

Health Letter

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The Fight against Disease Mongering

The following article is reprinted from PLoS Medicine, an online medical journal. PLoS journals are available to the public at <http://www.plos.org>. The following article can be found at <http://collections.plos.org/diseasemongering-2006.php>. The authors of the piece, Ray Moynihan and David Henry, both teach at the University of Newcastle in New South Wales, Australia.

Disease mongering turns healthy people into patients, wastes precious resources, and causes iatrogenic harm. Like the marketing strategies that drive it, disease mongering poses a global challenge to those interested in public health, demanding in turn a global response. This theme issue of PLoS Medicine is explicitly designed to help provoke and inform that response.

What Is Disease Mongering?

The problem of disease mongering is attracting increasing attention, though an adequate working definition remains elusive. In our view, disease mongering is the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatments. It is exemplified most explicitly by many pharmaceutical industry-funded disease-awareness campaigns — more often designed to sell drugs than to illuminate or to inform or educate about the prevention of illness or the maintenance of health. In this theme issue and elsewhere, observers have described different forms of disease mongering: aspects of

ordinary life, such as menopause, being medicalized; mild problems portrayed as serious illnesses, as has occurred in the drug-company-sponsored promotion of irritable bowel syndrome and risk factors, such as high cholesterol and osteoporosis, being framed as diseases.

Drug companies are by no means the only players in this drama. Through the work of investigative journalists, we have learned how informal alliances of pharmaceutical corporations, public relations companies, doctors' groups, and patient advocates promote these ideas to the public and policymakers — often using mass media to push a certain view of a particular health problem. While these different stakeholders may come to these alliances with different motives, there is often a confluence of interests — resulting in health problems routinely being framed as widespread, severe, and treatable with pills, as has happened recently with social anxiety disorder.

Currently, these alliances are working with the media to popularize little-known conditions, such as restless legs syndrome and female sexual dysfunction, in each case lending credence to inflated prevalence estimates. In the case of female sexual dysfunction, there has been a serious, though heavily contested, attempt to convince the public in the United States that 43% of women live with this condition. This is happening at a time when pharmaceutical companies perceive a need to build and maintain markets for their big-selling products and when pipelines for new and genuinely innovative medicines are perceived as being weak.

“The coming years will bear greater witness to the corporate sponsored creation of disease.”

A Context for Disease Mongering

Three decades ago, Ivan Illich argued polemically that the medical establishment was “medicalizing” life
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DISEASE MONGERING, from page 1 itself, and in the 1990s Lynn Payer described widening the boundaries of illness as “disease mongering”, highlighting the role of pharmaceutical companies. Today’s debate about this phenomenon, while still maturing, both acknowledges the axiomatic interest of corporations and professionals in maximizing turnover and appreciates that well-informed citizens may choose to embrace the medicalization of health problems previously regarded as troublesome inconveniences.

It can also be argued that disease mongering is the opportunistic exploitation of both a widespread anxiety about frailty and a faith in scientific advance and “innovation” — a powerful economic, scientific, and social norm. In many nations, government policy priority is to secure market-based economic development, while more equitable social policies, such as public health strategies, can become subordinate or redundant. Disease mongering can thrive in such a normative environment. The practical consequences are that many of the so-called disease-awareness campaigns that inform our contemporary understanding of illness — whether as citizens, journalists, health professionals, industry leaders, academics, or policymakers — are now underwritten by the marketing departments of large drug companies rather than by organizations with a primary interest in public health. And it is no secret that those same marketing departments contract advertising agencies with expertise in “condition branding,” whose skills include “fostering the creation” of new medical disorders and dysfunctions. As a recent Reuters Business Insight report on so-called lifestyle drugs — designed to be read by pharmaceutical industry leaders — pointed out, “The coming years will bear greater witness to the corporate sponsored creation of disease”. We hope the coming years will also bear witness to a much more vigorous effort from within civil society to understand and to challenge that corporate process.

Problems Defining Disease Mongering

While the term “disease mongering”

is now commonly used as shorthand to describe campaigns that inappropriately widen the boundaries of treatable illness, there is uncertainty about how to operationally define the concept. With most disorders or conditions, there will be a number of individuals who suffer severe forms of the problem, who will benefit greatly from treatment and may be helped enormously by the publicity and marketing given to both the treatment and the disorder. For example, industry-funded awareness raising about the treatment and prevention of HIV/AIDS has surely been valuable. But in other cases, the same marketing/awareness-raising campaign will be viewed very differently depending on the perspective of the observer: what an industry-linked professional group may consider to be legitimate public education about an underdiagnosed disease, an activist group free from industry sponsorship may regard as a crude attempt to build markets for potentially dangerous drugs.

The Eli Lilly-sponsored promotion of premenstrual dysphoric disorder to help sell a re-branded version of fluoxetine (rebranded from Prozac to Sarafem) is a case in point. Considered by some as a serious psychiatric illness, premenstrual dysphoric disorder is regarded by others as a condition that does not exist.

These discordant views of the same activity reinforce the fact that there are often different motives for the different individuals who get caught up in disease-mongering campaigns. In the pharmaceutical industry and in the public relations companies that serve them, the marketers often now dominate. But these corporations are not heterogeneous, and staff working in research or medical departments may express the same doubts as many working outside industry. For their part, the motives of health professionals and health advocacy groups may well be the welfare of patients, rather than any direct self-interested financial benefit, but we believe that too often marketers are able to crudely manipulate those motivations. Disentangling the different motivations of the different actors in disease mongering will be

a key step towards a better understanding of this phenomenon.

Generating Better Knowledge

The views in this article are based on observations and interpretation informed by interviews with stakeholders and other more journalistic research methods, rather than a deeper academic investigation that employs qualitative and quantitative research techniques. Before embarking on research agendas to investigate disease mongering and its impacts, a broader conception of the phenomenon is warranted — requiring researchers to explore the uncertainty surrounding the definition of the problem, how and why different stakeholders understand it differently, and the deeper social and economic contexts. For example, the broad shift away from government-run programs and towards the marketplace within social democracies worldwide, and the consequent commercialisation and commodification of health services, may be a useful framework for a more profound explanation of this problem. In a climate where governments are encouraging corporations to vigorously pursue for-profit activities within the health-care sector, it is hardly surprising that pharmaceutical companies will use a range of promotional activities to widen the definitions of disease in order to grow the potential markets for their products.

Along with deeper reflection, we suggest researchers start to develop strategies for generating data on the impact of disease mongering. More conventional health-science methodologies may prove to be valuable ways of investigating the potential influences of a disease-marketing campaign on outcomes such as public perceptions of a particular disease, prevalence/incidence rates for that disease, prescription patterns for the drugs linked to that disease, and even health status of those diagnosed with and/or treated for that disease. Multisite controlled studies of drug company-funded disease-awareness campaigns would be the ideal. However, defining appropriate control groups and devising indices to measure outcomes such as inappropriate medicalization will prove extremely

challenging since almost everyone is exposed to disease mongering in some form. Similarly, rigorous studies of publicly funded “counter-detailing” — where noncommercially oriented information about disease is promoted to physicians and citizens — may be warranted, though, again, it is very difficult methodologically.

A challenge to the excesses of disease mongering may come from within the industry.

Apart from these more challenging approaches, we believe there is a range of research projects that are both achievable and urgently needed. First, academic investigation of the prevalence of this problem would be highly desirable. Researchers could, for example, take a group of the most common (high-burden) diseases/conditions, and investigate how and why the definitions of those diseases/conditions have changed over time in different nations. Such retrospective investigations could include analysis of the decisions and recommendations of the panels that define and redefine illness, the evidence informing those decisions, the conflicts of interest of panel members and their respective professional bodies, and the sponsorship of these processes. Early versions of this investigation are happening in a random, ad hoc way, but a coordinated systematic effort by a multinational group of respected researchers or research institutes is obviously preferable. As part of such an examination, a series of case studies would inevitably emerge, warranting deeper study and research and serving as a way to popularize awareness of the process of disease mongering.

Another potentially rich research method might involve a prospective study of the launch of a new or recently expanded disease or condition. A global collaboration could, for example, study the way female sexual dysfunction is being constructed and then promoted. “Creating the need” is now an established and integral part of the promotion of any new blockbuster drug, and sometimes that involves introducing a whole new condition to the wider public. The success of sildenafil depended on

corporate-funded disease-awareness campaigns promoting erectile dysfunction, and similarly the commercial success of any pharmaceutical treatments for female sexual dysfunction will hang in part on similar campaigns. While activists and scholars have begun the process of observing these activities, it is our view that the magnitude of public and private resources spent on these products, the potential harm that can flow from inappropriate medicalization, and the opportunity cost in terms of treating and preventing genuine pathology demands more rigorous scientific investigation.

Time for Action?

Around the world, there are tentative steps to identify, understand, and combat the threat to human health from the corporate-sponsored selling of sickness. These small steps are being taken by several players within the health field, and we trust this theme issue may support and augment these developments.

At a consumer level, Health Action International (<http://www.haiweb.org>) — the activist group working for a more rational use of medicines globally — has for a long time been concerned about what it has described as the blurring of boundaries between ordinary life and medical illness in order to expand markets for drugs and other technologies. Unlike many patient advocacy groups, Health Action International does not accept pharmaceutical company sponsorship, and actively warns others about the threats to independence from doing so. By way of contrast, many consumer/advocacy groups around the world now rely on such funding, raising questions about their credibility, particularly as they are often used as the human face of disease-awareness campaigns sponsored by their funders. An open debate within the health consumer movement about its close engagement with industry, and its involvement in disease mongering, would be welcome.

Likewise, amongst journalist circles, there are nascent debates about the media’s propensity to exaggerate disease prevalence and severity, and

how to deal with this problem. In this issue of *PLoS Medicine*, two high-profile scholars with an interest in the area of medicine and the media, Lisa Schwartz and Steven Woloshin, present a timely and relevant case study on the “selling” of restless legs syndrome. In Australia and Canada, a new media watch group called Media Doctor is also investigating the extent to which media stories on medicine either report appropriately on the nature and extent of illness or tend to simply regurgitate the promotional messages of disease-mongering campaigns (<http://www.mediadoctor.org.au>).

While many professional organizations remain reliant on industry support, some are actively debating the problem of disease mongering. In a submission to the recent House of Commons inquiry into the influence of the pharmaceutical industry in Britain, the Royal College of General Practitioners outlined serious concerns about the process. The subsequent report recommended that industry-funded disease-awareness campaigns should no longer be “veiled advertising” of branded drugs.

Shareholders in the world’s large pharmaceutical companies have the strongest financial interest in widening the boundaries of treatable illness in order to widen markets for their products. Yet in the debate about research and development for treatments for neglected diseases in the developing world, there are strong signs that shareholders can support policies driven by motivations other than profit. It may be that as key shareholders and company executives alike understand more of the implications of what their marketing departments do, a challenge to the excesses of disease mongering may come from within industry, just as other parts of the health sector challenge excesses of disease mongering from within.

Conclusion

Genuine sustainable change, however, will not come until policymakers better understand the phenomenon of disease mongering and the potential benefits of responding against it. In

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From Unease to Disease

Sex sells, and nowhere is this more obvious than in the market for pharmaceuticals aimed at enhancing sexual performance. Campaigns designed to turn healthy people into patients were the topic of an International Conference on Disease-Mongering held in Australia April 11-13, 2006. In anticipation of the conference, a recent issue of *PLoS Medicine* issued by the Public Library of Science (PLOS) was devoted to the same topic, defined as “the selling of sickness that widens the boundaries of illness and grows the markets for those who sell and deliver treatment” (See article by Moynihan and Henry in this issue). PLOS is a non-profit organization of scientists and physicians committed to making the world’s scientific and medical literature a freely available public resource. The journal examined two case studies of the interaction between anxiety over sexual performance and the marketing of pharmaceutical products.

The first of these is titled “Bigger and Better: How Pfizer Redefined Erectile Dysfunction,” by Joel Lexchin, who is affiliated with York University and with the University of Toronto. The article examines how Pfizer transformed Viagra from a product to treat erectile dysfunction (ED) due to medical prob-

lems such as diabetes and spinal cord damage into a drug that ‘normal’ men can use to achieve and maintain an erection for a longer period of time.

If Viagra had been confined to men with ED related to organic causes, writes Lexchin, the drug would probably have been a modest success for Pfizer. But expanding the market required appealing to a wider population of men, and that meant redefining the criterion for those who could benefit from the available treatment. Thus, Viagra had to be seen as an option for men with any degree of ED, including sporadic failures to achieve and maintain erections. Using questionable data and trumpeting success rates of “more than 80%,” Pfizer’s marketing materials and advertising campaign aimed at a younger cohort of men, and included the message of relief for occasional erection problems. The results were not insignificant: between 1998 and 2002, men between the ages of 18 and 45 showed the largest increase in Viagra use, although only one-third had a possible etiologic reason for needing the drug. Part of this trend may be attributed to an increase in gay and bisexual men using Viagra to enhance their sexual performance. As a result, studies on men who have sex with men reveal that the drug has

been associated with potentially dangerous interactions with HIV medication, as well as with a rise in high-risk sexual behavior, including intercourse with a greater number of sex partners, higher levels of unprotected anal sex with HIV+ partners, and a higher incidence of STDs.

The Viagra story, Lexchin writes, presents “a microcosm of the debate surrounding drugs that enhance lifestyle choices. The drug is effective... for people with medical problems..., but it can also be used by a much wider population.” Targeting the larger community and narrowing treatment options to the single option of medication assures the health of the manufacturing company. But this may also inflict an array of potential dangers on the broader population, and raise questions about how finite resources are spent and decisions on treatment are made.

No sooner had Viagra been launched than the media began calling for a “female Viagra.” In a second case study published in *PLoS Medicine*, Leonore Tiefer, a clinical associate professor of psychiatry at New York University School of Medicine, describes the creation of “female sexual dysfunction (FSD),” a disease entity plagued by definitional issues and a

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Australia, for example, it has been estimated that winding back the public subsidy for inappropriate prescriptions of several high-profile drugs to people with milder health problems could save hundreds of millions of dollars per year. Those responsible for managing Australia’s publicly funded national formulary, the Pharmaceutical Benefits Scheme, have become increasingly concerned about what is described as “leakage” — the process where subsidised drugs are prescribed by physicians to people for whom use of the drug has been deemed not cost-effective because of a poor cost-benefit ratio. We suspect that the estimated hundreds of millions of dollars of

public money wasted on leakage in Australia annually is in part a result of drug companies promoting their products, through physicians, to people with mild problems for whom a powerful prescription may be unnecessary or even do more harm than good. In summary, combating disease mongering may improve the personal health of individuals, as well as the financial health of public (and private) insurers.

As an initial step toward combating disease mongering at a health policy level, we would urge decision makers to promote a renovation in the way diseases are defined. Continuing to leave these definitions to panels of self-interested specialists riddled with professional and commercial conflicts

of interest is no longer viable. As a priority, new panels should be assembled, free of commercial conflicts of interest, involving a much wider, and less self-interested, group of players, who would ultimately generate more credible information.

Until a rigorous research agenda is initiated, and the social renovations and policy reforms that research might inform are enacted and evaluated, our beliefs, like those who argue for the benefits of corporate-sponsored disease-awareness campaigns, will remain based more on opinion than evidence. We hope this theme issue can start to change that. ■

Blurring the Boundaries between Health and Illness

“The desire to take medicine,” wrote Dr. William Osler, “is perhaps the greatest feature which distinguishes man from animals.” This desire, however, is neither innate nor stable over time. At present, it is actively promoted by direct-to-consumer advertising on TV and Internet pop-up ads on the Internet as well as by industry-funded disease-awareness campaigns. New diseases may result from new pathogenic agents, of course. But they are most often the result of three deliberate processes: the medicalization of aspects of everyday life (menopause), the portrayal of mild problems as serious illnesses, and the framing of risk factors

(high cholesterol, obesity, osteoporosis) as diseases. The recent issue of *PLoS Medicine* cited elsewhere illustrates how these processes have affected the diagnosis and treatment of a number of relatively new disease entities, three of which are described here.

ADHD

The line between quirky behavior and disease is often fuzzy. Behavioral conditions are therefore particularly susceptible to being labeled as diseases. Attention Deficit Hyperactive Disorder (ADHD) is one that has evolved from largely unrecognized to increasingly prevalent in a relatively short period of time, a trend accompanied by aggres-

sive advertising and pharmaceutical interventions. In the process, the drug industry has cultivated new allies within the education establishment.

Christine B. Phillips, Senior Lecturer in Social Foundations of Medicine at the Australian National University Medical School in Acton, Australia, looks at the role of teachers in the growth of ADHD and the resulting use of psychostimulants to treat the condition. While there has been much debate and controversy concerning the veracity of ADHD as a disease entity and the personal cost-benefit ratio of treatment with psychostimulants, there is not doubt that this type of intervention has increased in

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history of unsuccessful pharmaceutical interventions. FSD was defined as disorders of libido, arousal, orgasm, and pain leading to personal distress and interpersonal difficulties, a definition broad enough to encompass 43% of a sample of women between the ages of 18 and 59 who were surveyed in 1999.

Eager to capitalize on its success with men, Pfizer promoted FSD and sought to have Viagra approved to treat “female sexual arousal disorder.” But its efforts ended in 2004 following consistently poor clinical-trial results. Procter & Gamble, however, was ready to join the quest for a potential drug for FSD. The company developed a transdermal testosterone patch (Intrinsa) to treat “hypoactive sexual desire disorder.” As Tiefer points out, the shift from arousal to low libido suggests that “the effort to match up some drug with FSD moved freely among symptoms and labels.” Despite its versatility, Procter & Gamble was no more successful than Pfizer, and an FDA advisory panel voted unanimously not to approve Intrinsa, saying that P&G had not provided sufficient long-term safety data and questioning the clinical significance of the Intrinsa trials.

The patch failed to meet the FDA’s

main criterion, that it would show “clinically significant changes in the number of successful and satisfying sexual events experienced by a woman.” Indeed, the risk-benefit calculus posed by the patch was clearly unacceptable. As Dr. Sidney Wolfe, testifying on behalf of Public Citizen’s Health Research Group, stated in December 2004 at the FDA Advisory Committee meeting, the key question was the following: “Is an increase in approximately one sexually satisfying encounter a month (not from zero to one, but from approximately four to five times per month) worth the possibility of an increase in breast cancer or coronary artery disease?”

In addition to the opposition from researchers and patient advocates, FSD also met with the activist opposition of a group of women who questioned the wisdom of transposing to women the mechanistic, physiology-driven view of sexuality that had been applied to men. Led by Leonore Tiefer, the “Campaign for a New View of Women’s Sexual Problems” presented a theoretical critique of the medical model of sexual problems, and adopted an activist stance that viewed with skepticism any emerging FSD drug. The critique seeks to debunk the prevailing sexual dysfunction classification; the activism, to challenge recurring biases in clinical

trials, the dangers of off-label promotion, researchers’ conflicts of interest, and neglect of nonmedical theory and research on sexuality.

While ED was a marketing success, at least for a time, FSD has proved to be a more elusive target, thanks in part to the watchdog activities of Tiefer, her associates, and other allies. Still, Tiefer points out that the pharmaceutical industry’s aggressive interest in sex has led to the use of “public relations, direct-to-consumer advertising, promotion of off-label prescribing, and other tactics to create a sense of widespread sexual inadequacy and interest in drug treatments.” And Susan Kelleher, a reporter from the *Seattle Times*, states that “today, FSD has all the trappings of a well-established disease: spokespeople, alarming statistics, a political lobby, a medical specialty and an academic journal.” With such ammunition on their side, the pharmaceutical industry can be counted on to mount a fierce battle. In the words of Ray Moynihan, guest editor of the *PLoS Medicine* issue on disease-mongering, “we might all have to start relying a little less on marketing and promotion of new diseases, dressed up as science and education.” ■

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popularity. Prescription of the drug methylphenidate (Ritalin) increased 2.5 times in the United States and fivefold in Canada between 1990 and 1995.

Because ADHD affects educational performance, teachers have become active participants in detecting the condition and referring potential patients for treatment. As Phillips indicates, "with ADHD, the teacher's work extends beyond simply ensuring the disorder is understood by parents. Instead, the teacher participates in the diagnosis, and may broker different forms of treatment, or rejection of treatment." In this role, teachers may administer specialized assessment instruments and even supervise the administration of psychostimulant medication during the school day. Not surprisingly, this new role for teachers has provided the pharmaceutical companies with an entry into the schools. Working with patient advocates, companies have sponsored educational programs for teachers and supported online science materials. The incursion of the drug industry into schools has in effect made teachers franchisees in the medical marketplace. "While there is an argument for providing unbiased education to teachers about a high-profile condition," writes Phillips, "education provided by pharmaceutical companies is self-serving in that it often provides education which references their own products, and channels the reader toward medical therapy."

Bipolar disorder

A similar attempt at expanding the

market for drugs has occurred with respect to bipolar disorder, as David Healy has indicated in his article "The Latest Mania: Selling Bipolar Disorder" in the issue of PLoS Medicine. Patients have been enlisted in an effort at self-diagnosis that can either alert them that they may be suffering from manic-depressing illness or alarm them about mood shifts that serve to label normal variations in behavior as illness. Broadening the criteria used to diagnose bipolar disorder has expanded the 'need' for medication and extended the use of antipsychotics from the treatment of acute manic states to prophylaxis against bipolar disorders. As initial estimates of the prevalence of the disease have been revised upward, academic interest in the condition has grown, thereby fueling the "bipolar market" with all its attendant activities: the creation of new journals and scholarly societies, and the holding of annual conferences on the topic.

At present, however, there is very limited evidence to support any claims for the prophylactic drug treatment to prevent the emergence of manic-depressive illness. Related to this, there are several disturbing trends in the diagnosis and treatment of the condition. In the United States there has been a surge in the diagnosis of bipolar disorder among children, some as young as 2, and pediatric bipolar disorder is being treated by drugs such as Zyprexa and Risperdal. While the disorder has not been recognized outside the US, it is only a matter of time before both the label and its treatment transcend national boundaries.

Restless Legs Syndrome

The most recent entrant into the diagnostic lexicon is "restless legs syndrome." This disease is defined by four criteria: an urge to move the legs, onset or worsening of symptoms when at rest, relief by movement, and symptoms that can occur primarily at rest and can interfere with sleep or rest. While some people may experience symptoms that are severe enough to be disabling, many who are labeled as "sick" may suffer more from the label than from the restlessness.

In a case study on restless legs and how the media makes people sick, Steven Woloshin and Lisa M. Schwartz from the Center for the Evaluative Clinical Sciences at Dartmouth Medical School examined news coverage of the new disease and its progression from unrecognized condition to the centerpiece of a multimillion dollar international campaign to bring it to the consciousness of both doctors and consumers. Originally approved for Parkinson's disease, the drug ropinirole (Requip) was touted by GlaxoSmithKline as effective for treating restless legs. After examining the media coverage of the condition, the authors found that many articles tended to exaggerate the prevalence of the disease; encouraged self-diagnosis and linked the condition to other problems such as insomnia, daytime fatigue, ADHD in children, and depression; suggested the possibility of treatment; and omitted or minimized adverse effects. Woloshin and Schwartz therefore conclude that, in publicizing rest-

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Product Recalls

March 16, 2006 — April 21, 2006

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.

DRUGS AND DIETARY SUPPLEMENTS

CLASS I Recalls

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

a) **Cytosol Ophthalmics Balanced Salt Solution** (Sterile Irrigating Solution), b) AKORN Balanced Salt Solution; Product not manufactured in accordance with cGMPS as finished product positive for endotoxins resulting in serious injury. All lots, Cytosol Laboratories, Inc.

a) **Miracle II**, by Tedco, Neutralizer Gel, 8 oz (232mL); b) Miracle II, by Tedco, Neutralizer Gel, 8 oz (232mL), 7X; c) Miracle II, by Tedco, Neutralizer, 22 oz (638mL); d) Miracle II, by Tedco, Neutralizer, 2X; e) Miracle II, by Tedco, Neutralizer, 3X; Microbial contamination. All lots, Tedco, Inc.

Medline Alcohol-Free Mouthwash; Alcohol-free mouthwash is contaminated with Burkholderia cepacia and is associated with an illness outbreak. All products with lot codes beginning with the numbers 0503 through 0508 followed by 3 or 4 additional digits; Carrington Laboratories, Inc.

Morphine Sulfate, 1 mg/mL in 0.9% Sodium Chloride, 100 mL Medication Cassette Reservoir; Mislabeling: Product labeled as Morphine Sulfate contained Fentanyl Citrate/Bupivacaine HC1. Lot number 053570081, Service code number 2K8821; PharMEDium Services, LLC.

CLASS II Recalls

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

Benlyn Pediatric Oral Solution, in each 5mL (dextromethorphan HBr) 7.5mg; Product exceeds the maximum amount allowed per daily dose, under U.S. FDA regulation for the quantity of FD&C Red Dye No. 33. Lot numbers 21934L, exp. 02/2006 and 403N4L, exp. 10/2006; Pfizer, Inc.

Minitran (nitroglycerin) Transdermal Delivery System. 0.1 mg/hr; Subpotent: partial patches will deliver less than the labeled amount of 0.1 mg/hr. Lot no. 050359, exp. 05/2008, 3M Company.

Oncaspar (Pegaspargase), 750 I.U. per mL; Superpotent: At the 18 month stability station, the enzymatic activity is above specification coming in at 907 IU/mL. Lot AF02424, exp. 8/24/2006, Enzon Pharmaceuticals, Inc.

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less legs syndrome, "the media seemed to have been coopted into the disease-mongering process."

These case studies, while discrete vignettes of particular conditions and

specific drugs, highlight the dangers of indiscriminate labeling, inflating the benefits of treatment, and enlisting advocates with a vested interest in the disease entity. They also illustrate the wisdom encapsulated in another of Dr.

Osler's aphorisms: "One of the first duties of the physician," he counseled his students, "is to educate the masses not to take medicine." ■

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

Backpack blowers. On the RedMax Gas-Powered Backpack Blowers and Shindaiwa Backpack Blowers, the backpack blower's muffler support bracket can break, creating an opening in the muffler body. Hot exhaust gases could then escape from the muffler, posing a fire hazard. Komatsu Zenoah America, doing business as RedMax, (866) 217-4152 or www.redmax.com; Shindaiwa, (800) 521-7733 or www.shindaiwa.com.

Batteries. The Rechargeable Battery Packs sold with MAX Wireless Conference Phone Models 910-158-001 and 910-158-070 can short circuit, causing them to overheat and melt the protective plastic covering, posing a burn hazard to consumers. ClearOne Communications, (800) 283-5936, Option #5, or www.clearone.com/support.

Battery charger. The circuit board of the Pelican Power Brick Battery Charger (used to charge the Sony PSP) can overheat and cause its plastic cover to melt which poses a fire and burn hazard to consumers. Electro Source LLC, (800) 263-1156 or www.powerbrickrecall.net.

Candle holders. The Egg-Shaped Candle Holders is constructed of plastic and could ignite if exposed to flame, posing a fire hazard to consumers. Nordstrom, Inc., (800) 695-8000 or contact@nordstrom.com.

Chairs. The weld which holds the rear chair leg of Tropitone Impressions Side Chair to the seat can separate from the seat, causing the chair to become unstable and possibly collapse. Tropitone, (800) 654-7000 x 2003.

Charm bracelets. The recalled Beaded Photo Charm Bracelets contain high levels of accessible lead, posing a serious risk of lead poisoning to young children. Oriental Trading Company Inc., (800) 723-6155 anytime or www.orientaltrading.com.

Child's bracelet. The Reebok Heart-Shaped Charm Bracelet contains high levels of lead, posing a risk of lead poisoning and adverse health effects to young children. Reebok International Ltd., (800) 994-6260 or www.reebok.com.

Children's jewelry. The recalled American Girl Children's Jewelry contains high levels of lead. American Girl Inc., (800) 659-0164 or www.americangirl.com/recall.

Cigarette lighters. The flame of the "Speedway" Cigarette Lighters can flare up or the lighter can catch fire when ignited, posing risks of unexpected fires and burn injuries. Speedway SuperAmerica LLC, (800) 643-1948 or www.speedway.com.

Computer desk set. The seat on the chair can break and fall through during use causing an individual to fall and suffer injuries. Office Depot Inc., (800) 944-3340 or www.officedepot.com.

Emergency escape hoods. The EVAC-U8™ and EVAC+™ Emergency Escape Smoke Hoods could fail to work properly, exposing the user to harmful carbon monoxide. Brookdale International Systems Inc., (866) 823-4416 or www.evacsafety.com.

Engines. The fuel line on Tecumseh engines used in various Two-Stage Snow Throwers, Ice Augers, Generators, Lawn Mowers, Weed Trimmers, Log Splitters and Fun-Karts can become loose or disconnected, resulting in a fuel leak. This can pose a fire hazard to consumers. Tecumseh Power Co., (888) 271-4048 or www.tecumsehpower.com.

Espresso machines. The electrical connectors in the Jura Impressa Automatic Coffee Center Espresso Machine can erode, posing a fire hazard. Jura-Capresso LLC, (888) 406-4440 or www.capresso.com.

Girl's sweaters. A drawstring is threaded through the hood of "Who's That Girl!" Sweaters, 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. Trendset Originals, (800) 908-8308 or customer-service@trendsetny.com.

Hair dryers. The Eusonic Hair Dryer's power cord does not have an immersion protection plug. Therefore, if the hair dryer falls into water during use, it can pose a shock and/or electrocution hazard. Saroj International Inc., (877) 277-1055 or sales@sarojusa.com.

Hiking boots. Product testing has demonstrated that Men's Safety Toe Waterproof Hiker Boots may not comply with applicable safety standards for crush and impact resistance. Consumers could suffer impact foot injuries. Rocky Shoes & Boots Inc., (866) 762-5972, Ext. 2539 or www.georgiaboot.com.

Name of Product; Problem; Manufacturer and Contact Information

Home gym. One end of the leg extension cable on the Bowflex Ultimate 2 Home Gym can release from the guide pulley and swing around, potentially striking the user or a bystander. Nautilus Inc., (800) 413-3121 or www.bowflex.com.

Iron supplement. The Walgreens High Potency Iron Supplements are not in child-resistant packaging as required by the Poison Prevention Packaging Act. Inverness Medical Nutritionals Group, 1-(888) 698-5032 or www.walgreens.com.

Magnetic building sets. Tiny magnets inside the plastic building pieces and rods in the Magnetix Magnetic Building 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 to each other and cause intestinal perforation or blockage, which can be fatal. Rose Art Industries Inc., (800) 779-7122 or www.roseart.com.

Massaging bedrest. Electrical circuits within the Brookstone Foldable Massaging Bed Rest with Heat can overheat causing the back side of the product to overheat, posing a fire and burn hazard. Brookstone Company Inc., (888) 318-7455, www.brookstone.com, or bedrest-recall@brookstone.com.

Mountain climbing anchor. The cables that support climbers using these Camming Anchors can fail, causing climbers to fall. Colorado Custom Hardware (CCH) Inc., (800) 776-9185 or www.aliencamsbycch.com.

Neon signs. The AC adaptor used with these Underground Neon Signs can overheat, posing a burn hazard to consumers. Signals Catalogue Corp., (800) 669-5225 or www.signals.com.

Notebook computer batteries. An internal failure can cause the HP and Compaq Notebook Computer Batteries to overheat and melt or char the plastic case, posing a burn and fire hazard. Hewlett-Packard Company, www.hp.com/support/BatteryReplacement or (888) 202-4320.

Personal DVD players. The battery packs sold with Disney®-Brand DVD Players can overheat and possibly burst when recharging, posing a risk of burns. Memcorp Inc., (800) 326-0315 or www.disneyelectronics.com.

Piano bench. On some benches sold with Digital Pianos, one or more bench bolts do not meet tensile strength specifications, which can result in collapse of the bench while in use, posing a risk of injury. Yamaha Corp. of America, (800) 510-6933 or www.yamaha.com.

Plastic fuel tank. The fuel tank of the Valsi Single Phase Portable Generator can crack and leak fuel, posing a risk of fires and burn injuries. (866) 260-4842 or export@valsi.com.mx.

Portable projectors and lamps. The InFocus LP120 Projector, ASK Proxima M1 Projector, and SP-LAMP-013 Replacement Lamp Modules have improper wiring with inadequate insulation which could degrade over time, posing a shock and fire hazard. InFocus Corp., (877) 398-6086 or www.infocus.com/service.

Radio control toy trucks. Electrical circuits within the truck can overheat causing the toy to overheat, posing a risk of fire. QVC Inc., (800) 367-9444 or www.qvc.com under the product recall section.

Rocking chairs. Poor construction and over-curvature of the Mainstays Love Seat Rocker and Porch Rocker runners can cause instability, imbalance, fracturing of the wood, and tip-over during use. This poses a fall hazard to consumers. Wal-Mart Stores Inc., (800) 925-6278 or www.walmart.com.

Roller skates. The wheels on these roller skates can detach and the brakes can fail. Either one of these hazards can cause the skater to fall and suffer serious injury. LandRoller Inc., (877) 923-5500, recall@landroller.com, or http://www.landroller.com/terra9_recall.

Snowmobiles. Cracks can appear in the starter ring gears of the Ski-Doo® Model Year 2005 and 2006 Mach Z® and Model Year 2006 MX Z Renegade 1000 Snowmobiles, causing ring gear fragmentation at high speeds. The debris can act as a projectile causing injury or death to riders or bystanders. Bombardier Recreational Products Inc. (BRP), (888) 864-2002 or www.ski-doo.com.

Snowmobiles. The recalled Artic Cat snowmobile's fuel tank could crack and leak, allowing fuel or fuel vapors to escape, posing a fire and burn hazard. Arctic Cat Inc., (800) 279-6851 or www.artic-cat.com.

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OUTRAGE, from page 12

Creole, common languages in Massachusetts). In sum, the reform plan wishes away 248,000 uninsured people who don't have phones or don't speak English or Spanish. It provides no funding or means to get them coverage.

Second, the linchpin of the plan is the false assumption that uninsured people will be able to find affordable health plans. A typical group policy in Massachusetts costs about \$4500 annually for an individual and more than \$11,000 for family coverage. A wealthy uninsured person could afford that — but few of the uninsured are wealthy. A 25-year-old fitness instructor can find a cheaper plan — but few of the uninsured are young and healthy. According to Census Bureau figures, only 12.4% of the 748,000 uninsured in Massachusetts are both young enough to qualify for low-premium plans (under age 35) and affluent enough (incomes greater than 499% of poverty) to readily afford them. Yet even this 12.4% figure may be too high if insurers are allowed to charge higher premiums for persons with health problems — only half of uninsured persons in those age and income categories report that they are in “excellent health.”

The legislation promises that the uninsured will be offered comprehensive, affordable private health plans. But that's like promising chocolate chip cookies with no fat, sugar or calories. The only way to get cheaper plans is to strip down the

coverage — boost copayments, deductibles, uncovered services etc.

Hence, the requirement that most of the uninsured purchase coverage will either require them to pay money they don't have, or buy nearly worthless stripped-down policies that represent coverage in name only.

Third, the legislation will do nothing to contain the skyrocketing costs of care in Massachusetts — already the highest in the world. Indeed, it gives new infusions of cash to hospitals and private insurers. Predictably, rising costs will force more and more employers to drop coverage, while state coffers will be drained by the continuing cost increases in Medicaid. Moreover, when the next recession hits, tax revenues will fall just as a flood of newly unemployed people join the Medicaid program or apply for the insurance subsidies promised in the reform legislation. The program is simply not sustainable over the long-or even medium — term.

The legislation offers empty promises and ignores real-and popular-solutions. A single payer universal coverage plan could cut costs by streamlining health care paperwork, making health care affordable. Massachusetts Blue Cross spends only 86 percent of premiums paying for care. It spends the rest-more than \$700 million last year-on billing, marketing and other administrative costs. Harvard Pilgrim and Tufts Health Plan-the state's other big insurers-are little better; each took in about \$300 million more than it paid out. That's 10 times as much over-

head per enrollee as Canada's national health insurance program. And our hospitals and doctors spent billions more fighting with insurers over payments for each band-aid and aspirin tablet.

Overall, Massachusetts residents will spend \$13.3 billion on health care bureaucracy this year — nearly one third of our total health bill. If we cut bureaucracy to Canada's levels we could save \$9.4 billion annually, enough to cover all of the 748,000 uninsured in Massachusetts and to improve coverage for the rest of us.

Study after study-by the Congressional Budget Office, the General Accounting Office and even the Massachusetts Medical Society — have confirmed that single payer is the only route to affordable universal coverage.

And single payer is popular. The Massachusetts Nurses Association supports it along with dozens of other labor, seniors and consumer groups; so do 62 percent of Massachusetts physicians according to a recent survey. National polls find that almost two-thirds of Americans favor a tax-funded plan like Medicare that would cover all Americans.

But single payer national health insurance threatens the multi-million dollar paychecks of insurance executives, and the outrageous profits of drug companies and medical entrepreneurs.

It's time for politicians to stand up to the insurance and drug industries and pass health reform that can work. ■

CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Toy cars. The hubcaps on the Primary Sounds Toy Vehicle's plastic wheels can detach posing a choking hazard to young children. Kids Preferred LLC, (866) 763-8869 or Nicole@kidspreferred.com.

Toy jewelry. The Dollar Tree Mood Necklace and Ring, Glow-in-the-Dark Necklace and Ring, and UV Necklace and Ring contain high levels of lead, posing a serious risk of lead poisoning and adverse health effects to young children. Dollar Tree Distribution Inc., (800) 876-8077 or www.dollartree.com.

Toy pliers. The sliding yellow knob on Child Guidance Toy Pliers can detach, posing a choking hazard to young children. RadioShack Corp., (800) 843-7422 or www.radioshack.com.

Trampolines. If a person assembles the InMotion Trampoline alone and the outside rail is released momentarily, the trampoline can snap back into the folded position and strike the consumer, posing a risk of serious injury. Stamina Products Inc., (800) 375-7520 or www.staminaproducts.com.

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Massachusetts' Mistake

Steffie Woolhandler and David Himmelstein are primary care physicians at Cambridge Hospital and associate professors at Harvard Medical School.

It's a stirring scene. The governor, legislative leaders and leaders of Health Care For All standing in the Massachusetts State House Rotunda declaring victory in the fight for universal health coverage. Yet, this week's tableau is merely a repeat from 20 years ago when Governor Michael Dukakis celebrated passage of his universal healthcare bill. That plan imploded within two years, and today about 250,000 more people are uninsured in Massachusetts than the day it was signed. Unfortunately, Massachusetts' new health reform legislation looks set to repeat that disaster.

The new bill includes three key

provisions meant to expand coverage. First, it would modestly expand Medicaid eligibility. Second, it would offer subsidies for the purchase of private coverage to low-income individuals and families, though the size of the subsidies has yet to be determined. Finally, those making more than three times the poverty income (about \$30,000 for a single person) would have to buy their own coverage or pay a fine.

To help make coverage more affordable, a new state agency will connect people with the private insurance plans that sell the coverage, and allow people to use pre-tax dollars to purchase coverage (a tax break that mostly helps affluent tax payers who are in high tax brackets). This new agency is also supposed to help design affordable plans.

Businesses that employ more than 10 people and fail to provide health

insurance will be assessed a fee (not more than \$295) to help subsidize care. Additionally, hospitals won a rate hike assuring them better payments from state programs, and several provisions were included that are meant to attract additional federal funding to help pay for the Medicaid expansion.

What's wrong with this picture? First, the politicians assumed that only about 500,000 people in Massachusetts are uninsured. The Census Bureau says that 748,000 are uninsured. Why the difference? The 500,000 figure comes from a phone survey conducted in English and Spanish. Anyone without a phone or who speaks another language is counted as insured. The 748,000 figure comes from a door-to-door survey carried out in many languages (including Portuguese and Haitian

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