PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Improving Public Access to Clinical Trial Information

In May, a study in the *New England Journal of Medicine* informed the public about the link between the diabetes drug Avandia and heart attacks.

The authors of the article didn't conduct an independent analysis to discover the link, it analyzed and compiled data from a variety of sources – including a clinical trial registry database maintained by Avandia's drugmaker, GlaxoSmithKline.

Publicly available clinical trial registries and databases of the trials' outcomes exist to prevent pharmaceutical companies from suppressing unfavorable study results.

Clinical trial registry databases contain information about the trial, such as the drug being tested and the study's purpose, before the trial begins. The information is available regardless of whether the trial is completed. Ideally, when and if clinical trials are completed, the results would be logged in another database, whether or not they are published in medical literature.

However, the problem with clinical registry databases is that they all contain different information. Public Citizen wants the databases to be standardized and government-regulated to make sure they contain the same kinds of information, according to a new report released in July.

"All of the currently available clinical trial registries and results databases are inadequate," according to the report.

Access to complete, comprehensive clinical trials registries is essential for scientists who review studies to see if any health risks are overlooked, such as in the case of Avandia. The database for Avandia contained enough easily searchable information about the drug to make the study successful, but this may not always be the case. That's why these registries and results databases should be regulated, according to Public Citizen.

Public Citizen's report compares existing and proposed registries and results databases, finding that while private registries and databases exist, they are of variable quality. Further, because these private registries are voluntary, they are designed inconsistently and information is included inconsistently. This can limit the accessibility of the information because online visitors have to search harder for information which, in some registries, may not even exist. As with any non-public venture, there are significant questions as to transparency, enforceability and quality assurance.

The lack of standardized databases for clinical trial registries and results prevents pharmaceutical companies from truly being held accountable, according to Public Citizen. Currently, only federally and privately funded trials of experimental treatments for "serious or life-threatening diseases and conditions" are required to be included in a registry.

(There are four public registries which are generally of high quality, but none is a results database, the report found.)

"Requiring full disclosure from the pharmaceutical companies prevents them from manipulating information by purposely excluding results that conflict with their business models," said Dr. Peter Lurie, deputy director of the Health Research Group at Public Citizen and co-author of the report. "Without any secrets, other members of the scientific community can moni-

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Scapegoating Immigrants: Bad Policy, Worse Public Health

Two years ago, two Congressional representatives from Georgia played into nativist concerns and proposed legislation to limit access to care for undocumented immigrants. They succeeded in enacting a proof-of-citizenship rule that restricted eligibility to Medicaid to those who could produce "satisfactory documentary evidence of citizenship" such as a passport or the combination of a birth certificate and driver's license. The rule ended the previous practice of self-attestation of citizenship. Instead, potential applicants and re-enrolling beneficiaries are now required to submit original documents which are often elusive or difficult to get.

The rule has now been effect for more than a year, and several recent reports look into its implementation and effects. The Government Accountability Office (GAO) was asked to examine the requirement's effect on individuals' access to Medicaid benefits, and assess the administrative and fiscal implications of implementing the new rule. The GAO surveyed state Medicaid offices in the 50 states and the District of Columbia. They obtained complete responses from 44 states representing 71 percent of total Medicaid enrollment in FY2004, and their findings are based on these respondents.

Half of the states (22) reported declines in Medicaid enrollment due to the requirement, a trend that the majority of states attributed to delays in or losses of Medicaid coverage for individuals who appeared to be eligible citizens. The requirement had a more negative impact on applicants (as opposed to re-enrolling beneficiaries) because these were given less time to comply in some states and were not eligible to receive program benefits until they documented their citizenship.

Because the rule imposed new administrative oversight on the process of eligibility verification, it was expected to cause a slight increase in program costs. This, however, was anticipated to both taper off and to be more than offset by program savings resulting from the exclusion of ineligible beneficiaries.

The GAO found that all 44 states had to adopt additional administrative measures to comply with the rule. These measures included training Medicaid agency staff, community agencies and providers, and expanding staff capacity. One state that carefully monitored its activities reported a 60 percent rise in phone calls, a tenfold increase in voice messages and an 11 percent increase in the length of calls. In addition to raising the "hassle factor," implementing the citizenship requirements increased the administrative costs of the Medicaid program. Ten states reported having appropriated a total of $28 million in FY 2007 for this purpose, and 15 states budgeted additional funds for FY2008. Even after increasing their personnel, however, states found their staffs spending more time completing applications and redeterminations, and individuals needing more assistance in person during the process.

At the same time, these additional costs were not offset by the exclusion of ineligible applicants. While the Center for Medicare and Medicaid Services (CMS) had estimated that the latter would result in savings of $50 million for the federal government and $40 million for states in FY2008, the states feel that this is overstated because it does not account for the

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tor progress and will know about any changes or abandoned studies, which would make the public more comfortable with the actions of these mistrusted corporate giants. Further, registries help recruit patients into clinical trials, which is also important."

The only way to force standardized databases is for Congress to enact legislation, which would also assess penalties for non-compliance, according to Public Citizen.

Both the US House and Senate have recently passed bills that seek to formalize the information that must be posted in clinical trial registries and, potentially, results databases. The House bill, H.R. 2900, is better than the Senate bill, S. 1082, in creating and enforcing a standardized registry and results database. Unlike the Senate version, the House bill has an important provision requiring a summary of clinical trials for patients that would describe the most important elements of the study design and results – and the risks involved – in non-scientific terms.

The Senate bill's approach has the potential to completely gut the results database initiative. It requires a feasibility study for the results database as well as a subsequent "negotiated rulemaking." The 18-month study would recommend what types of information should be disclosed, the timeframe in which disclosure would occur and how the information would be released. The "negotiated rulemaking" would guarantee involvement by members of the pharmaceutical industry and could lead to an ineffective results database.

"We hope that Congress passes a law that will help to make the information in these databases more consistent. The law also needs to have an enforcement mechanism," Lurie said. "Without such a mechanism, pharmaceutical companies will have no motivation to release all the information about their clinical trials."

To read the report, visit www.citizen.org/publications/release.cfm?ID=7534. ■

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increases in administrative expenses. Moreover, the "outright theft of Medicaid benefits by illegal aliens" which the legislation and the proof-of-citizen requirement were expected to end proved to be largely mythical. The GAO report found only one state that reported potential savings as a result of individuals being denied or terminated from coverage because they were ineligible due to citizenship status. Thus it appears that the enacted requirements not only targeted a problem that did not exist, but also imposed fiscal and logistical burdens on state Medicaid programs and beneficiaries alike.

Complementing and partly overlapping with the GAO report, the majority staff of the Committee on Oversight and Government Reform surveyed nine states to assess if the enacted rule had saved taxpayer money by barring illegal immigrants from Medicaid coverage. Of this sample, six states were able to provide data on both (1) the additional state expenditures due to the citizen documentation provisions and (2) the number of undocumented immigrants discovered as a result of the new requirements.

These states reported spending an additional $16.6 million in administering the program; half of these costs are estimated to be federal spending. Implementing the new requirement yielded a total of eight undocumented immigrants who were therefore dropped or excluded from the Medicaid program; most of these (6 of the 8) were in Louisiana, where the population has undergone massive upheavals and the Medicaid program has suffered major disruptions since Katrina. The report therefore concluded that, for the six states, the costs of implementing the documentation requirements far exceeded the savings to the taxpayers: it is estimated that the federal government saved $11,048 in services for the $8.3 million it spent. This represents a return of 14 cents for every $100 spent, a dismal payoff by any standard.

Another study by the George Washington University School of Public Health and Health Services focused on the effects of the proof-of-citizenship requirements on health centers and their patients. A random national survey of 30 health centers found that more than 90 percent of all centers reported disruptions in coverage and enrollment difficulties. More than one-third had to add staff to process applications and monitor documentation. The study estimates that the requirements would reduce Medicaid coverage for 105,100 to 319,500 patients, which in turn translate into losses of between $28 and $85 million in Medicaid revenues for these health centers.

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Finally, and most usefully, a report by the Center for American Progress examines the basis for the restrictive policy, namely, the belief that immigrants in the US are a burden on the health care system. It dissects five myths that have been widely disseminated by talking heads who see themselves as policy wonks. These myths are as follows:

1. US public health insurance programs are overburdened with documented and undocumented immigrants;
2. Immigrants consume large quantities of limited health care resources;
3. Immigrants come to the US to gain access to health services;
4. Restricting immigrants' access to services will not affect American citizens; and
5. Undocumented immigrants are "free riders" in the system.

In fact, immigrants are more likely to be uninsured; account for a lower per capita expenditure of public sector funds than do native-born citizens; are less likely to seek and receive health services (including emergency care); and come to the United States to work primarily in high-risk, low-paying jobs and not to take advantage of services. Moreover, limiting immigrants' access to care jeopardizes the public's health in multiple ways. Lack of immunization results in a higher prevalence of vaccine-preventable diseases, and lack of insurance results in shifting costs which are ultimately paid for by state and federal governments, local communities and American citizens. Most blatantly misleading is the myth that undocumented immigrants are getting more than their "fair share" as free riders in the US health system. In fact, undocumented workers contribute more in revenues than they consume in social benefits. Additionally, the National Research Council has concluded that immigrants will pay an average of $80,000 more per capita than they will use in government services over their lifetimes. In social security alone, undocumented immigrants have paid billions of dollars that they cannot draw from, thereby subsidizing the income of others.

The barriers that Medicaid has adopted to restrict care to immigrants have therefore not only been largely ineffectual and costly, but also shortsighted and unfair. Myths have overtaken evidence, and ideology has eclipsed an assessment of effects. As a result, the proof-of-citizenship restriction has succeeded only in further burdening the already complex system of Medicaid eligibility, increasing costs and creating distinctions between the "worthy" and "unworthy" when the health of the public is at stake. ■

Product Recalls

July 19, 2007 — August 23, 2007

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

H S Joy of Love Sexual Energizer 100% Pure Herbal Extract 500mg/Cap, 12 Caps/box; Unapproved New Drug. Product has been found to contain piperadino vardenafil, an analogue of Vardenafil, an FDA-approved drug used to treat Erectile Dysfunction (ED). "USEBY 09-05-09 LOT # I-05-06-2"; Herbal Science International, Inc.

Long Weekend, Natural Libido Enhancer, (Epimedium P.E. 300 mg, Fructus Lycii P. E. 50 mg); Unapproved new drug; product was found to contain undeclared tadalafil, the active pharmaceutical ingredient in an FDA-approved drug used to treat erectile dysfunction. All lots, Confidence, Inc.

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

Denta-kleen Junior Fluoride Toothpaste, Strawberry and Blueberry flavors, Net Weight 50 g tubes, labeled ingredients include Sodium Monofluorophosphate 500 ppm, Glycerin, and Sorbitol; Toothpaste from China may contain the poisonous chemical diethylene glycol (DEG). All lots; Goldcredit International Enterprises.

ShiR Fresh Anticavity Fluoride Toothpaste, Cool ShiR Mint flavor, Kids Mint, Net Weight 6.4 oz., labeled ingredients include: Sodium Monofluorophosphate 0.70%, Glycerin, Sorbitol; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). Lot #: 2471B; Gold City Enterprise, LLC.

Oxycodone and Aspirin Tablets USP 4.5 mg -0.38 mg; Product may not meet aspirin dissolution specifications through the labeled expiration dates. Batch # M920110 Lot #: L6E0600A exp. date 09/2007; Batch # M947980 Lot #: L6E0602B exp. date 12/2007; Batch # M975710 Lot #: L6G0851A exp. date 03/2008; and Batch # 992490 Lot #: L6K1209A exp. date 04/2008; Watson Laboratories Inc.

DentalPro Fresh Spearmint Flavor Fluoride Toothpaste and Toothpaste with Brush Combo, 6.4 oz. tubes, labeled ingredients include Sodium monofluorophosphate 0.8% and Diglycol; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). All lots; Goldcredit International Enterprises.

BrightMax Cool Peppermint Flavor Cavity Fighting Fluoride Toothpaste and Toothpaste/Brush combo, 1.76 oz and 6.4 oz tubes, labeled ingredients include Sodium monofluorophosphate 0.8%, Sorbitol and Diglycol; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). All lots; Goldcredit International Enterprises.

Dentakleen Fluoride Toothpaste, multiple flavors including Regular, Fresh Mint and Winterfresh, 6.4 oz tubes, labeled ingredients include Sodium Monofluorophosphate 0.7% and Sorbitol; Toothpaste from China may contain the poisonous chemical diethylene glycol (DEG). All lots; Goldcredit International Enterprises.

Recalls and Field Corrections: Drugs — CLASS II *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

ShiR Fresh Anticavity Fluoride Toothpaste, Ice ShiR Mint Flavor, Net Weight 6.4 oz., labeled ingredients include: Sodium Monofluorophosphate 0.70%, Glycerin, Sorbitol; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). Lot #: 2471A; Gold City Enterprise, LLC.

ShiR Fresh Anticavity Fluoride Toothpaste, Mint Flavor, Net Weight 9 oz., labeled ingredients include: Sodium Monofluorophosphate 0.70%, Glycerin, Sorbitol; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). Lot #s: 777A, 777B, 777C, 777D; Gold City Enterprise, LLC.

Illinois Walgreens Recall

The following recall applies only to roughly 8,000 individual units sold in Walgreens in Illinois. The affected lots are shipment numbers 874497, 874503, 874542, 875023, 875114, 877282, 875296, all shipped on 02/16/2007. The products were exposed to below freezing temperatures which may impact their safety and effectiveness. If you live in Illinois and have recently bought one of the following products from a Walgreens, please contact your pharmacist to find out if your dose is one of the recalled drugs.

- 70% Human Insulin Isophane Suspension 30% Human Insulin Injection (rDNA origin)
- Acetaminophen & Codeine Phosphate Oral Solution USP
- Acetaminophen Elixir
- ALPHAGAN® P (brimonidine tartrate)
- ALREX® (loteprednol etabonate) ophthalmic suspension
- Androderm extended release transdermal patch, testosterone
- AZOPT® (brinzolamide) ophthalmic suspension 1%
- Bacitracin Ophthalmic Ointment
- Belladonna Alkaloids with Phenobarbital Oral Elixir
- Betimol® (timolol) ophthalmic solution 0.5%
- Carafate (sucralfate) Suspension
- Ceron Oral Drops
- Cheratussin AC Syrup
- Cheratussin DAC Syrup
- Ciloxan (ciprofloxacin hydrochloride) Ophthalmic Ointment 0.03%
- Cipro HC Otic Suspension
- Ciprodex (ciprofloxacin 0.3% and dexamethasone 0.1%) Sterile Otic Suspension
- Ciprofloxacin Hydrochloride Ophthalmic Solution 0.3%
- Climara estradiol transdermal system
- Climara Pro (Estradiol/Levonorgestrel Transdermal System)
- Cosopt (dorzolamide hydrochloride-timolol maleate)ophthalmic solution
- Cyproheptadine Syrup
- Cytra-K Oral Solution
- EpiPen Auto-Injector
- Erythromycin Ophthalmic Ointment USP 0.5%
- Fluorometholone Ophthalmic Suspension
- Fluoxetine Oral Solution
- Flurbiprofen Sodium Ophthalmic Solution 0.03%
- Furosemide Oral Solution
- Gentamicin Sulfate Ophthalmic Solution 0.3%
- Glucagon Emergency Kit for Low Blood Sugar (Glucagon for Injection [rDNA origin])
- Griseofulvin Oral Suspension
- H-C Tussive Syrup
- Humalog Insulin Lispro Injection (rDNA origin)
- Humalog Mix 75/25, 75% Insulin Lispro Protamine Suspension 25% Insulin Lispro Injection (rDNA origin)
- Ibuprofen Oral Suspension
- Keppra Oral Solution
- Levemir Insulin Detemir Injection, (rDNA origin)
- Levobunolol hydrochloride ophthalmic solution 0.5%
- Lidocaine Hydrochloride Oral Topical Solution
- Lidoderm (lidocaine 5%) Patch
- Loratadine Syrup
- Lotemax (loteprednol etabonate) Ophthalmic Suspension 0.5%
- Lovenox Injection, enoxaparin sodium 100 mg/mL
- LUMIGAN® (bimatoprost) ophthalmic solution 0.03%
- Medroxyprogesterone Acetate Injection Suspension
- Neomycin And Polymyxin B Sulfates And Dexamethasone Ophthalmic Suspension
- Neomycin, Polymyxin B, Hydrocortisone Otic Suspension
- Novolin R Regular Human Insulin Injection (rDNA origin)
- Novolog Insulin Aspart Injection (rDNA origin)
- Novolog Mix 70/30, 70% Insulin Aspart Protamine Suspension and 30% Insulin Aspart Injection (rDNA origin)
- NPH Human Insulin (rDNA origin) Isophane Suspension
- Nystatin Oral Suspension USP
- Ofloxacin Ophthalmic Solution 0.3%
- Optivar Azelastine Hydrochloride Ophthalmic Solution, 0.05%
- Ortho Evra Transdermal System
- Oticaine (benzocaine) 20% Otic Drops
- PATANOL® (olopatadine hydrochloride) ophthalmic solution 0.1%
- Phenobarbital Elixir
- Phenyl Chlor-Tan Pediatric Suspension
- Phenytoin Oral Suspension
- Polmyxin B Sulfate And Trimethoprim Ophthalmic Solution
- Potassium Chloride Oral Solution 20%
- Prednisolone Acetate Ophthalmic Suspension 1%
- Prednisolone Sodium Phosphate Oral Solution
- Prednisolone Syrup
- Progesterone Injection
- Promethazine Hydrochloride and Codeine Phosphate Syrup
- Q-Dryl AF Elixir
- Q-Pap Drops, Acetaminophen Oral Drops
- RESTASIS® (cyclosporine) ophthalmic emulsion 0.05%
- Sulfacetamide Sodium and Prednisolone Sodium Phosphate Ophthalmic Solution
- Sulfatrim Suspension Pediatric, Grape
- Tannate-12D S Suspension
- Timolol maleate ophthalmic gel forming solution 0.25%
- Timolol maleate ophthalmic gel forming solution 0.5%
- Timolol maleate ophthalmic solution 0.5%
- Tobradex® (tobramycin and dexamethasone) ophthalmic suspension
- Tobramycin Ophthalmic Solution USP 0.3%
- Vigamox (moxifloxacin HCl) ophthalmic solution 0.5%
- Vivelle Dot Estradiol Transdermal System
- Voltaren (diclofenac sodium) Ophthalmic Solution 0.1%
- Zyrtec Syrup

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; Manufacturer and Contact Information

"Cars" Movie Toy Cars. Surface paints on the "Sarge" die cast toy cars could contain lead levels in excess of federal standards. Lead is toxic if ingested by young children and can cause adverse health effects. Mattel Inc., (800) 916-4997 or www.service.mattel.com.

Aerosol Cans. Hi-Heat Aerosol Coating Cans can over-pressurize and explode, posing a risk of injury to consumers. The Sherwin-Williams Co., (888) 304-3769 or www.sherwin-williams.com.

Air Filters. Electrical arcing inside the collection cells of the Stand-alone CleanEffects and AccuClean Air Filtration Systems can cause the collection cell material to overheat or ignite, posing a fire hazard. Trane, (888) 556-0125, www.trane.com (for CleanEffects owners) or www.americanstandardair.com.

Barbie and Tanner Toys. A small magnet inside the "scooper" accessory of the Barbie and Tanner™ play sets can come loose. 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 perforation or blockage, which can be fatal. Mattel Inc., (888) 597-6597 or www.service.mattel.com.

Bicycles. The forks can break during normal use, causing the rider to lose control, fall and suffer serious injuries. Raleigh America Inc., (888) 805-6396 or www.raleighusa.com.

Children's Charm Bracelets. Children's Divine Inspiration Charm Bracelets contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Buy-Rite Designs Inc., (888) 777-7952 or www.buyriteinc.com.

Children's Jewelry. TOBY & ME Jewelry Sets contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. TOBY N.Y.C., (866) 235-0588 or info@tobynyc.com.

Circular Saws. The trigger switch on the Skil® brand Circular Saws can be locked on or the switch can be turned on without the use of the safety lock-out. This can cause unexpected operation of the saw, posing a risk of laceration. Robert Bosch Tool Corp., (866) 761-5572 or www.skil.com.

Coca Cola-Themed Drinking Glasses. The inner wall of the double-walled Drinking Glasses can break easily, posing a laceration hazard to consumers. Formation Inc., (866) 428-1176 or www.formationinc.com.

Coffeemakers. The *Signature Gourmet*™ and *Kitchen Gourmet*® 12-Cup Coffeemakers can ignite due to an electrical failure, posing a fire hazard. Atico International USA Inc., (877) 546-4835 or www.aticousa.com.

Crib Bumpers. The decorative stitching on the Matelassé Crib Bumper's edge can come loose, posing an entanglement hazard to young children. Pottery Barn Kids, (877) 800-9720 or www.potterybarnkids.com.

Doggie Day Care Toys. Small magnets inside the Doggie Day Care™ play sets can fall out. 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 perforation or blockage, which can be fatal. Mattel Inc., (888) 597-6597 or www.service.mattel.com.

Easy-Bake Ovens. Young children can insert their hands into the Easy-Bake Oven's front opening, and get their hands or fingers caught, posing entrapment and burn hazards. Easy-Bake, (800) 601-8418 or www.easybake.com.

Electric Blankets. Bunching, folding or tucking of Classic Beauty Rest Electric Warming Throws can cause them to overheat, resulting in smoldering, melting, fire and burn hazards. International Home Fashions Inc., (800) 905-0799 or www.intlhomefash.com.

Electric Leaf Blowers. The Toro Power Sweep Electric Blower's impeller, which is a rotating component on the blower, can break, resulting in pieces of plastic flying out of the blower. This poses a risk of serious injury to the user or a bystander. The Toro Company, (888) 279-3191 or www.toro.com.

Fisher Price Character Toys. Surface paints on the Sesame Street, Dora the Explorer, and other children's toys could contain excessive levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Fisher-Price Inc., (800) 916-4498 or www.service.mattel.com.

CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Frozen Carbonated Beverage Dispensers. A problem with the Frozen Carbonated Drink Dispenser's florescent lamp can cause electrical arcing, which poses a fire hazard to consumers. IMI Cornelius, (800) 238-3600 ext. 5 or www.cornelius.com.

Horseback Riding Stirrups. Stübben Steeltec SEQ Stirrups' hinges can break, posing a fall hazard to riders. Stübben North America, Inc. at (800) 550-1110 or www.stubbennorthamerica.com.

Junction Boxes. Wiring connections within the junction box can become loose, posing an overheating and fire hazard. Electric Cooperative, (800) 824-5102 or www.eiec.coop.

LED Lights. The circuit board in the E Lights can overheat, posing a risk of fire. Plan 9 Inc., (866) 522-1368 or www.E-Light-Recall.com.

Log Splitter. The Log Splitter's hydraulic cylinders can have defective rod retention, causing the seals to leak and the rods to detach. This can result in serious injury to the operator, as the rod can rapidly and unexpectedly extend the splitting wedge. Brave Products Inc., (800) 350-8739 or www.logsplitters-ironoak.com.

Lounge Chairs. Faulty support brackets and/or weak frames of the Lounge Chairs can cause the chairs to collapse, posing a fall and severe laceration hazard to consumers. Yotrio International LLC, (800) 793-7055 or www.yotrioint.com.

Magnetic Action Figures. Small, powerful magnets inside the accessories of the toy figures can fall out and be swallowed or aspirated by young children. If more than one magnet is swallowed, they can attract inside the body and cause intestinal perforation, infection or blockage which can be fatal. Mattel Inc., (888) 597-6597 or www.service.mattel.com.

Metal Folding Chairs. The Bistro Chairs can collapse due to faulty rivets, posing a fall hazard to consumers. Cost Plus Inc., (877) 967-5362 or www.worldmarket.com.

Notebook Computer Batteries. Rechargeable lithium-ion batteries containing Sony cells used in Toshiba notebook computers can overheat, posing a fire hazard to consumers. Toshiba America Information Systems Inc., (800) 457-7777 or www.bxinfo.toshiba.com.

Outdoor Lounge Chairs. Garden Treasures Cloud 9 Beyond Chairs can break when in the reclined position, posing a fall hazard to consumers. L G Sourcing, Inc., (866) 493-6560 or www.lowes.com.

Pine Cone Candles. Gold Pine Cone Candle Sets' exterior paint and coating can ignite and catch fire, igniting nearby combustibles. Giftco Inc., (888) 448-6728.

Polly Pocket Play Sets. Small magnets inside Various Polly Pocket dolls and accessories with magnets can come loose. The magnets can be found by young children and swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforation or blockage, which can be fatal. Mattel Inc., (888) 597-6597 or www.service.mattel.com.

Remote Control Airplanes. Sky Rangers Park Flyer Radio Control Airplanes are launched by hand and can explode near the consumer's head, posing a risk of temporary hearing loss and injuries to eyes, face and hands. Estes-Cox Corp., (800) 576-5811 or www.estesrockets.com.

Safety Release Plugs. Relief Plugs Used on Nitrous Oxide Systems and HVAC Service Tools can allow pressure to build in the cylinder of an HVAC pressure testing tool or Nitrous Oxide system. If the cylinder is overfilled and overheated it can burst, posing an injury hazard to consumers. Rehvac Manufacturing Co., (800) 856-5668 or www.oemregs.com.

Sandal Clogs. The leather ankle strap of Birchwood Sole Sandal Clogs can tear or separate from the clog sole, posing a fall hazard. Hanna Andersson Inc., (800) 222-0544 or www.hannaandersson.com.

Sippy-Cups. Young children can chew through the plastic spout of the Playskool Toddler "NoSpill" Sippy Cups, which can pose a choking hazard. CVS/pharmacy, (866) 434-0098 or www.cvs.com.

Sleeping Bag Toys. The plastic button eyes on the Stuffed Plush Horse/Pillows and Fairy Dolls sold with sleeping bags can easily detach, posing a small parts choking hazard to young children. The Orvis Company, (866) 531-6199 or www.orvis.com/recall.

Spinning Tops. Surface paints on the wooden handles of the Spinning Tops and Tin Pails and pails contain excessive levels of lead, which violates the federal lead paint standard. Lead is toxic if ingested by young children and can cause adverse health effects. Schylling Associates Inc., (800) 767-8697 or www.schylling.com.

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Name of Product; Problem; Manufacturer and Contact Information

SpongeBob SquarePants Address Books and Journals. The paint on the metal spiral bindings of SpongeBob SquarePants™ Address Books and Journals can contain excessive levels of lead, which violates the federal lead paint ban. Lead is toxic if ingested by young children and can cause adverse health effects. Martin Designs Inc., (866) 898-0261 or www.martindesigns-ltd.com.

Studded Pacifiers. These pacifiers fail to meet federal safety standards for pacifiers. The pacifiers' crystals can separate easily, posing an aspiration and ingestion hazard to young children. Dara Linda's Baby Bling and Jewelry Design, www.jewelryandbabyblingbydara.com or (954) 600-8988; Bling Toes, www.blingtoes.com or (815) 718-1280; Baby Bling Things, (920) 832-9161 or email: Blingthings4you@yahoo.com; PeaNaPod Bling and Accessories, (260) 422-3630 or PeaNapod Bling and Accessories; and MJM Crystal Designs, (561) 715-9591or email: realta@aol.com.

Sweaters. The Shawl Collar Sweaters fail to meet Federal flammability requirements. Should the sweater come in contact with an ignition source, such as a stove burner, candle flame or cigarette lighter, it could catch fire and cause serious burns to consumers. Coldwater Creek, (800) 262-0040 or www.coldwatercreek.com.

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The Number of Uninsured in the United States Reaches a Record 46.6 Million

Whatever the official seasons, the end of August marks the end of summer for many. But for those in the health policy arena, the end of August (a slow-news period) is when the US Census Bureau releases its most recent data on the uninsured. This pre-election year, as health reform becomes a more politically charged issue, the numbers are not encouraging for those who feel that the current system needs tweaking rather a fundamental rethinking: a record-setting 47 million Americans lacked health insurance in 2006. That means the proportion of uninsured rose from 15.3 percent in 2005 to 15.8 percent in 2006.

These data confirm what other economic indicators suggest: a growing proportion of employers are finding it too expensive to offer health coverage to their employees. And faced with a choice between losing employer-based health insurance and losing jobs, unions are opting to protect jobs. As a result, the percent of Americans with employer-sponsored insurance decreased from 60.2 percent in 2005 to 59.8 percent in 2006. And, because many workers losing their insurance are unable to obtain adequate health coverage on the market, the number of people with privately purchased plans has also dropped. Thus a growing proportion of workers are caught in a bind: their incomes are too high for them to qualify for Medicaid, yet too low to allow them to buy a policy that will cover them and their families. Not unexpectedly, the number of full- or part-time workers who were uninsured rose by 1.3 million between 2005 and 2006.

The fact that health care is becoming increasingly unaffordable means that those who perceive themselves as being at lower risk of illness may opt to go without coverage. As a result, young adults between the ages of 18 and 34 comprised the largest proportion of the uninsured, accounting for 40.4 percent of those without coverage.

Another at-risk group is children. In 2006, 11.7 percent of children under the age of 18 were uninsured, up from 10.9 percent the previous year. In absolute numbers, this means that more than 8.7 million children were without coverage, one million more than in 2004. This represents a reversal of a prior trend: between 1999 and 2004 the expansion of Medicaid and the State Children's Health Insurance Program (SCHIP) increased the number and proportion of those covered, thereby bucking the prevailing trend for the other age groups. But for the past two years the programs' growth has not kept pace with the falling number of those left out because of falling job-related coverage. The data showing a rise in uncovered children are therefore likely to fuel the debate on the expansion of SCHIP, with some states looking to expand eligibility threshold to include children whose family incomes are 400 percent the federal poverty index.

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In addition to children, the rise in the uninsured has not affected all groups equally. The breakdown by ethnicity shows that the rate for whites remained stable at 10.8 percent while that for Asian-Americans fell from 17.2 percent to 15.5 percent. For blacks, the uninsurance rate rose from 19 percent to 20.5 percent. The rate for Hispanics increased more dramatically, with 34.1 percent uninsured compared with 32.7 percent a year ago.

The rise and high level of uninsured Hispanics highlight the relative disadvantage of this segment of the population. While Hispanics account for 14 percent of the US population, they represent nearly half the increase in the number of uninsured. This reflects the precarious economic status of many Hispanics as well as their recent arrival. For a proportion of this population, Medicaid, which is largely limited to citizens, is not an option. Fully 45 percent of undocumented Hispanics are not insured.

The construction industry is the largest employer of Hispanics, followed by the leisure and hospitality industries. Employers in these economic sectors tend to hire workers to meet their short-term, fluctuating needs, and make no long-term commitments to (or investments in) their workforce. Unauthorized workers are thus seen as both necessary and expendable, constituting a reserve army of labor that can be hired and laid off at will. Many of these workers are parents, so their children are also reflected in the rising number of children that are uninsured. The problem of lack of insurance is therefore inextricably tied to the immigration issue, adding yet another layer of complexity to the political debate.

Because neither children nor unauthorized Hispanics can vote, the lack of health coverage among these two groups has been distinctly muted as a national political issue up to now. At present, however, the reauthorization of the SCHIP program has fueled the debate on coverage for children. But the political fight has pitted those who want to increase eligibility against

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those who feel that expanding the program will result in reductions in those who are now privately insured, a phenomenon known as "crowd out," with not much ground for compromise. And the situation varies greatly from one state to another, with the lack of health coverage gaining political prominence in some jurisdictions. While only 8.5 percent of Minnesotans are uninsured, 24.1 percent of Texans are in that position. In the absence of a national commitment to provide universal health insurance to all residents of the United States, the states have borne the burden of health coverage for their populations. But, as we repeatedly stated, a state-by-state approach will only create a patchwork of coverage that is not portable across states, and only exacerbate the geographic, economic and ethnic disparities that afflict our health care system overall.

The fact that uninsurance is at a record high is not surprising given increasing costs, squeezed wages, erosion in job-related coverage and continued unwillingness to abandon the current dysfunctional financing of health care in United States. But as we spend one-sixth of our GDP on health, approximately twice as much as the rich-country average, it is disgraceful that we have failed to guarantee universal health coverage for all, and that headlines such as the one accompanying this article continue to be news.

If you would like to make your voice heard on single payer, tell your Congressman/woman by joining our online letter-writing campaign at http://action.citizen.org/campaign.jsp?campaign_KEY=12356.

Public Citizen supports a single payer health care plan, which would provide universal health care for all US residents. We believe this is the best option for a variety of reasons. For example, single payer builds on the existing experience of the single payer Medicare program and would therefore dramatically cut down on administrative costs; currently the US pays 50 to 100 percent more on administration than countries with a single payer system, wasting an estimated $350 billion a year. Such a system would also facilitate quality control by providing comprehensive, accurate and timely national data based on health service utilization and health outcomes. Plus, single payer gives the government greater leverage to control costs, including for prescription drugs, promotes greater accountability to the public and fosters transparency in coverage decisions.

There is currently a bill in the House of Representatives, HR 676, that would establish a single payer system in the US. Public Citizen supports this legislation. If you would like to make your voice heard on single payer, tell your Congressman/woman by joining our online letter-writing campaign at http://action.citizen.org/campaign.jsp?campaign_KEY=12356. ■

OUTRAGE, *from page 12*
tance to address ED.

Under the banner of cultural competence and sensitivity, the report then goes on to generalize about Latino patients, oblivious to the fact that in-group differences may trump any pan-Latino similarities. The importance of respect and courtesy are stressed, as should be the case with all patients. In the case of Latinos, however, certain key phrases are suggested as verbal signs of respect: for example "Con su permiso" (with your permission) is recommended before beginning a physical examination. Similarly, the pointers play on the idea of Latinos as "touchy-feely" and doctors are urged to place their hand on the patient's shoulder or pat them on the back. Describing the Hispanic community as "profoundly spiritual," the report also suggests tapping into religious beliefs to connect with patients. One member of the expert roundtable prescribes using the phrase "God willing" – most often associated with other-worldly powers, fatalism and resignation – as one that projects encouragement and warmth.

Equally disturbing is the text's obvious exclusions and myopia when addressing gender-related issues. Perhaps because all the physicians invited to the roundtable were men, the publication assumes that all doctors are male. As a result, no mention is made of female physicians in their interactions with patients. Similarly, patients' sexual partners are assumed to be female; the concerns of men who have sex with men therefore go unmentioned. The report thus falls prey to the same sexual taboos it is attempting to address, even as the Viagra market owes a significant share of its sales to gay and bisexual men.

We should not be surprised that Pfizer should seek to woo all potential allies in its quest for greater market share. But we would expect that a not-for-profit professional organization be less eager to sell its name to a purely commercial enterprise which obliterates any distinction between education and propaganda. And we would also hope that "cultural sensitivity" not serve as an excuse to reinforce sexual and ethnic stereotypes. ■

Manipulating the Hispanic Market: The Case of Viagra

More than 350,000 prescriptions of Viagra were filled the 3 weeks after Pfizer launched the drug to treat erectile dysfunction (ED). Viagra is currently used by 20 million men in 110 countries. With annual sales of over $1.5 billion but facing increasing competition from other ED drugs, Pfizer has left no potential market niche untouched.

In this effort, Pfizer has enlisted the all-too-available support of the Interamerican College of Physicians and Surgeons, a not-for-profit organization founded in 1979 to "promote cooperating among US Hispanic physicians and to advance their professional and educational needs." As part of its activities supported by "an unrestricted educational grant from Pfizer, Inc.," the College convened a roundtable of physician experts to discuss the diagnosis and treatment of ED. The results of this discussion have now been published in Spanish and sent to a broad roster of Hispanic/Latino physicians. The report, titled *Rompiendo el Silencio de la Disfunción Eréctil* ("Breaking the Silence on Erectile Dysfunction"), purports to provide pointers to Spanish-speaking physicians concerning Latino patients and their presumed reticence on the topic of ED. But the publication is also a blatant infomercial for Viagra. The drug's safety and efficacy are touted, with references to the one research study – funded by Pfizer, of course – that included Hispanic American men with ED. And care is taken to suggest a response for any patient who should balk at the drug's cost. Not affluent? Not insured? The doctor is advised against not prescribing solely because of the patient's inadequate health coverage: "The correct questions may elicit coverage unknown to the patient or his eligibility to receive additional benefits."

If the fact that the Interamerican College has lent itself to being an unabashed promoter of a particular drug were not offensive enough, the offense is compounded by the patronizing tone of the suggestions and its obvious exclusions. Predictably, the text begins with a discussion of *machismo*, or masculine pride, because of its obvious links to a reluc-

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