PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JULY 2010 – VOL. 26, No. 7

Public Strongly Supports Substantially Reducing Work Hours for Resident Physicians, New Research Finds

The American public greatly underestimates the extended hours currently worked by resident physicians nationwide and overwhelmingly disapproves of shifts lasting longer than 24 hours, which are currently required by teaching hospitals. New findings, published in the online journal BMC (BioMed Central) Medicine, indicate that Americans strongly favor tighter regulation of the number of consecutive hours that resident physicians are allowed to work. This is the first systematic study of public perceptions of resident work hours.

The authors of the manuscript, which included academic experts as well as consumer and labor advocates, found that ninety percent of Americans believe that the maximum shift duration for resident physicians should be 16 hours or less, as recommended by the Institute of Medicine (IOM). The IOM concluded in 2008 that allowing resident physicians to work more than 16 consecutive hours without sleep is unsafe both for patients and resident physicians themselves. More than four of five respondents in the study believe patients should be informed if the doctor treating them has been working for 24 hours; a similar majority of respondents said that if told that their doctor had been awake for a day, they would request care from a different doctor.

The Accreditation Council on Graduate Medical Education (ACGME), the private sector group that oversees the training of physicians in the U.S., has yet to implement the IOM recommendations. The ACGME currently allows resident physicians to work for 30 consecutive hours and allows such extended shifts to occur up to twice per week. The ACGME has been reviewing the IOM recommendations for limiting resident physician work hours for the past 18 months and is expected to announce its decision later this month.

The national telephone survey of a representative sample of 1,200 U.S. adults revealed that:

- Only 1 percent of the general public supports shifts longer than 24 hours for medical residents. Current work hour rules permit residents to work 30-hour shifts twice weekly.
- The majority of respondents said they believe that resident physicians work shifts of less than 12 hours.
- 81 percent of the general public believes that reducing resident physician work hours would be very or somewhat effective in reducing medical errors.
- 81 percent of the public believes that patients should be informed if a treating resident physician has been working for more than 24 hours; 80 percent said they would then want a different doctor.
- When asked about specific recommendations of the IOM, four of five respondents support limiting the duration of individual work shifts to 16 hours, capping weekly work hours at a maximum of 80 hours in any single week and ensuring that medical residents have at least one day off per week.
- 68 percent favor the IOM recommendation that resident physicians not work more than 16 hours over an alternative IOM proposal that would permit resident physicians to remain in the hospital for 30 hours, as long as they were provided the opportunity to sleep for five hours without interruption after 16 hours of work.

"Our research shows that the general public clearly does not support continuing to allow hospitals to schedule resident physicians to work for 24 consecutive hours or more," said lead author Dr. Alex Blum, a health and evidence policy fellow at Mount Sinai School of Medicine. "Though the debate about resident work hours has raged for decades, this is the first time we have heard directly from our patients. Our patients underestimate the hours that resident physicians currently work and

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The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and give consumers more control over decisions that affect their health.

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are concerned about the safety of their working 24-hour shifts."

Added Dr. Charles Czeisler, a senior author of the study and Baldino professor of sleep medicine at Harvard School of Medicine, "The American public realizes that the 19th century practice of scheduling resident physicians to work marathon 24-hour shifts is unsafe for patients. The 108,000 resident physicians in the U.S. provide much of the direct medical care in our nation's teaching hospitals, where more than half of all hospitalized patients in the U.S. receive their care. Implementation of a 16-hour work-hour limit for resident physicians, as recommended by the IOM, is long overdue."

Ninety percent of Americans believe that the maximum shift duration for resident physicians should be 16 hours or less.

Patients are very concerned about being cared for by a fatigued physician. Four-fifths of the general public believes that reducing resident work hours would reduce medical errors, the study found.

Patient safety groups have formed a coalition to bring light to the issue of resident hour reform and created a website, www.WakeUpDoctor.org, to raise public awareness of the problem. The full study and action that people can take, joining a petition urging the ACGME to change this dangerous situation, can be found on this web site.

"The leaders within academic medicine who are resisting these sensible changes are out of step with the public, and that jeopardizes the notion of patient-centered care and threatens the health of patients," said Dr. Sidney Wolfe, director of the Health Research Group at Public Citizen, a coalition member.

Added Dr. Farbod Raiszadeh, a study co-author, president of Committee of Interns and Residents/SEIU and clinical cardiology fellow in the Montefiore Medical Center at the Albert Einstein College of Medicine, "It is patients who bear the brunt of substandard care sometimes delivered by mistakes made by fatigued and overworked resident physicians. Finally their voices have been heard."

Fatigue is common among medical residents, as are medical errors, the researchers noted.

"One of five resident physicians admits to making a fatigue-related error that has injured a patient, and one in 20 admits to making a fatigue-related error that has resulted in the death of a patient," Czeisler said. "Working for 24 hours without sleep impairs performance to a degree that is comparable to being legally drunk. Patients have a right to be concerned for their safety when doctors work marathon 24-hour shifts. Reducing resident physician work hours is an effective way to improve patient safety."

"The finding that patients do not find it acceptable to be cared for by fatigued, poorly supervised residents should not come as a surprise," said Helen Haskell, founder of Mothers Against Medical Error, a coalition member. "The fact that the public is almost completely unaware of the actual working conditions of medical residents is symptomatic of the gulf in thinking between patients and those who are responsible for setting the standards for the residents who care for patients."

The research was conducted by Lake Research Partners and sponsored financially by the Committee of Interns and Residents/SEIU and Public Citizen. The manuscript authors included representatives from Harvard Medical School, Mount Sinai School of Medicine, Montefiore Medical Center at Albert Einstein College of Medicine, the Committee of Interns and Residents/SEIU, and Public Citizen.

The background leading up to this study is summarized on the next page.

History of the Issue

The first forceful beginning in this country of the movement to reduce Medical Residents' Work Hours came in the 1980's following the tragic death of reporter Sidney Zion's daughter Libby in circumstances which included a fatigued medical resident and inadequate supervision. This led to a New York state regulation in 1989 in placing limits on hours residents could work and improving their supervision. This was subsequently strengthened by a law passed in New York in 1999 funding unannounced inspections of hospitals to determine compliance with these regulations.

Also in 1999, the Institute of Medicine of the National Academy of Sciences published a report To Err is Human, estimating that as many as 98,000 people a year were killed in American hospitals because of errors by medical personnel, primarily physicians. A small portion of the report dealt with the role of fatigued physicians as a cause of some of these errors. In a sense, the implication of the report was that the inhumane treatment of resident physicians put a different light on the idea that to err is human.

In 2001, Public Citizen, the American Medical Students Association (AMSA), the Committee of Interns and Residents (CIR) of the SEIU, Dr. Bertrand Bell of Albert Einstein College of Medicine, the head of the Bell Commission that wrote the regulations in New York and a sleep researcher from Case Western Reserve School of Medicine, Dr. Kingman Strohl petitioned the Occupational Safety and Health Administration (OSHA) concerning this issue. We asked that OSHA take over the regulation of residents' work hours from the private sector organization the Accreditation Council on Graduate Medical Education (ACGME) that currently is charged with this task. The grounds for the petition were studies showing that the health of medical residents suffered from excessive work hours in the form of post-call automobile crashes, depression and premature labor and delivery in female residents.

Our petition was denied after ACGME convinced OSHA that it was adequately regulating residents' work hours and that there was no need for such federal regulation, despite multiple precedents of federal regulation of sleep hours for airline pilots, train and bus drivers as well as truck drivers.

By 2003, however, ACGME put forth new regulations for residents' work hours, ones that were grossly inadequate and fell far short of those requested in our petition.

In 2007, the US House of Representatives Committee on Energy and Commerce requested the Agency for Healthcare Research and Quality to sponsor an evidence-based assessment of the issue by the Institute of Medicine (IOM), prompted by evidence that 20% of physicians in training admitted making a fatigue-related error that injured a patient and 5% admitted making a fatigue-related error that resulted in the death of a patient during their internship

In December 2008, following a year-long investigation, the IOM released a report, Resident Duty Hours: Sleep, Supervision and Safety, in which it concluded, among other suggested improvements, that scheduling resident physicians to work for more than 16 hours consecutively without sleep is unsafe both for patients and resident physicians themselves.

It is now 18 months since that report and, during this time the ACGME convened a Duty Hours Congress in 2009, at which considerable opposition to the IOM recommendations was voiced. The ACGME is expected to announce its own recommendations shortly. ✦

Patient Safety Advocates Give Plan to Reform Medical Residency a Failing Grade

Accreditation Group's Proposal on Resident Physician Work Hours Do Not Measure Up to Institute of Medicine Recommendations

The coalition of public interest and patient safety groups that have spearheaded the WakeUpDoctor campaign issued a "report card" in response to the June 23, 2010, proposal by the Accreditation Council on Graduate Medical Education (ACGME) to restructure medical residency programs, published in *The New England Journal of Medicine.*

Since February 2010, the Wake Up Doctor campaign has been instrumental in raising awareness about the dangers posed by medical residents working shifts as long as 30 hours, frequently with limited support or supervision, leaving them exhausted and prone to mistakes. The coalition, which includes Public Citizen, Mothers Against Medical Error and other patient advocates, based their grades on the landmark 2008 report by the Institute of Medicine (IOM), Resident Duty Hours: Enhancing Sleep, Supervision and Safety. The IOM report made a thorough review of issues related to residency and listed 10 recommendations for change, including an increase in supervision of junior residents and a significant reduction in work hours.

Although ACGME, the group responsible for training physicians in the United States, demonstrated some progress in reconciling its regulations with the mounting body of scientific evidence linking acute and chronic sleep deprivation with preventable medical errors, the coalition judged that the proposal fails compared to the more comprehensive recommendations of the IOM report.

Common Sense Limits on Resident Duty Hours - **Grade: F**

The IOM report called for a reduction in resident duty hours from 30 consecutive-hour shifts to continuous shifts lasting no longer than 16 hours. The ACGME's proposal implements that change only for medical residents in their first year (interns). This change would therefore only apply to 22 percent of total residents in hospitals throughout the country. Most medical residents could continue to be scheduled for a maximum of 24 consecutive hours, a duration rejected by the IOM in late 2008. Ample evidence has shown that marathon shifts in excess of 16 hours can have a detrimental effect on a physician's abilities and judgment.

> **"Although it's a positive step for the ACGME to make any acknowledgement of the evidence linking resident fatigue and medical error, its proposed solution misses the mark," said Dr. Alex Blum**

Additionally, the IOM made a number of recommendations ranging from the minimum time off between scheduled duty periods, the maximum number of consecutive nights a resident may work night duty, adjustments to the minimum amount of time off per week, and an immediate, urgent requirement for hospitals to provide safe transportation home for fatigued residents. Nearly all of these recommendations are left out of the ACGME's proposal.

"Although it's a positive step for the ACGME to make any acknowledgement of the evidence linking resident fatigue and medical error, its proposed solution misses the mark," said Dr. Alex Blum, one of the authors of the recent study, "US Public Opinion Regarding Proposed Limits on Resident Physician Work Hours," which was published in BMC Medicine. "Physicians do not cease to be human beings when they complete their first year of residency, nor does an additional year of training make them impervious to the physiological effects of sleep deprivation. Patients both deserve and expect to be treated by a well-rested physician. The ACGME's proposal on work hours won't come close to making that a reality."

Adequate Direct, Onsite Supervision - **Grade: B**

The IOM report called for first-year residents not to be "on duty without having immediate access to a residency program-approved supervisory physician in-house" The ACGME adopts this measure, but only somewhat vaguely addresses the IOM report's recommendation for measurable standards of supervision for each level of residency.

"The ACGME has taken an important step in regard to supervision of first-year residents and to setting specific standards for different levels of supervision," said Helen Haskell, founder and president of Mothers Against Medical Error. "I think the acid test will be in the details. We need to be sure that residents of all levels have sufficient backup and reasonable limits on their workloads."

Structured, Institutionalized Handover Processes - **Grade: C**

The IOM report called for medical residents to be trained to communicate clearly and accurately when handing over patients after residents' shifts end, a process known as "handovers" or "signouts." The ACGME proposal includes this provision, as well as requiring a system to quickly and accurately communicate to staff and patients the roles and patient responsibilities of both residents and attending physicians at any given time.

However, the IOM report also called for dedicated, protected and overlapping time for patient care teams to conduct these transitions. The ACGME proposal does not include this solution to reduce errors related to handovers and improve team communication among providers.

"Without question, the environment in which handovers take place must be closely monitored to prevent errors and potential harm for our patients," said Dr. Farbod Raiszadeh, president of the Committee of Interns and Residents/ SEIU Healthcare, the nation's largest union for housestaff. "However, I can say from experience that part of that environment is how long the outgoing resident has been working in the hospital and how fatigued they are at the time of transition. Handovers are safer, more thorough and less prone to error when they occur in hour 16 than in hour 30 of a shift."

Increased Oversight of Residency Programs - Grade: F

Although the ACGME plans to dramatically increase the number of site visits, its oversight proposal falls far short of the IOM's standard. The IOM report called for rigorous oversight on the part of the ACGME, including unannounced visits to teaching hospitals, strengthened complaint procedures and confidential, protected reporting of hours by residents and teaching hospitals — none of which is directly addressed by the ACGME's proposal. Additionally, the IOM report called for independent monitoring by the Centers for Medicare and Medicaid Services and the Joint Commission — a recommendation that is also absent from the ACGME proposal, thus leaving the major control in the hands of the non-governmental ACGME instead of increasing the role of the government in oversight.

"The improvements in the new ACGME guidelines are largely swamped by the failure to cover the majority of medical residents with the protection of not having to work more than 16 hours continuously," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "This is the second revision of ACGME requirements in the last seven years and the organization still does not get it right."

The coalition will continue to educate the public concerning the areas where the ACGME proposal fails to meet the standards set by the 2008 IOM report.

To learn more about the issue of resident work hours, supervision and safety, and to sign the campaign's letter to the ACGME in support of the IOM recommendations, visit www.WakeUpDoctor.org. ✦

10 Things You Need to Know About Healthcare Reform

Reprinted from The Nation, May 5, 2010

Drs. David U. Himmelstein and Steffie Woolhandler, longtime advocates for single payer with Physicians for a National Health Program, have sifted through the mounds of information and misinformation to bring you ten things you need to know about the new law and a few actions to bring true reform to the healthcare industry.

1 The act risks ensconcing skimpy coverage as the norm. Participating plans are required to cover only 60 percent of expected healthcare costs, leaving families responsible for huge out-of-pocket expenses. The law will also tax "Cadillac plans," hitting millions of working families. Work with union activists to repeal the tax, maintain comprehensive healthcare benefits and fight for Medicare for all.

2 The law reduces Medicare's out-of-pocket costs for drugs by closing the infamous "donut hole," covering 75 percent of these costs by 2020. But the deal is even better for drug firms, who'll be getting paid full price for their products. Push to replace the privatized Medicare drug-coverage program with a fully public plan that would use its bargaining power to force down drug prices by about 40 percent.

3 HMOs were allowed into Medicare on the promise that they would save money, but over time they successfully lobbied Congress to increase their Medicare payments to 14 percent above costs. The new healthcare law cuts about $136 billion from these overpayments. Advocate for eliminating them entirely and phasing out investor-owned health providers that deliver inferior care at inflated prices.

4 The law will reduce federal subsidies to public and other safety-net hospitals. Yet 23 million Americans will remain uninsured and tens of millions more will continue to rely on safety-net providers because hospitals often shun insured patients with unprofitable illnesses. Unless the assault on public hospitals is stopped, millions of sick Americans may find they have nowhere to go. Advocate on behalf of Safety Net Hospitals.

5 Insurance and Big Pharma lobbyists' fingerprints are all over the new law. It's time to curb their influence. Join efforts for public funding of political campaigns. Support the Fair Elections Now Act. Ask your elected officials to stop taking funds from the health insurance lobby and push for tougher regulation of Big Pharma.

6 Expose and agitate against insurance firms' abuse of their customers and the outrageous incomes paid to their executives. Share your story at the excellent site maintained by the California Nurses Association: www.guaranteedhealthcare.org/node/add/user-story.

7 The law excludes undocumented immigrants from buying insurance in the new exchanges, even if they can pay full price, and bars green-card holders from receiving any publicly subsidized insurance for five years. Defend the right to healthcare for everyone. Sign the petition at The Center for Immigrant Healthcare Justice: www.cihj.org.

8 Keep up to date on reform at PNHP or Trudy Lieberman's blog. Show Michael Moore's "Sicko" in your community, and start a dialogue about what true reform should look like. Trudy Lieberman's blog: http://cjr.org/campaign_desk/trudy_lieberman_campaign_desk.php.

9 Work with state-based single-payer groups. Vermont passed a law that mandates the design of new healthcare models, including the possibility of single payer. Similar bills have been introduced in California, Maryland and Minnesota.

10 Exercise, eat right and advocate for public policies that facilitate healthier lives. Learn how to get active as a physician, a medical student, a citizen or labor advocate. The fight for real national health insurance will carry on into the 2010 election cycle and beyond. We need you around for the long haul.

A Doctor's Word: Deciphering the New Mammography Guidelines

The following article by Erin Marcus, M.D., was posted on www.newamericamedia.org on Nov. 29, 2009.

Whenever I order a mammogram for a woman in her 40's, I also give her a warning: "Don't get scared if it's abnormal." I tell her this because research shows that a woman who undergoes 10 routine screening mammograms has a 50-50 chance of having something unusual that requires her to go for more tests. The vast majority of these mammographic abnormalities aren't cancer, but she still needs to get the additional tests, just to make sure.

One out of a thousand screened women will have a breast cancer that's not picked up by their mammogram, while close to one out of 10 women in this age group will have a false positive result.

So the new mammogram recommendations by the United States Preventive Services Task Force really didn't surprise me. While there's pretty good evidence that mammograms save lives in women age 50 and older, it's not a great test in younger women. Women under 50 are more likely than older women to have false positive mammograms, resulting in their needing additional testing for something that turns out not to be cancer. They are also far less likely than older women to have breast cancer detected by mammograms.

When you look at the overall population, mammography's lack of precision in picking up cancer in younger women is pretty astounding. According to data from the Breast Cancer Surveillance Consortium, a network of mammogram registries, 556 women in their 40's have to get a screening mammogram for the test to pick up one invasive, or potentially life-threatening, cancer. One out of a thousand screened women will have a breast cancer that's not picked up by their mammogram, while close to one out of 10 women in this age group will have a false positive result. For older women, the test is more precise. For example, 200 women in their 60's have to be screened to find one invasive cancer, and there are fewer false positives.

One recent academic article pointed out that even though the advent of mammography 30 years ago led to a surge in the number of women diagnosed with tiny, localized breast cancers, it hasn't significantly decreased the number of women found to have disease that's already spread to other parts of the body. If mammograms were truly effective, the article's authors argued, there should have been a bigger drop in the number of women with advanced cancer, because their disease should have been caught before it was able to spread. Some researchers contend that many of these tiny cancers, called ductal carcinomas in situ, won't grow, and, by finding them, widespread mammography has resulted in lots of women being "overtreated" with aggressive therapies.

Despite all these concerns, the fact remains that breast cancer kills 40,000 women in the United States every year, more than any cancer except lung cancer. Given all the questions about mammograms' effectiveness, we clearly need better ways to screen women. An ideal screening test would pinpoint women who are at high risk of developing an aggressive breast cancer. This would allow doctors to monitor these women more vigilantly, perhaps with more frequent mammograms and other tests, such as ultrasounds, while those at low risk wouldn't need to be tested as often. It would also help women make a well-informed decision about whether to take medicine to prevent breast cancer.

Such tests could be especially important for black women, who are more likely than whites to develop aggressive cancers at a younger age. Routine mammograms often miss fast-growing cancers, which can pop up during the one or two year interval between screening tests.

Unfortunately, we're not there yet. True, there are a few tests to identify some women at high risk, such as those who have abnormal changes, or mutations, in genes called BRCA 1 and 2. But these gene changes account for only a small fraction of breast cancers. The National Cancer Institute has a computer tool that uses information about a woman's personal history to calculate her overall risk, but it only gives a very general estimate (available at http://www.cancer.gov/bcrisktool/). The institute spent more than $36 million last year to fund studies looking at such tests, including one called ductal lavage, which collects cells from inside the breast. But these tests aren't yet ready for widespread use.

Finally, it's important to note that the new guidelines don't say women in their 40's should avoid screening mammograms. Instead, they recommend that these women talk with their doctors about mammography's benefits and harms before deciding what's best for them.

Unfortunately, given the sad state of primary care medicine today, in which doctors spend less and less time talking to patients, these conversations often don't occur. Too often, the mammogram is a test that's just ordered with little discussion and not much thought. Hopefully, the new guidelines will spur more conversations between doctors and women about what mammograms can and can't do and women will be better prepared to understand their results. ✦

Product Recalls
May 12, 2010 - June 21, 2010

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 II

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

GlipiZIDE and Metformin HCL Tablets 2.5 mg/250 mg; 100 count bottle, Rx only; NDC # 0781-5304-01. Volume of Product in Commerce: Unknown. Tablets have the potential to contain metal particulates. Lot #s: 100606 exp. date 04/2011; 102466 exp. date 10/2011; Corepharma LLC.

GlipiZIDE and Metformin HCL Tablets 2.5 mg/500 mg; 100 count bottle, Rx only, NDC # 0781-5305-01. Volume of Product in Commerce: Unknown. Tablets have the potential to contain metal particulates. Lot #s: CPI870 exp. date 08/2010; CPB931 exp. date 01/2011; 100387 exp. date 03/2011; 100824 exp. date 05/2011; 101101 exp. date 05/2011; 101651 exp. date 07/2011; 102482 exp. date 10/2011; 102483 exp. date 10/2011; Corepharma LLC.

GlipiZIDE and Metformin HCL Tablets 5 mg/500 mg, 100 count bottle, Rx only. NDC # 0781-5306-01. Volume of Product in Commerce: Unknown. Tablets have the potential to contain metal particulates. Lot #s: CPK825 exp. date 10/2010; CPB914 exp. date 01/2011; CPB915 exp. date 01/2011; 100353 exp. date 03/2011; 100354 exp. date 03/2011; 100573 exp. date 03/2011; 100602 exp. date 03/2011; 100939 exp. date 05/2011; 101096 exp. date 05/2011; 101097 exp. date 05/2011; 101652 exp. date 07/2011; 101653 exp. date 07/2011; 102484 exp. date 10/2011; 102486 exp. date 10/2011; 102485 exp. date 10/2011; Corepharma LLC.

Glyburide (Micronized) and Metformin HCL Tablets, 1.25 mg/250 mg, 100-count bottle NDC 0781-5170-01; 500-count bottle NDC 0781-5170-05; Rx only. Volume of Product in Commerce: Unknown. Tablets have the potential to contain metal particulates. Lot #s: CPI869 exp. date 08/2010; CPK819A exp. date 10/2010; CPB968A exp. date 02/2011; 100980 exp. date 05/2011 101423B exp. date 06/2011; CPK819B exp. date 10/2010; CPB968B exp. date 01/2011; 101423A exp. date 06/2011; Corepharma LLC.

Glyburide (Micronized) and Metformin HCL Tablets; 2.5 mg/500 mg,100 count bottle NDC 0781-5171-01, 2.5 mg/500 mg, 500 count bottle NDC 0781-5171-05, Rx only. Volume of Product in Commerce: Unknown. Tablets have the potential to contain metal particulates. Lot #s: CPI812 exp. date 08/2010; CPK818 exp. date 10/2010; CPK829 exp. date 10/2010; CPA961 exp. date 12/2010; CPA962 exp. date 12/2010; CPB939 exp. date 01/2011; CPB940 exp. date 01/2011; CPB941 exp. date 01/2011; CPB955 exp. date 02/2011; CPB956 exp. date 02/2011; 100278 exp. date 02/2011; 100279 exp. date 02/2011; 100280 exp. date 02/2011; 100657 exp. date 04/2011; 100658 exp. date 04/2011; 100925 exp. date 05/2011; 100926 exp. date 05/2011; 101098 5/2011; 101099 exp. date 05/2011; 101100 exp. date 05/2011; 101419 exp. date 06/2011; 101420 exp. date 06/2011; 101931 exp. date 09/2011; CPK816 exp. date 10/2010; CPK817 exp. date 10/2010; CPK830 exp. date 10/2010; CPL801 exp. date 11/2010; CPB942 exp. date 01/2011; Corepharma LLC.

Glyburide (Micronized) and Metformin HCL Tablets; 5 mg/500 mg, 100 count bottle, NDC 0781-5172-01, 5 mg/500 mg, 500 count bottle NDC 0781-5172-05, Rx only. Volume of Product in Commerce: Unknown. Tablets have the potential to contain metal particulates. Lot #s: CPK821C exp. date 10/2010; 100281 exp. date 02/2011; 101564 exp. date 07/2011; CPK832B exp. date 10/2010; CPL802B exp. date 11/2010; CPK822 exp. date 10/2010; CPK823 exp. date 10/2010; CPK832 exp. date 10/2010; CPL802 exp. date 11/2010; CPL803 exp. date 11/2010; CPL804 exp. date 11/2010; Corepharma LLC.

Glycopyrrolate Tablets, USP, 2mg, 100 tablets (10 x 10) Carton, Rx Only; NDC 68084-232-01. Volume of Product in Commerce: 74 cartons. Impurities/Degradation Products: Some lots of Glycopyrrolate 2 mg tablets have the potential to exceed specifications for Impurity-I content over the shelf life of the product. Lot #: 096785 exp. date 06/2011; Rising Pharmaceuticals, Inc.

Tylenol (Acetaminophen) Recall. On June 16, 2010, an unknown number of Tylenol products was recalled by McNeil Consumer Healthcare due to chemical contamination, described as a presence of a chemical called 2,4,6-tribromoanisole. The following 16 products were included in the recall. If you have purchased any of these products, call your local pharmacist to see if yours is one of the lots affected: Tylenol Extra Strength Caplets; Tylenol Extra Strength Cool Caplets; Tylenol Extra Strength EZ Tabs; Tylenol Extra Strength Rapid Release Gels; Tylenol Extra Strength Tablets; Tylenol Caplets; Tylenol Regular Strength Tablets; Tylenol 8HR Extended Release Caplets; Tylenol 8 Hour Extended Release Caplets; Tylenol Arthritis Pain Extended Release Caplets; Tylenol PM Extra Strength Caplets; Tylenol PM Extra Strength Geltabs; Tylenol PM Extra Strength Rapid Release Gelcaps; Children's Tylenol Meltaways; Children's Tylenol Meltaways; Tylenol Day & Night Value Pack contains Tylenol Extra Strength Caplets; Tylenol Arthritis Pain Extended Release Geltabs.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call its hotline at (800) 638-2772. The CPSC 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

"Pirates of the Caribbean" Twin Trundle Beds. The headboard has a storage bin that poses an entrapment hazard to young children. Bayside Furnishings (a division of Whalen), (877) 494-2536 or www.baysidefurnishings.com.

"Shrek Forever After 3D" Collectable Drinking Glasses. The designs on the glasses contain cadmium. Long term exposure to cadmium can cause adverse health effects. McDonald's Corp., (800) 244-6227 or www.mcdonalds.com.

830B and 830D Voltaire Swivel Chairs. The chair frame can separate from the seating section of the chair, posing a fall hazard to consumers. Brunswick Bowling & Billiards Corp., (800) 937-2695 or www.brunswickbowling.com.

All-Star Basketball Chair and Ottoman Sets. Surface paints on the lettering on both sides of the chair could contain excessive levels of lead, violating the federal lead paint standard. Colleen Karis Designs LLC, (866) 278-7938 or www.colleenkarisdesigns.com.

Ameristep Plastic Strap-On Tree Step. The plastic portion of the step can break, posing a fall hazard to the user. Primal Vantage Co., Inc., (866) 972-6168 or www.treestandcustomerservice.com.

Animal Crackers Giant Stacking Toys. The fabric covering the stacking ring's center pole can come apart at the seam exposing the foam material inside. The foam material poses choking and aspiration hazards to young children. One Step Ahead, (866) 271-4536 or www.onestepahead.com.

Beado Handheld Bead Play Toys. The toys' plastic wires can detach from the hubs due to insufficient adhesive, allowing the beads to slide off. The loose beads pose a choking hazard to young children. Rhino Toys Inc., (877) 887-4433 or www.rhinotoys.com.

Bicycle Frame. A welding deficiency can cause the bicycle frames to crack along the welds of the front triangle of the bicycle. This can cause the rider to lose control and crash. Niner Bikes, (877) 646-3792 or www.ninerbikes.com.

Boys' and Girls' Belts. The belt buckles contain excessive levels of lead, violating the federal lead paint standard. Target Corp., (800) 440-0680 or www.target.com.

Boys' Hooded Jackets. The jackets have a drawstring through the hood which can pose a strangulation hazard. In Feb. 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Hind Fashions, (888) 643-4463.

BRP Ski-Doo® Snowmobiles. Friction between the fuel hose and the electronic control can cause the fuel hose to wear and leak fuel, posing a fire hazard. BRP US Inc., (800) 366-6992 or www.brp.com.

Buckyballs® High Powered Magnets Sets. The magnets sets were labeled "Ages 13+" and do not meet the mandatory toy standard F963-08 (effective Aug. 17, 2009) which requires that such powerful magnets are not sold for children under 14. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Maxfield and Oberton LLC, (888) 847-8716 or www.maxfieldandobertonsafety.com.

Children's Hooded Sweatshirts with Drawstrings. The sweatshirts have a drawstring through the hood that can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Chocolate Soup, (314) 576-1221. Junk Food Clothing Co., (877) 458-5865 or www.junkfoodclothing.com.

CYBEX 2.GO Infant Carriers. A shoulder strap slider buckle can break, posing a fall hazard to babies. Regal Lager Inc., (866) 678-8940 or www.regallager.com/recalls.

Denim Cargo Shorts. The denim shorts' metal snaps could detach from the shorts, posing a choking hazard. The Children's Place Services Company LLC, (877) 752-2387 or www.childrensplace.com.

Dishwashers. An electrical failure in the dishwasher's heating element can pose a serious fire hazard. Maytag Corp., (800) 544-5513 or www.repair.maytag.com.

Dritz Quick Cut™ Electric Scissors. The electric scissors can overheat, posing fire and burn hazards. Prym Consumer USA, 800-255-7796 or www.prym-consumer-usa.com.

CONSUMER PRODUCTS

Entertainment Centers. The recalled entertainment centers' shelves can detach and fall onto consumers when the entertainment centers are moved. American Signature Inc., (877) 793-3423 or www.asfurniture.com.

GE Front-Load Washing Machines. A wire can break in the machine and make contact with a metal part on the washtub while the machine is operating, posing fire and shock hazards to consumers. GE Appliances & Lighting, (888) 345-4124 or www.geappliances.com.

General Electric®-Branded 12-Cup Digital Coffee Makers. The coffee maker can overheat, posing fire and burn hazards to consumers. Walmart Stores Inc., (800) 925-6278 or www.walmart.com.

Giraffe Security Blankets. The balls on top of the giraffe's horns can detach, posing a choking hazard to young children. Rashti & Rashti, (888) 594-3730 or www.rashtiandrashti.com.

Girls' coats. Strings on the detachable cape can pose a strangulation hazard to young children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. S. Rothschild & Company Inc., (800) 223-2664 or www.srothschild.com.

Hoover® WindTunnel T-Series™ Bagless Upright Vacuum Cleaners with Cord Rewind Feature. The power cord is not properly routed or securely seated in the cord rewind assembly allowing the power cord to be pulled loose. This poses fire and shock hazards. Hoover Inc., (888) 891-2054 or www.hoover.com/tseriesrewindrecall.

IKEA Sultan Heidal spring mattresses. The mattresses fail to meet the federal mandatory open flame standard for mattresses, posing a fire hazard to consumers. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Infant onesies and rompers. Snaps on the onesies and rompers can detach from the garment, posing a choking hazard to young children. Holtrop & McIndoo LLC dba Kiwi Industries, (877) 509-4891 or www.kiwiindustries.com.

Lithium-Ion Batteries Used in Hewlett-Packard and Compaq Notebook Computers. The recalled lithium-ion batteries can overheat, posing a fire and burn hazard to consumers. Hewlett-Packard Co., (888) 202-4320 or www.hp.com/support/BatteryReplacement.

Moroccan Tea Glasses. The Moroccan tea glasses contain excessive levels of lead in the exterior coloring. Lead is toxic if ingested by young children and can cause adverse health effects. Cost Plus Inc., (877) 967-5362 or www.worldmarket.com.

Night Train Amplifier Carrying Cases. The clasp on the shoulder strap is defective and can fail, allowing the amplifier to fall and pose a risk of injury to consumers. VOX Amplification, (800) 645-3188 or www.voxamps.com.

Portable Generators. Fuel can leak through the carburetor during normal usage, posing a fire hazard to consumers. Cummins Power Generation, (800) 344-0039 or www.cumminsonan.com/portable/.

Programmable Thermostat Communication Module. The communication module in the thermostat can overheat, posing a risk of fire hazard. Comverge Inc., (866) 277-7001 or http://www.comverge.com/recall.

Rim Rocka Boys' Hooded Jackets and Pelle Pelle Girls' Hooded Jackets. The jackets have a drawstring through the hood and the vests have a drawstring through the waist which can pose strangulation and entanglement hazards to young children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Lollytogs Ltd., (800) 637-9035 or www.ltapparel.com.

Roller, Roman, and Roll-Up Blinds. Roller Blinds: Strangulations can occur if the blind's looped bead chain is not attached to the wall or the floor with the tension device provided and a child's neck becomes entangled in the free-standing loop. Roman Blinds: Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. An additional hazard exists when the Roman blind has a continuous looped bead chain that if not attached to the wall or floor, which poses a strangulation hazard to children. Roll-up Blinds Strangulations 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. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Sandy the Squirrel Plush Toys. Young children can remove and ingest the squirrel's nose, which poses a choking hazard. MOA Entertainment Co. LLC, (877) 336-9716 or www.nickelodeonuniverse.com.

CONSUMER PRODUCTS

Succulent Plant-Shaped Decorative Candles in a Pot. The wax in this candle melts quickly inside and overflows outside the pot and can ignite, posing a serious burn and fire hazard to consumers. Crate and Barrel, (800) 451-8217 or http://www.crateandbarrel.com.

Tommy Hilfiger Sweatshirts. The sweatshirts fail to meet federal flammability standards for wearing apparel, posing a risk of burn hazard to consumers. Tommy Hilfiger U.S.A. Inc., (800) 866-6922 or www.tommy.com.

Utility Sled Tow Hitch. The screw(s) in the hitch can become loose and fall off due to vibrations when items are being towed, allowing the sled and hitch to detach from the towing vehicle. This poses an injury hazard to the user and bystanders. Pelican International, (888) 669-6960 or www.pelicansport.com.

Woven Storage Trunks. The lid of the trunk can drop suddenly when released, posing a strangulation hazard to children opening or reaching into the trunks. Target Corp., (800) 440-0680 or www.target.com.

Remembering the Flexner Report as a Drug Firm Pays $520 Million for Misleading Marketing

The following article by Morton Mintz was posted on NiemanWatchdog.org on May 15, 2010. Mr. Mintz is a senior adviser to the Nieman Watchdog project.

According to company e-mail unsealed in civil lawsuits, AstraZeneca 'buried' a manager's term a 1997 study that showed Seroquel users gained 11 pounds a year, while publicizing a study that claimed users lost weight.

The one-hundredth anniversary of a prescient warning about the "education" of physicians should not pass unmarked.

"[T]he practitioner is subjected, year in and year out, to the steady bombardment of the unscrupulous manufacturer, persuasive to the uncritical, on the principle that 'what I tell you three times is true'," wrote Abraham Flexner, whose Flexner Report for the Carnegie Endowment for the Advancement of Teaching reformed medical education in the United States. "The laity has in this matter more to fear from credulous doctors than from advertisements themselves: for a nostrum containing dangerous drugs is doubly dangerous if introduced into the household by the prescription of a physician who knows nothing of its composition and is misled as to its effect."

A recent example is AstraZenca's agreement "to pay $520 million to settle federal investigations into marketing practices for its blockbuster schizophrenia drug, Seroquel," the *New York Times* reported in April. Seroquel sales were put at $4.9 billion just in 2009.

"The company, based in London, has been accused of misleading doctors and patients by playing up favorable research and not adequately disclosing studies that show Seroquel increases the risk of diabetes," Duff Wilson wrote in the Times. "According to company e-mail unsealed in civil lawsuits, AstraZeneca 'buried' — a manager's term — a 1997 study that showed Seroquel users gained 11 pounds a year, while publicizing a study that claimed users lost weight.

Company e-mail messages also refer to doing a 'great smoke-and-mirrors job' on unfavorable studies."

(See this earlier Nieman Watchdog story dealing with Seroquel.)

There's nothing extraordinary about the AstraZenca case, as Wilson pointed out:

The company will join a series of American pharmaceutical companies that have admitted to illegal marketing after federal investigations and whistle-blower filings and have signed agreements with the government to monitor and avoid such activity in the future.

In the largest such case, Pfizer paid $2.3 billion last September, including $1.3 billion in the biggest criminal fine of any type in United States history, for off-label marketing of the painkiller Bextra and other drugs. Bextra was withdrawn from the market in 2005.

The Pfizer fine included $301 million for off-label marketing of its antipsychotic drug Geodon.

Eli Lilly paid $1.4 billion in January 2009 to settle investigations into illegal marketing of its antipsychotic drug Zyprexa. Lilly's settlement included a $515 million criminal fine, which until the Pfizer case was the largest such fine ever imposed on a corporation.

In 2007, Bristol-Myers Squibb and a subsidiary paid $515 million to settle federal and state investigations into marketing of its antipsychotic drug Abilify.

The more things change ...

PUBLICCITIZEN Health Letter

Outrage! They Said What?!

There seems to be no end to the lack of self-consciousness of the pharmaceutical industry in the way it describes some of the venal things it is doing. For example, in an article recently published in Bioethical Inquiry, based on inside documents from drug companies, the following internal memos were revealed:

"The larger issue is how we face the outside world when they begin to criticize us for suppressing data…" (AstraZeneca publications manager in internal e-mail Dec. 6, 1999)

"We will select tactics for each strategy that offer us best chance of success and execute the *%#&*! out of them." (Eli Lilly drug representative training for managing physician concerns about weight gain and diabetes from the company's antipsychotic drug olanzapine [Zyprexa])

A recent note in a publication called Next Generation Pharmaceutical had this to say about the growth potential for big sales of pharmaceuticals in rapidly developing, "under-exploited" countries:

> "….seven countries Brazil, China, India, Indonesia, Mexico, Russia and Turkey along with other currently under-exploited areas of the world represent a huge opportunity for the pharmaceutical industry. At the same time,

> pressure at home from patent cliffs [expiration of patents on drugs and the availability of much lower-priced generic versions] and dry pipelines [few important innovations in process] has even the big players looking for new ways to increase their bottom lines while at the same time bringing new treatments to previously unserved populations. It seems like a win-win situation."

More people are now learning about "inside" talk in the pharmaceutical industry such as concerns about the public finding out that companies are suppressing data and about industry plans to " push" phar¬maceuticals in rapidly developing "under-exploited " countries. All of these revelations are leading to the industry being viewed by the public in a much more accurate perspective than its expensive, often misleading advertising campaigns have tried to accomplish. ✦