PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Back to Basics: Clean Water as a Medical Milestone

The word "breakthrough" is regularly heard in medical reports, especially in relation to a drug, device, or other technology that is being promoted as the "next big thing" in medical practice. But not all innovations are breakthroughs, not all breakthroughs are advances, and not all advances are milestones. The latter represent markers of accomplishment; in medicine, a true milestone often alters how a phenomenon is seen and how it is addressed. Moreover, it has a dramatic effect on health and disease.

Recently, the *British Medical Journal* gave its readers the opportunity to ponder what constitutes a significant medical milestone. Specifically, readers were asked to choose "the most important medical milestone" since 1840, when the *BMJ* began publication. After an initial round of nominations, a panel of experts whittled down the list to 15 milestones. Readers then had the opportunity to vote for their choices over the course of 10 days. More than 11,000 persons from all over the world cast their votes. The winner: the "sanitary revolution," with 15.8 percent of the vote. This was followed by antibiotics, with 15 percent, and anesthesia with 14 percent. Some notches down were two additional options: the introduction of vaccines (12 percent) and the discovery of the structure of DNA (9 percent).

The *BMJ*'s selection pays tribute to the valiant efforts of Edwin Chadwick, a 19th century lawyer who pioneered the introduction of piped water and sewage disposal in England. The choice also recognizes that, although lacking the razzle-dazzle of disease-specific cures, improved sanitation has had a widespread and lasting effect on many of the causes of disease, proving that "passive protection against health hazards is often the best way to improve population health."

Yet even an "intervention" as seemingly innocuous as sanitation and clean water met with the opposition of interested parties in Chadwick's time, and he had to wage a long battle against these. But his tenacious advocacy ultimately prevailed, and he changed how people lived as well as how they died.

Chadwick's challenges

Born in 1800, Chadwick was a young lawyer when he became a Member of the Royal Commission of Inquiry on the Poor Laws, which sought to study the social security system which had been in place in England since the 16th century to give relief to the unemployed, the old, and the sick. This piqued his interest in what we now call the "social determinants of health": those factors that influence the health status of a population, including not only their access to medical care, but also the environment in which they live, where they work, what they do, and the habits

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CLEAN WATER, *from page 1*
they adopt. In 1837 and 1838, in the wake of influenza and typhoid epidemics which devastated England, Chadwick headed an inquiry into sanitation. His report, *The Sanitary Conditions of the Labouring Population* (1842), was an eye-opener. Combining Dickensian images of squalor and hopelessness with data on class-based mortality, Chadwick's treatise called attention to socio-economic differences in death rates and highlighted the importance of addressing the preventable causes of death.

At that time, neither the germ theory nor the doctrine of "specific etiology," which linked specific diseases to particular pathogens, had taken hold. Like most of his contemporaries, Chadwick believed that disease was caused by miasmas, or air made impure by decomposing matter. He therefore underlined the significance of the circumstances that caused or aggravated disease ("atmospheric impurities..., damp and filth, and close and overcrowded dwellings") and urged that these be removed by "drainage, proper cleansing, better ventilation, and other means of diminishing atmospheric impurity." Even when his understanding of disease causation was flawed and incomplete, Chadwick's prescriptions were sound: he pressed for measures aimed at cleaning the environment, including removing refuse and improving the water supply.

Although an advocate of using the power of government to better individual and collective health, Chadwick was a conservative at heart: he believed that a healthier population would be able to work harder and therefore cost less to support. His major concern was therefore reducing the number of persons seeking poor-law relief, and he considered the promotion of civic and personal cleanliness a precondition to improving the moral condition of the population and nurturing "sound morality and refinement in manners and health." But his call to action was disavowed by the Poor Law commissioners, who disclaimed all responsibility for the report, saying that it had been prepared by Chadwick on his own. And because the report threatened the private water companies and a number of "offensive trades" such as slaughtering and tanning, Chadwick also earned the enmity of the business community.

Moreover, Chadwick's 1842 report challenged the prevailing laissez-faire of the government, and he had to wait for a more congenial political environment for his ideas to gain notice. In 1848, both pressure from Chadwick and fear of an impending cholera epidemic led Parliament to pass the first British Public Health Act establishing central and local boards of health. Chadwick headed the central Board of Health between 1848 and 1854, when he was dismissed following pressure from local authorities who resented both his reforms and his abrasive personality. Some found him rude and dictatorial; indeed, those who favored local autonomy proclaimed that they would rather take their chances with cholera than abide by Chadwick's dictates. The Board was subsequently disbanded.

As the world economy is globalized, more and more governments, non-profit organizations, and companies are recognizing the wisdom of investing in clean water technologies.

This effectively ended Chadwick's civil service career, although it freed him to be a public citizen. He continued to testify before royal commissions, and drew up reform plans and programs over the next 36 years. His agenda, in addition to the "sanitary idea," included factory reform, public administration, and increased accountability in government. In his 90th year, he was knighted by Queen Victoria. His name has been immortalized in a bas-relief frieze on the façade of the prestigious London School of Hygiene and Tropical Medicine, where he is recognized among the "great and the good" in the fields of hygiene and public health.

The sanitation movement in the U.S.

In the United States, Chadwick's counterpart was Lemuel Shattuck, a bookseller, publisher, and Massachusetts legislator whose mission was to prompt government response to social ills by collecting statistics to provide evidence of problems and suggest how these could be addressed. As Chadwick was preparing his survey in England, Shattuck was analyzing Boston's vital statistics for the period from 1810 to 1841. Shattuck proposed the registration of births, marriages, and deaths ("hatches, matches, and dispatches") and in 1842 succeeded in enacting the Registration Act, thus introducing the system for collecting vital statistics that became a model for the rest of the Union.

In 1849 Shattuck published the *Report on the Sanitary Conditions of Massachusetts*, which has been called "one of the most remarkable documents... in the history of public health." Shattuck analyzed mortality data by place, season, occupation, and cause. Using an early version of cost-benefit analysis, he also calculated the cost of illness versus the cost of health. He estimated the cost of preventable disease in Massachusetts at $7,512,000 per year, and requested an annual sum of $3,000 to support of a Board of Health. The analysis was followed by some 50 recommendations, 36 of which eventually were adopted in Massachusetts and elsewhere. These covered much ground, ranging from the establishment of a State Board of Health to the collection of vital statistics, the control of smoke and other environmental nuisances, the protection of mill ponds

and other sources of water, and the regulation and monitoring of food and medicines. Nevertheless, his recommendations took two decades to become accepted wisdom: it was not until 1869, a decade after Shattuck's death, that they were incorporated into the plans of the Massachusetts Board of Health.

Today Shattuck is recognized as the father of American vital statistics and records; he, too, is memorialized on the frieze of the London School of Hygiene and Tropical Medicine, one of four Americans so honored.

The sanitary revolution's unfinished business

The movement to which Chadwick and Shattuck devoted a major part of their lives had a major impact on health and disease in the United States. In fact, clean water is responsible for dramatic reductions in mortality and morbidity: economists David Cutler and Grant Miller have credited clean water technologies with reducing all deaths in a number of U.S. cities between 1900 and 1940 by nearly half. They conclude that clean water reduced typhoid deaths by 26 percent initially and by another 65 percent after five years. Moreover, sanitation technology also reduced deaths caused by other infectious diseases, including pneumonia, tuberculosis, and meningitis. The combined effects of chlorination and filtration were responsible for three-quarters of the reduction in infant mortality and for nearly two-thirds of the reduction in childhood mortality over the same period. In addition, Cutler and Miller have calculated the economic benefits of these striking declines, estimating that every dollar invested in clean water produced $23 in benefits due to increased longevity. And this is a conservative estimate, because it excludes the ancillary benefits accruing from reduced illness and increased productivity.

In many countries, however, the promises of the Sanitary Revolution remain unfulfilled. Much of the technology that we take for granted until it fails us (e.g., when a dam breaks, or water becomes a medium of contamination, or sewage backs up) is inaccessible to large swaths of the world's population. Worldwide, approximately 1.1 billion people lack access to safe water; about 2 million people die each year from waterborne diseases.

It is therefore not surprising that clean water is seen as an indispensable requirement for the success of many health and development initiatives. As the world economy is globalized, more and more governments, non-profit organizations, and companies are recognizing the wisdom of investing in clean water technologies. The Millennium Water Alliance, a group of nongovernmental associations, is working worldwide to achieve one of the United Nations' Millennium Goals for Sustainable Development: to reduce by half the proportion of people without access to safe and affordable drinking water and sanitation by the year 2015. And Global Water Challenge is a coalition of corporations and organizations based at the United Nations Foundation; its goal is to provide safe drinking water, sanitation, and hygiene education worldwide to those who lack these services.

The sanitation goal has attracted the interest of a number of companies who, spurred by enlightened self-interest, have made clean water their cause. Because these companies are major consumers of water, they recognize that they can do good at the same time that they do well by increasing water stewardship and protecting the safety and availability of the water supply. The Coca-Cola Company, for example, is sponsoring 70 water partnerships in 40 countries, budgeting $35 million in 2007 for community water projects and waste-water treatment. Similarly, PepsiCo, which is battling criticism over its own water use in India, is helping people capture and store water in India and China. And Starbucks and Procter & Gamble are also funding projects to bring drinking water to poor communities. It therefore appears that entrepreneurs and secular philanthropists have replaced individual advocates as the purveyors of sanitary practices. As in Chadwick's time, these initiatives stem from mixed motives and a belief in what has been called the "gospel of cleanliness." We can only hope that these efforts, like their predecessors, will yield the desired health results and not be just a drop in the bucket. ■

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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 to give consumers more control over decisions that affect their health.

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Doctors and Drug Company Favors

The life of a doctor must be tough. To judge by most of their offices, doctors are unable to afford pens, mugs, refrigerator magnets, or pads of paper. Even lunch is beyond their reach, it seems. And dinner at a fancy downtown restaurant? Fuhgeddaboutit.

Fortunately, there's a group willing to step into the breach and supply these missing morsels and amenities. You guessed it: the pharmaceutical industry.

Despite the growing prevalence of direct-to-consumer advertising on television ($4.2 billion in 2005), the pharmaceutical industry continues to lavish the lion's share of its advertising budget on physicians ($7.2 billion, excluding the ubiquitous free samples). After all, it is the physician who wields the power of the prescription pen.

Somehow, doctors operate under the delusion that the pharmaceutical industry is misguided enough to squander close to $20 billion on promotion annually even though, according to many doctors' reasoning, all this largesse has no influence upon their prescribing habits. Much research suggests otherwise. When doctors were sent on expensive junkets to exotic locales, purportedly to receive objective education on a drug or disease, researchers noticed that prescribing of the sponsoring drug companies' products went up in those doctors' hospitals upon their return. Doctors accepting gifts from drug companies are more likely to request that their hospital add drugs to the hospital's formulary, its list of preferred drugs.

Some people have had enough. Recently, a number of prominent medical schools, including Stanford, Yale, and the University of Pennsylvania, have sharply limited interactions between their physicians and pharmaceutical representatives. And now states are getting in on the action.

In 1993, Minnesota passed a law that required drug companies to report to the state all gifts to doctors exceeding $100. Five other states followed suit between 2001 and 2005, and in 2006, 11 more states considered such bills.

In March, Public Citizen published the first evaluation of these programs in the *Journal of the American Medical Association*, focusing on the only two states that have so far made doctor gift data publicly available:

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Minnesota and Vermont. Actually, "publicly available" would be a bit of a stretch. In Minnesota, we had to literally go to the state agency housing the records, dust off boxes containing the companies' paper reports, and arrange for copies to be made. In Vermont, the legislation permitted drug companies to decide for themselves if the reports were trade secrets – and then unilaterally withhold the information from the public (they still have to provide the data to the state). And withhold them they did; in dollar terms, two-thirds of the records reported to the state were kept from public scrutiny. Public Citizen's Litigation Group then sued the state of Vermont and obtained additional records through a settlement agreement.

Still, the records told a compelling tale. In Minnesota, there were 6238 payments of $100 or more to physicians for a total of $22 million over three years. In Vermont, despite data withholding by the larger companies, 2416 payments of $100 or more to physicians were publicly disclosed, totaling $1 million over two years. The purposes of the gifts ran the gamut from speakers' honoraria and research studies to detailing and marketing.

Taking a leaf from the book of courting couples, who know that the path to loves passes through the stomach, pharmaceutical companies seem to pay as much attention to the alimentary tract as they do to the cranium, where most patients would hope prescribing decisions are being made. The voluntary guidelines of both the pharmaceutical industry and the American Medical Association suggest a $100 limit on gifts and require that gifts be educational in nature. (This is no coincidence as drug company executives sat on the AMA's task force on gift-giving.) Yet, in Minnesota there were at least 164 payments of over $100 to physicians for food, totaling $25,685. In Vermont, nearly 68% of such payments were for food, for a total of $381,455. Until such time as someone can show us that the educational content of these meals approached their fat content, we'll believe that many of these meals violated the guidelines.

Our study demonstrates that in these two states the efforts of legislators to make doctor-gift data available to the public have been thwarted by loopholes, industry non-compliance, lack of standardization in reporting, and lackluster enforcement. These are valuable lessons for states currently considering similar legislation. ■

Drugs for Weight Loss

Should children be put on weight loss drugs? Should people who are taking drugs that cause weight gain take additional drug(s) to try to lose this weight? Should people take more than one weight loss drug at a time? And how should studies examining these questions be conducted? These are some of the questions raised in a new Guidance for Industry published by the Food and Drug Administration (FDA) for which the FDA is asking for public comment and to which the Health Research Group has responded.

Drugs, past and present

For many years, the Health Research Group has been very concerned about weight-loss drugs. None of the drugs in this group have been shown to have the efficacy and safety that one would want to treat a chronic non-lethal condition and several have had to be removed from the market. Amphetamines caused addiction while the combination of fenfluramine and phentermine ("fen-phen"), very popular in the early and mid-nineties, ended up causing severe damage to heart valves. The fenfluramine portion along with a close chemical relative, dexfenfluramine, was finally removed from the market in September 1997.

Currently, two drugs are approved for "long-term" use (most studies were for only one year). These are Xenical (orlistat) and Meridia (sibutramine). We have petitioned the FDA to remove both from the market. We urged that Xenical be removed because of anal leakage (with loss of fat soluble vitamins) and an increased number of breast cancers, as well as potential cancers of the colon. We urged that Meridia be removed since it has been responsible for heart attacks partly as a result of causing an increase in blood pressure.

However, there is such a demand for weight loss drugs that the FDA feels great pressure to approve drugs lacking the evidence for safety and efficacy that ordinarily would be needed for approval. The relatively low bar for approval is either an average weight loss of 5 percent of baseline bodyweight for the treated group as a whole or at least a 5 percent loss of baseline bodyweight for at least 35 percent of patients. Even if these criteria are met, there is no trial that has shown that this weight loss leads to any benefit in terms of chronic illnesses or an increased lifespan. Furthermore, since weight is usually regained after stopping treatment, drugs must be taken for a long spans of time and there is, again, no information as to the safety of this lengthy exposure.

Length of clinical trials

Most past information comes from studies of only one year in length. The length of the study is important since serious and life-threatening adverse effects may take a long time to emerge as clearly drug-related. The FDA is suggesting trials of only one year; we are suggesting that they be extended to two or, preferably, three years.

Lifestyle modification

The most important and the healthiest actions any individual can take are to eat a healthy diet and increase their exercise level; one cannot expect to attain or maintain a normal weight by simply taking pills. Adherence to this might even obviate the need for any medications.

Pediatric studies

The FDA suggests starting with adolescents (12 to 16 year olds) who have a history of failing to lose weight by lifestyle modification. The FDA recommends that they also be in the top 5 percent of weight for their group (by age and sex) and have a weight-related health problem (such as type 2 diabetes, high cholesterol, and/or high blood pressure). We are recommending that these drugs be tested first in young animals, preferably young obese animals, to see how they affect development.

Long-term safety

Drugs that are to be taken for life, especially for a non-lethal condition, need to be especially safe. Xenical, soon to be available over-the-counter, produced pre-malignant growths in animal studies at very low drug exposures (levels at or below those seen in people). However, we do not know what will happen to people since clinical trials were much too short to pick this up (one or two years in length whereas cancer may take many years to develop). Information on this potential tumor development was not included in the drug's label so patients and physicians are unlikely to report cancer as an adverse event to the FDA. Without these reports, we are limited from an eventual understanding of Xenical's human safety.

Using combinations of drugs to lose weight

Combining two drugs always carries more potential risks since adverse drug reactions would have two individual sources as well as those from interactions between the two. Very careful testing would be required to assure safety and efficacy.

Medication-induced weight gain

This is especially tricky as it is rarely known by what means a drug is causing the weight gain, and even if one does know, it might be very difficult to counteract it. For two diabetes drugs, Avandia and Actos, for example, weight gain can be due to fat deposition (the drugs activate genes that cause new fat cells to form as well as causing fat to accumulate in existing fat cells). In fact, one of the ways the drug works to lower sugar in the blood is to turn it into fat and store it in fat cells. If one stopped this process, the drug might not work or at least not as well.

Conclusions

Since all drugs have potential adverse effects, and the efficacy for diet drugs is so limited, it would make better sense to work on lifestyle changes with diet and exercise. ■

Product Recalls

March 16, 2007 — April 18, 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 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

BI-MART Day Time Cold Medicine, New Pseudoephedrine-Free Formula, oral liquid, active ingredients: Acetaminophen 325 mg, Dextromethorphan hydrobromide 15 mg; Peel-back labels may delaminate so that drug use information may not be readable. Lot # 334420, exp. date 02/2008; Lot # 334748, exp. date 02/2008; Lot # 334869, exp. date 02/2008; Magno Humphries Inc.

Children's non-aspirin pain and fever reliever, oral liquid, active ingredient: Acetaminophen 160 mg, cherry flavor, Peel-back labels may delaminate so that drug use information may not be readable. Packaged under two labels: 1) *MHL Children's Non-Aspirin Oral Suspension*, Lot # 334558, exp. date 02/2008; 2) *BI-MART Children's Non-Aspirin Pain Relief Liquid*, Lot # 334439, exp. date 02/2008, Lot # 334980, exp. date 02/2008; Magno Humphries Inc.

Coricidin "D", (acetaminophen 325 mg with Phenylephrine HCl 5 mg and Chlorpheniramine Maleate 2 m; Stability data does not support expiration date. Lot # 6D01WN, 6E01WN, 6E02AWN, 6E02WN, 6G02WN, 6H01WN, 6H02WN, 6K01WN, 6K02WN, 6K03WN; Leiner Health Products LLC.

CVS Pharmacy brand Sinus Pain & Congestion Nighttime, (acetaminophen 325 mg, Phenylephrine HCl 5 mg and Chlorpheniramine Maleate 2 mg), also labeled under other brand name as follows; QC-Quality Choice brand Multi-Symptom Allergy Relief; Stability data does not support expiration date. Lot # 6NB0698; Lot # 6NB0369; Leiner Health Products LLC.

Cough suppressant/expectorant, oral liquid, active ingredients: Dextromethorphan HBr, 10 mg, Guaifenesin, 100 mg; Peel-back labels may delaminate so that drug use information may not be readable. Packed under two labels: 1) *MHL Tussin DM Cough Suppressant/Expectorant*, Lot # 334767, exp. date 02/2008; 2) *BI-MART Tussin DM Cough Suppressant/Expectorant*, Lot # 334445, exp. date 02/2008; Lot # 334624, exp. date 02/2008; Lot # 334646, exp. date 02/2008; Lot # 334749, exp. date 02/2008; Lot # 334846, exp. date 02/2008; Lot # 335115, exp. date 02/2008; Lot # 335228, exp. date 02/2008; Lot # 335283, exp. date 02/2008; Magno Humphries Inc.

Extra strength pain reliever, oral tablet, active ingredients: Acetaminophen 250 mg, Aspirin 250 mg, Caffeine 65 mg; Peel-back labels may delaminate so that drug use information may not be readable. Packed under 2 labels: 1) *MHL Extraprin Pain Reliever/Pain Reliever Aid, Extra Strength*, Lot # 334735, exp. date 05/2008; Lot # 334890, exp. date 05/2008; 2) *BI-MART Extra Strength Combination Pain Reliever*, Lot # 334888, exp. date 05/2008; Lot # 334994, exp. date 05/2008, Lot # 335121, exp. date 05/2008; Magno Humphries Inc.

Ibuprofen, oral tablets, 200 mg; Peel-back labels may delaminate so that drug use information may not be readable. Packed under 3 labels: 1) *MHL Ibuprofen*, Lot # 334842, exp. date 06/2008; Lot # 335042, exp. date 06/2008; 2) *Aurora Pharmacy Ibuprofen*, Lot # 334985, exp. date 06/2008; Lot # 335185, exp. date 06/2008; 3) AARP Pharmacy Services Ibuprofen, Lot # 334761, exp. date 06/2008; Lot # 335062, exp. date 06/2008; Magno Humphries Inc.

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

Name of Drug or Supplement; Problem; Recall Information

Levoxyl, Levothyroxine Sodium Tablets, USP, 125mcg; Adulterated presence of foreign tablet found in bottle (Levoxyl 50mcg). Lot # 37187, exp. date 04/2008; Lot # 37188 exp. date 04/2008, King Pharmaceuticals, Inc.

Medicap Pharmacy Aler-Caps, oral capsule, active ingredient: Diphenhydramine hydrochloride 25 mg; Peel-back labels may delaminate so that drug use information may not be readable. Lot # 333512, exp. date 01/2008; Lot # 334067, exp. date 01/2008; Lot # 334080, exp. date 01/2008; Magno Humphries Inc.

MHL Diphenhydramine hydrochloride Nighttime Sleeping Aid, 50 mg, oral tablet; Peel-back labels may delaminate so that drug use information may not be readable. Lot # 334764, exp. date 07/2008; Lot # 335114, exp. date 07/2008; Magno Humphries Inc.

MHL Sleep-Tabs Nighttime Sleeping Aid, oral tablet, active ingredient: Diphenhydramine hydrochloride 25 mg; Peel-back labels may delaminate so that drug use information may not be readable. Lot # 335208, exp. date 06/2009; Lot # 335304, exp. date 06/2009; Magno Humphries Inc.

Night time cold medicine cherry flavored, oral liquid, active ingredients: Acetaminophen 500 mg, Dextromethorphan hydrobromide 15 mg, Doxylamine succinate 6.25 mg; Peel-back labels may delaminate so that drug use information may not be readable. Packed under 2 labels: 1) *MHL Nite Time New Pseudoephedrine-free Formula Cherry Cold Medicine*, Lot # 335074, exp.date 07/2008; 2) *BI-MART Cherry Flavor Night Time Cold Medicine New Pseudoephedrine-Free Formula*, Lot # 334446, exp. date 07/2008; Lot # 335272, exp. date 07/2008; Lot # 334419, exp. date 01/2008; Lot # 334647, exp. date 01/2008; Lot # 335006, exp. date 01/2008; Lot # 335116, exp. date 01/2008; Magno Humphries Inc.

Night time cold medicine, oral liquid, active ingredients: Acetaminophen 500 mg, Dextromethorphan hydrobromide 15 mg, Doxylamine succinate 6.25 mg; Peel-back labels may delaminate so that drug use information may not be readable. Packed under 2 labels: 1) *MHL Nite Time New Pseudoephedrine-free Formula Regular Cold Medicine*, Lot # 334679, exp. date 05/2008; 2) *BI-MART Night Time Cold Medicine New Pseudoephedrine-Free Formula*, Lot # 335347, exp. date 09/2008; Lot # 334417, exp. date 01/2008; Lot # 334625, exp. date 05/2008; Lot # 334721, exp. date 05/2008; Lot # 335020, exp. date 05/2008; Lot # 335347, exp. date 09/2008; Lot # 334418, exp. date 01/2008; Lot # 334656, exp. date 01/2008; Lot # 334720, exp. date 01/2008; Lot #335005, exp. date 01/2008; Lot # 335348, exp. date 01/2008; Magno Humphries Inc..

Pain Reliever PM, oral caplet, active ingredients: Acetaminophen 500 mg, Diphenhydramine HCl 25 mg; Peel-back labels may delaminate so that drug use information may not be readable. Packaged under two labels: 1) *MHL Pain Reliever PM*, Lot # 334900, exp. date 02/2008; Lot # 335267, exp. date 04/2008; 2) *MEDICAP PHARMACY Pain Reliever PM*, Lot # 333365, exp. date 11/2007; Magno Humphries Inc.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the 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

Above-Ground Pool Ladders. The "Intex®," "Easy Set®" and "Sand N Sun™" Above-Ground Pool Ladder's plastic steps can be assembled backward on the support brackets. If this happens, the ladder steps can break and the user can fall. Intex Recreation Corp., (800) 549-8829 or www.intexcorp.com.

Activity Cart Toys. The orange hubcaps on the wheel of the Little Tree Wood Activity Cart Toys can detach, posing a choking hazard to young children. Target, (800) 440-0680 or www.target.com.

All-Terrain Vehicles. The bushing pivot mount boss on the left and right suspension arm of Suzuki 2007 Model Year QuadSport Z90 ATVs may not have been welded completely and could break off during riding. If this occurs, the rider could lose control of the ATV and crash, posing risk of serious injury or death. American Suzuki Motor Corp., (714) 572-1490 or www.suzukicycles.com.

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Name of Product; Problem; Manufacturer and Contact Information

Back Pack Baby Carriers. The stitching on the strap of the Baby Trend Back Pack Carriers can loosen or detach, causing the carrier to shift, posing a fall hazard to young children. Baby Trend Inc., (800) 328-7363 or www.babytrend.com.

Bathrobes. "Quacker Factory" Chenille Robes fail to meet Federal flammability requirements. Should the robe come in contact with an ignition source, such as a stove burner, candle flame or cigarette lighter, it could catch fire and possibly cause serious burns to consumers. QVC Inc., (800) 367-9444 or www.qvc.com.

Bicycle Brake Caliper Sets. The SRAM Force Road Brake Caliper Sets could break and detach from the bicycle's fork or frame. This could cause the rider to lose control and crash. SRAM Corp., (800) 346-2928 or www.sram.com.

Chanukah Candles. Chanukah Oil Candles can become engulfed in flames and melt the plastic cups holding the candles in place, allowing hot wax to leak out, which poses fire and burn hazards to consumers. Ahron's Judaica, (866) 669-1708.

Children's Bracelets. The paint on the metallic band beneath the decorative cover of Children's "Groovy Grabber" Bracelets contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. A&A Global Industries, (800) 638-6000 ext. 314 or www.aaglobalind.com.

Children's Footed Pajamas. Baby Einstein Caterpillar Sleepwear and Baby Einstein Duck Sleepwear fails to meet the children's flammability standard, posing a risk of burn injury to children. Disney Stores North America, (866) 902-2798.

Children's Loungewear. Hanna Andersson Children's Crossover Tee and Lounge Pant Sets and Cropped Johns fail to meet the children's sleepwear flammability standards. The Crossover Tee and Lounge Pant sets were marketed as loungewear. The Cropped Johns were not marketed as loungewear, but could be used as loungewear. The children's sleepwear flammability standards require sleepwear, including loungewear, to be either snug-fitting or flame resistant. Hanna Andersson, (800) 222-0544 or www.hannaandersson.com.

Children's Necklaces. The paint on Children's Charm Bracelets and "Sportswear" Necklaces contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Cardinal Distributing Co. Inc., (800) 368-2062 or www.vendingdepot.com.

Circular Saws. The "Craftsman" logo label located on the upper blade guard of Craftsman Circular Saws can become partially detached and interfere with the proper operation of the lower blade guard, exposing the saw's blade and posing a laceration hazard to consumers. Sears, (800) 659-7026 or www.Sears.com.

Clamps for Motorcross Motorcycles. The radius triple clamps on Radius Triple Clamps sold for use with Motocross Motorcycles can crack during operation, posing a risk that the fork of the bike could separate and result in serious injury or death to the rider. Universal Engineering, (866) 500-2090 or www.universalmotocross.com.

Disney Plush Easter Baskets. Silver beads and ribbons attached to the Disney Princesses Easter Baskets can detach, posing a choking hazard to young children. Gemmy Industries Corp., (800) 231-6879 or www.gemmy.com.

Dolls. "Lovely Baby" and "Happy Baby" dolls contain small parts, which can pose a choking hazard to young children. OKK Trading Inc., (877) OKK-TOYS or www.okktrading.com.

Electronic Keyboards. The Electronic Musical Keyboards can overheat when in use, posing a fire hazard to consumers. Casio® Inc., (866) 800-4302 or www.casio.com.

Flat Panel TV Tilt-Mount Brackets. If upward force is applied to a mounted television, the "Verge" Flat Panel Television Tilt-Mount Bracket's lock bar could unfasten. This could cause the television to fall and injure bystanders. Circuit City Stores Inc., (888) 666-9897 or www.circuitcity.com.

Floor Electrical Outlets. Carlon® Drop-In Floor Boxes are wired incorrectly resulting in reverse polarity. This poses a shock or electrocution hazard to consumers. Lamson & Sessions, (866) 636-1531 or www.lamson-home.com.

Foot Warmers. The wiring in Mastex Twin Foot Warmers has a defect which can cause it to overheat. This poses a burn hazard to consumers. Mastex Industries, LLC, (804) 732-8300 or Sales@mastex.com.

Gas Boilers and Water Heaters. Internal black plastic venting components in Laars 9600 CB Condensing Boilers & 9600 HWG Condensing Water Heaters can crack and leak flue gases, including carbon monoxide (CO), posing a risk of CO poisoning. Laars Heating Systems Co., (800) 900-9276 or www.Laars.com.

CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Gel Candles. The martini glass containing the Tequila Rose Strawberry Cream candle sets can break while the candle is burning, posing fire and burn hazards to consumers. Tequila Rose Distilling, (800) 567-7303 or www.tequilarose.com.

Heat Recovery Ventilators. The motors in Heat Recovery Ventilators can overheat, posing a fire hazard. Venmar Ventilation Inc., (866) 441-4645 or www.venmar.ca.

Hooded Sweatshirts. Life is good® Children's Sweatshirts have a drawstring through the hood, posing a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. RedEnvelope Inc., (877) 733-3683 or www.RedEnvelope.com.

Hot Water Boilers. Acidic liquid in a drain line can cause a fitting in the NTI Trinity Gas-Fired Hot Water Boilers to leak, posing a risk of carbon monoxide (CO) poisoning to consumers. NY Thermal Inc., (800) 688-2575 or www.nythermal.com.

Infant Bouncer Seats. The tubular metal frame of Infant Bouncer Seats can break, posing a fall hazard to infants in the seat. Oeuf LLC, (800) 691-8810 or www.oeufnyc.com

Infant Sling Carriers. The plastic slider on the fabric strap of SlingRider Infant Carriers can break. This can cause the strap supporting the carrier to release and infants to fall out of the carrier. Infantino, LLC, (888) 808-3111 or http://service.infantino.com.

Inflator Pumps. West Marine Inflator Pumps can explode during use, ejecting sharp plastic parts and posing a serious laceration hazard to consumers. Steams, Inc., (800) 262-8464 or www.westmarine.com.

Metal Key Chains. Metal Key Chains contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Dollar General Merchandising, Inc., (800) 678-9258 or www.dollargeneral.com.

Radio Control Airplanes. Radio Control Model Airplanes (Models 4153 and 4161) with Lithium Polymer Batteries can overheat while recharging the battery, posing a fire hazard. Estes-Cox Corp., (800) 576-5811 or www.estesrockets.com.

Shrek Headbands. A small wire can protrude through the fabric of the ears on the Shrek Ears Headbands, posing a risk of cuts to consumers. Paramount Pictures Corp., (800) 782-6116.

Smoke Detectors. Digital Security Controls FSA and FSB Series Smoke Detectors could fail to reliably detect smoke during a fire. Digital Security Controls, (877) 666-1250 or www.dsc.com.

Stuffed Ball Toys. Stuffed Fun Balls contain lead paint, which is toxic if ingested by young children and can cause adverse health effects. Regent Products Corp., (800) 940-4869 or www.regentproducts.com.

Target Bicycles. The frame of Triax PK7 and Vertical PK7 Bicycles can crack while in use, causing the rider to lose control and suffer injuries from a fall or collision. Dynacraft BSC Inc., (800) 551-0032 or www.dynacraftbike.com; Target, (800) 440-0680 or www.target.com.

Tree Harnesses. Safety harnesses sold with tree stands and harnesses provided as replacements could fail during use, resulting in a hunter falling from the tree stand and suffering serious injuries or death. Hunter's View, (888) 878-0440 or www.huntersview.com.

Wall Sconces. A missing back plate of Home Decorators Collection Wall Sconces exposes consumers to live wires, posing a risk of electrical shock to consumers changing the light bulb. Home Decorators Collection, (800) 464-0164.

Washing Machines. Water leakage onto the electrical connections to the Maytag and Samsung Brand Front Loading Washing Machine's thermal sensor could cause an electrical short and ignite a circuit board, posing a fire hazard to consumers. Maytag Corp., (800) 868-5109 or www.washerrecall.com; Samsung Electronics America Inc., (800) 515-7902 or www.Samsung.com/washerrecall.

Wooden Sound Puzzles. The knobs on the "Sounds on the Farm" Puzzle and "Sounds on the Go" Puzzle pieces can come off, posing a choking hazard to young children. Small World Toys, (800) 421-4153 or www.smallworldtoys.com.

Do Not Use Dextromethorphan (Delsym, Robitussin DM) for Cough and Cold Relief

In our March 2007 edition of *Health Letter*, we re-printed an original *Health Letter* article from 1993 entitled *Colds: How to Treat Them*. The article promoted the use of dextromethorpan (Delsym, Robitussin DM – DM stands for dextromethorphan), an over-the-counter drug that is sold alone and in combination with other products as a cough suppressant for children and adults. However, since we first wrote that article, new studies have led us to change our minds about dextromethorphan and reclassify the cough suppressant as a Do Not Use drug.

The study tipping the balance for us to a Do Not Use classification for this drug was published in the July 2004 issue of the journal *Pediatrics* and was conducted by researchers from the Pennsylvania State College of Medicine, Hershey, Pennsylvania.

Sleep quality for children with coughs was used as the measure of effectiveness to compare over-the-counter cough medication dextromethorphan to placebo. The study involved 100 children with coughs and used a five-question questionnaire to assess sleep quality in both children and their parents. The median age of the children was 4.5 years and their ages ranged from 2.0 years to 16.5 years. To be eligible to participate in the study, the children had to have an acute cough as a result of an upper respiratory tract infection.

No medication was given the first night and the second night patients received either dextromethorphan or a placebo. After both nights, parents were asked to assess the frequency and severity of the nighttime cough and the degree to which it was bothersome.

The study concluded that dextromethorphan was not superior to the placebo in providing nighttime symptomatic relief for children with a cough and sleep difficulty. In addition, the use of this medication did not result in improved sleep quality for the children's parents. In other words, the drug had no effect on the natural course of cough improvement in children with upper respiratory infection over a 24-hour period.

Older research on the value of these drugs as cough suppressants was conflicting. A type of statistical summary of multiple studies known as a meta-analysis published in the February 9, 2002, *British Medical Journal* concluded, for adults, that "Over-the-counter cough medicines for acute cough cannot be recommended because there is no good evidence for their effectiveness."

Even ineffective drugs have the potential to cause adverse effects. In usual doses, dextromethorphan has been associated with loss of muscle tone, severe allergic reactions, and blisters that occur due to the proliferation of a type of cell involved in allergic reactions.

The American Academy of Pediatrics' Committee on Drugs has not supported the use of dextromethorphan primarily because there is a lack of proven benefit and some potential for toxicity and overdose.

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In addition, in 2005 the FDA issued a public advisory about the abuse of dextromethorphan. This warning came after five reported deaths of teenagers that were associated with the consumption of powdered dextromethorphan sold in capsules. Dextromethorphan is generally safe at recommended doses, but abuse can lead to death or serious adverse effects such as psychosis, mania, hallucinations, seizures, loss of consciousness, brain damage, and arrhythmias.

The Netherlands Pharmacovigilance Center has reported nine cases of neuropsychiatric adverse drug reactions associated with the use of dextromethorphan. The World Health Organization database contained 17 reports of anxiety, three reports of delusions, and 37 reports of hallucinations associated with the use of this drug.

Parents and health professionals have a strong urge to "do something" to ease symptoms in children, even in a mild, self-limiting illness like an upper respiratory tract infection. The lesson from this study is that it is sometimes better to do nothing because the medications have no therapeutic benefit but do carry a known risk of potentially serious adverse reactions.

To read more about dextromethorphan and other cough and cold medications, visit www.worstpills.org. ■

What's Wrong With This Story?

Pharmaceutical Company Fires Sales Director for Telling the Truth

In a recent Harris Poll, only 7 percent of Americans thought that the pharmaceutical industry was "honest and trustworthy – so that you normally believe a statement by a company in that industry." If the public perception is correct, then how would this industry treat one of its own who does tell the truth? The answer comes in the form of a recent article in AstraZeneca's internal cancer newsletter by its own regional sales director Mike Zubillaga, who wrote the following in an effort to motivate drug representatives to sell more drugs to doctors:

> I see it like this: there is a big bucket of money sitting in every office. Every time you go in, you reach your hand in the bucket and grab a handful. The more times you are in, the more money goes in your pocket. Every time you make a call, you are looking to make more money.

After Zubillaga was fired, the company stated his comments had violated the company's "robust compliance program that calls for responsible sales and marketing practices and conduct."

Peter Rost, a former Pfizer executive who was also fired for speaking the truth, said that "AstraZeneca lacked the internal controls to make sure the truth didn't get out, and now they are trying to show they are holier than thou, by firing the guy who said what everyone knows to be true ... Instead of a reprimand, AstraZeneca created a sacrificial lamb to cover the corporate rear end."

Newark Star-Ledger reporter Ed Silverman, who closely follows the pharmaceutical industry, told a Philadelphia Inquirer reporter that "Of course, many docs know that's what the sales teams think of them. That's why some docs hold out for expensive meals, nice trips and good seats to good games, and why others won't let the sales rep past reception."

We strongly favor the tactic of the latter doctors and urge *Health Letter* readers to find out which group their doctors are in. ■

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