Natural Toys & Crafts LLC, (877) 668-2111 or www.novanatural.com.

Youth Hooded Sweatshirts. The sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Propac Distributing Corp., (888) 337-0011 or www.proclubinc.com.

OUTRAGE from page 12

the scope of the practice, the many physicians that were willing to lend their names to the scheme, the failure of peer review to detect tainted

science, the prestige of the journals involved, and the sheer magnitude of the entire enterprise. Indeed, it is likely that some medical faculty received tenure on the basis of their "literary production" when they had

merely agreed to stake their names (and, by extension, the reputations of their institutions) to enhance pharmaceutical company's profits and line their own pockets. ♦

Are we now twice as sad?

The drug industry and doctors think we are!

The use of anti-depressant medications nearly doubled in the 10-year period between 1996 and 2005. Nothing has changed fundamentally in the psyche of Americans to justify the dramatic rise. What, then, do the numbers mean, and what do they tell us about the medical market for these medications?

The data tell us that 27 million Americans are currently on antidepressants, which have become the most widely prescribed class of drugs in the U.S. Currently, 10 percent of the population over the age of 6 is taking some kind of psychotropic drug. Could “medicated” become the new normal?

Interestingly, the proportion of people actually being treated for depression has increased only slightly, so we cannot attribute the rise in antidepressant use to a greater incidence of the condition. Moreover, the share of the population using psychotherapy decreased from 31.5 to 19.87 percent. We thus appear to be witnessing two parallel trends. First, there seems to be a substitution effect, with more people and their doctors choosing drugs over “talking cures;” and, secondly, more people are now relying on such drugs to

deal with a much wider range of conditions, including anxiety and other mood disorders.

The researchers suggest that the rise in the use of antidepressants may be attributed to the introduction of new antidepressants, a broadening in the clinical indications for antidepressant treatment, an increase in direct-to-consumer (“talk to your doctor about...”) advertising, and a reduction in the stigma associated with mental conditions. Nevertheless, it is worth noting that the some of the increased consumption of antidepressants occurred at the same time that there was a growing concern with a rise in suicidal thoughts among young people, which resulted in the FDA carrying a “black box” warning to that effect.

Still, the medical market for these medications appears to be thriving. And, because there are now generic versions of some of the drugs, there are now cheaper alternatives to many of the most popular brands, making them more affordable and accessible. This has made the taking of drugs deceptively easy, with many patients not being fully aware of the adverse effects of the products they are taking. A UCLA study found that, for all prescriptions in general, two-

thirds of doctors do not say how long the medications should be taken and almost half did not state the dosage or frequency of the drug. And doctors mentioned possible side effects only one-third of the time. *Worst Pills, Best Pills News* and *WorstPills.org* are therefore careful to caution patients concerning the risks of these drugs.

One adverse effect that the FDA does not address is the use of these medications on the environment. The rise in the use of antidepressants creates an unexpected source of pollution. Both the pills people swallow and are excreted and leftover pills flushed down the toilet end up in water treatment plants that are not designed to remove pharmaceuticals. Water released by the plants into rivers and other bodies of water may therefore carry the drugs. Antidepressants detected in the brains of fish have been found to affect their behavior, leading to “laid-back” reactions that hamper their ability to fend off predators. This unwanted “trickle-down” effect demonstrates yet again the ecological web of which we are all part, and underlines the social importance of individual decisions. ♦



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Ghostly Prescriptions

Not so long ago, women of a certain age in the U.S. were made to believe that going on hormonal replacement therapy (HRT) was as much of a rite of passage as menarche or pregnancy. Over the past seven years, however, we have learned just how wrong that was: the science on which the prescription was based was flawed, the data were consistently misinterpreted, and the medical literature on which medical practices was based was in effect on a very shaky foundation. This whole edifice fell apart in 2002, when a large federally funded study stopped after finding that menopausal women who took certain hormones had an increased risk of invasive breast cancer, heart disease and stroke.

Now, we know that the rise of

HRT cannot be attributed to well-meaning but misguided scientists but rather out-and-out fraud. Wyeth, manufacturer of Premarin and Prempro, contracted with a medical communication firm to write articles favorable to its products, and then paid (until then) reputable doctors to appear as authors. The articles were published in 18 established medical journals such as the *American Journal of Obstetrics and Gynecology* and the *International Journal of Cardiology*. These articles in effect gave the imprimatur to practices which then spread widely. And the medical literature in turn spawned a variety of more popular “chick lit” articles and books with enticing titles that touted the benefits of being “forever feminine” while avoiding dry skin and a diminished libido. The result?:

millions of women being duped while Wyeth sold \$2 billion worth of drugs in 2001 alone.

Medical ghost-writing is not new, and has been involved in other cases. What is new in this case is

continued on page 10



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