

# Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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## Mandatory Disclosure of Pharmaceutical Industry-Funded Events for Health Professionals

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We are in a period of unprecedented scrutiny of the relationships between the pharmaceutical industry and doctors [1–4]. Legislators are now considering how they might become involved in the regulation of these practices. This is a telling comment on the perceived failure of the medical profession to regulate itself and of self-regulation by industry. But reliable and comprehensive data on the nature and extent of industry sponsorship are rare. Several states in the U.S. have mandatory disclosure laws for physician payments, but these data have proved difficult to access and analyze [5]. The U.S. Congress is considering new mechanisms for revealing industry–professional interactions (the so-called “Sunshine” Acts) [6,7].

One of the first countries to move towards greater transparency was Australia. The pharmaceutical industry representative body, Medicines Australia, has a self-regulatory Code of Conduct that sets standards for the ethical marketing and promotion of prescription pharmaceutical products for its member companies. In addition to monitoring of promotional activities, a Code of Conduct Committee adjudicates on

complaints regarding pharmaceutical company activities [8]. In 2007, the Australian Competition Tribunal placed disclosure requirements on Medicines Australia. It approved that body’s Code of Conduct for industry–professional relationships on the condition that details of every sponsored event, including the costs of any hospitality, were posted on their website [9,10]. Reporting commenced in July 2007 and data are updated six monthly [8].

In this Policy Forum we examine the Australian data and argue that although a definite advance, the Australian disclosure requirements fall short of what is required. We propose more comprehensive reporting standards, which should have application to other settings and jurisdictions.

### Australian Experience of Pharmaceutical Company Disclosures

In Australia, the emphasis in disclosure is on monitoring the level and type of sponsorship of educational events rather than documenting the dollar value of gifts and other payments to physicians. Since 2007 pharmaceutical companies have been required to report all functions (educational events) provided or sponsored for health professionals. They are required to disclose the following: the venue; the professional status of attendees; a description of the function and duration of the educational content of events; the nature of the hospitality; the total cost of hospitality; the numbers of

*continued on page 2*

## CONTENTS

Health Letter Volume Index, 2009 ..... 6

Opposition to Prophylactic Removal  
of Third Molars (Wisdom Teeth) ..... 7

### RECALLS

November 19, 2009 - December 14, 2009  
This month, Motrin IB and cookware are on the list ..... 9

### OUTRAGE

Tamiflu? More Like Scamiflu ..... 12



attendees; and the total cost of the function [11].

The first report, covering the period July to December 2007, provided details of 14,649 events [12]. This total is equivalent to almost 600 events per week nationally, at a cost of around AUD [AUD = Australian dollar] \$1 million/week (U.S.\$879,074.00). Put another way, the pharmaceutical industry spends, on average, around AUD\$1,000 annually on each doctor through sponsorship of such events. The top five companies in terms of the numbers of sponsored events were Astra Zeneca, Pfizer, Sanofi Aventis, Janssen Cilag, and Eli Lilly. The most generous of the active companies (those with 100 functions in 6 months) was Bristol Myers Squibb, with an average cost per head of AUD\$95.26. In contrast, Alphapharm (a generics manufacturer) sponsored 441 events (mostly in professional rooms with a sandwich lunch) at an average cost per head of AUD\$18.24.

Hospitality (food, beverages, travel, accommodation) accounted for around AUD\$17 million of the total of AUD\$31 million spent on functions. Thirty-five percent of sponsored events ( $n = 5,174$ ) were held in restaurants, hotels, or function centers. The average cost per head was much higher when the venue

was a restaurant (AUD\$71.35) than in a hospital (AUD\$12.11). In 7.2 percent of cases ( $n = 1,062$ ) expenditure exceeded AUD\$100 per head (examples are given in Box 1). There were 74 events (0.5 percent) with total outlays per head on hospitality in excess of AUD\$500.

Medical specialists were present at 62 percent ( $n = 9,018$ ) of events, family physicians at 30 percent ( $n = 4,437$ ), nurses at 26 percent ( $n = 3,820$ ), and pharmacists at less than 5 percent ( $n = 621$ ) of events. Registrars (medical specialists in training) were present at 19 percent ( $n = 2,827$ ) of events; in 179 instances they were the only attendees. The medical subspecialties most often featured were psychiatry (17.9 percent), and oncology (15.2 percent), who received industry hospitality roughly three times as often as any other subspecialty. The largest per head expenditure was directed at endocrinologists, oncologists, and cardiologists. Companies spent considerably more on restaurant meals for doctors (AUD\$76.73) than for nurses (AUD\$48.78).

Companies reported no responsibility for the educational content in only 9 percent of events ( $n = 1,287$ ). Likewise, continuing medical education (CME)/continuing professional development (CPD)

points were allocated to 9 percent of events ( $n = 1,270$ ). Just over 20 percent of all events were described as "journal club" or "grand rounds" ( $n = 3,035$ ), mostly conducted in hospitals. The majority of events ( $n = 10,723$ , 73.2 percent) were a mix of meetings of various kinds, including workshops and in-service training activities; only 4 percent ( $n = 591$ ) were described as "conferences." The most common specific topics were hypertension, osteoporosis, breast cancer, type-2 diabetes, and depression. All represent large and important markets for pharmaceutical products. Topic descriptions, where provided, often matched the product portfolio of the sponsor, although there were few mentions of specific drug names ( $n = 582$ , 4 percent).

Importantly, Australian companies are not required to disclose the names of the speakers, whether sponsors played a role in their selection or in the choice of the content of presentations. They are also not required to disclose the nature of any financial ties between their companies and the speakers.

### Why Do We Need Better Disclosure?

The information provided by Medicines Australia points to a

#### Box 1. Five examples of high-cost sponsored events.

1. Flights, accommodation, food, beverages, and conference registration fees for six ophthalmologists to attend a two-day conference in Spain, at a cost of AUD\$10,993 per person, sponsored by Novartis.
2. One-hour cocktail party for 45 respiratory physicians on the Gold Coast, with hospitality costs of more than AUD\$20,000, including flights and accommodation for one speaker, sponsored by Actelion.
3. A presentation by a Key Opinion Leader exploring the link between diabetes, severe mental illness, and antipsychotics for better patient management for 115 psychiatrists, general practitioners, and allied mental health workers at the Royal Automobile Club of Victoria in Melbourne with a hospitality cost of AUD\$186 a head sponsored by Eli Lilly. This amount included travel, accommodation, and extra meals for the speaker and 11 delegates.
4. Ten infectious diseases specialists given AUD\$1,000 each, to contribute to flights, accommodation, and registration for a conference at Conrad Jupiter's Casino, Gold Coast, sponsored by Novartis.
5. Eight general practitioners attended an event with 2 hours of education at the Truffleduck restaurant in Perth, and earned 30 CPD points, with hospitality costs of almost AUD\$140 a head, sponsored by Merck.



high level of contact between pharmaceutical manufacturers and health professionals, particularly doctors. The per-person expenditure was greatest for medical specialists who prescribe high cost drugs — oncologists, endocrinologists, and cardiologists. Generally, expenditure at individual events was modest; however the cumulative expenditure and the overall level of contact was high. The available information suggests that companies exert influence over the educational content of events in most cases, and doctors in training are often present at these functions. There is substantial evidence that attendance at company-sponsored events modifies prescribing practices [13–15]. The presence of doctors in training and students (in hospital-based sessions) may lead to a process of enculturation whereby they come to regard repeated contact with pharmaceutical companies as a normal and acceptable part of their professional practice. The data reviewed here indicate that, from a company perspective, it is cheap and easy to sponsor meetings in hospitals and health centres, and the return on this “investment” is likely to be high. Equally, it is straightforward for administrators to limit sponsorship of such activities, should they choose to do so. It is difficult to see a role for pharmaceutical companies at hospital grand rounds.

The evidence from this analysis of Australian data suggests that disclosure requirements should not stipulate thresholds — set dollar

amounts below which disclosure is not required. Physician-reporting requirements such as those in Vermont and Minnesota in the U.S., which exempt payments of less than U.S.\$100, could obscure the broad cumulative influence of a number of smaller payments [5,16]. The literature indicates that it is not only the size of the gift that matters — it is the sense of reciprocity that it engenders [17].

The types of activities described here need to be viewed within the broader context of other forms of pharmaceutical industry interaction with doctors, including face-to-face contact with representatives, advertising in medical journals, consultancies, membership of advisory boards, and stock holding [18–20]. While lavish gifts and generous travel support have been a focus of attention in the past, these have been progressively discouraged by industry and professional guidelines. It is likely that the frequent, more modest, sponsored educational events will become increasingly important and influential, and the principal form of contact between industry and health professionals.

There are a number of organisations that will benefit from more comprehensive disclosure of these activities. Professional organisations and accreditation bodies will have accurate data on the level and type of contact their members have with pharmaceutical companies. This will enable them to counter the undesirable effects of such relationships through the development of guidelines, or

the evolution of practice standards or disciplinary codes. They will benefit from sequential data to determine if practices are changing over time. The public, the media, and consumer groups will have access to reliable data on which to base their judgements about industry-health professional contact and, when appropriate, to lobby for change. Individual health professionals could have access to information on which to judge their own practices against those of their peers. If legislation is thought necessary, governments will have data on which to monitor its impact.

### Proposals for Greater Transparency

The Australian reporting standards are deficient in not including details that enable a judgment about the educational value of company sponsored events. We believe that reporting schemes should require the following details: the names of the speakers presenting, whether sponsors played a role in suggestion or selection of speakers or the development of the content of presentations, and the nature of any direct or indirect financial ties between the speakers and the sponsors. This type of information is routinely requested by professional journals; so there are ample precedents and it is particularly relevant when judging the appropriateness of educational events.

We experienced considerable

*continued on page 4*



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difficulty in accessing the Australian data, which are compiled in portable document format (pdf). As suggested in the U.S. Sunshine Acts it is important that summary reports listing each function are accessible to the public in a searchable, downloadable, and analyzable format [5–7].

Whether there should be a central register or database that identifies attendees at company-sponsored functions is more controversial. The data could be compiled from the records of names collected by the pharmaceutical companies. Reports could be provided to health professionals, which would enable them to compare their practices with their peers. We are not here advocating public disclosure of this information, but individuals could be asked to provide reports in particular circumstances — for instance when ethics committees are considering the industry ties of an investigator.

In Box 2 we have summarized the main data elements that we think should be included in disclosure programs. What we suggest is consistent with the recent Institute of Medicine (IOM) Report on conflicts of interest [21]. This report recommended that the U.S. Congress create a national program requiring companies and their foundations to publicly report

payments to physicians and other prescribers, biomedical researchers and their institutions, but did not suggest specific data elements. Some authors of the report argued that this database should also provide explanatory material about payments received (e.g., for an educational or marketing purpose) and information on all financial ties (e.g., equity ownership, patent rights) in addition to industry payments and gifts [22].

While it may be unrealistic and undesirable to ban contact between pharmaceutical companies and health professionals we should work to make those relationships completely transparent. We welcome further debate on this topic.

### Summary Points

- There are moves internationally to ensure greater disclosure of gifts and educational events for doctors paid for by pharmaceutical manufacturers. However, there is no agreement on appropriate standards of disclosure. In Australia, since mid-2007, there has been mandatory reporting of details of every industry-sponsored event, including the costs of any hospitality provided.
- Examination of the Australian data shows that although expenditure

at individual events is often modest, cumulative expenditure is high, particularly in the case of medical specialists prescribing high cost drugs — oncologists, endocrinologists, and cardiologists.

- Although a significant advance, the new Australian reporting standards do not allow assessment of the educational value of sponsored events, and do not include details of speakers or educational content for most events. However, doctors in training are often present at these events.
- At present, the standards of disclosure are inadequate and should not be tied to an arbitrary monetary value of gifts or sponsorship. Reporting standards should require the names of the speakers presenting, whether sponsors played a role in suggestion or selection of speakers or the development of the content of presentations, and the nature of any direct or indirect financial ties between the speakers and the sponsors. ♦

### Authors

Jane Robertson<sup>1</sup>, Ray Moynihan<sup>1</sup>, Emily Walkom<sup>1</sup>, Lisa Bero<sup>2</sup>, David Henry<sup>3</sup>

1: School of Medicine and Public

## Box 2. Details to be included in mandatory reporting schemes for pharmaceutical industry-sponsored events for health professionals.

### Included in existing reports from Medicines Australia

- The numbers of attendees and their professional status
- The venue, and a description of the function
- The nature of any hospitality provided
- The total cost of hospitality and the total cost of the function
- The nature of any entertainment provided
- The duration of the educational content of events
- Continuing professional development (CPD)/continuing medical education (CME) points provided

### Suggested additional compulsory reporting items

- The nature of any gifts provided

- The names of speakers Dollar value of honoraria and travel support provided to speakers
- Disclosure of other financial ties between sponsoring companies and speakers (e.g., equity ownership, consultancies, advisory panel membership)
- The role of the company in suggesting/choosing the educational topic and speaker
- The brand names of drugs discussed in the session

### For debate

- Registration of all attendees (limited access [Information available only to the individual and through him or her to other bodies])



Health, The University of Newcastle, Newcastle, New South Wales, Australia; 2: Department of Clinical Pharmacy, University of California San Francisco, San Francisco, California, United States of America; 3: Institute for Clinical Evaluative Sciences, Toronto, Canada

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## Author Contributions

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Public Citizen Endorses Single Payer National Health System,  
Joins Leadership Conference for Guaranteed Health Care  
U.S. Inmates Suffer from Chronic Illness and Poor Access  
to Health Care  
Informed Consent and Shared Decision-Making  
OUTRAGE: "Morning After" Contraception  
Too Difficult to Get

## March 2009, V25#3

Massachusetts' Plan: A Failed Model for  
Health Care Reform  
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Public Hospitals, Community Clinics Suffering Under  
Massachusetts Health Care Reform  
OUTRAGE: Ending the Insanity of Failed State Health  
Insurance Reforms

## April 2009, V25#4

Stretching the TARP to Cover Health Care  
Bereavement: A Look at the Grieving Process and  
How to Cope with Loss  
How Much Is A Year of Your Life Worth?  
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Drug Patches  
OUTRAGE: High Deductibles for Limited Eligibles

## May 2009, V25#5

Public Citizen's Health Research Group Ranking of the Rate of State  
Medical Boards' Serious Disciplinary Actions, 2006-2008  
OUTRAGE: Psychoprosstitution

## June 2009, V25#6

Vermont's Pharmaceutical Laws Move Toward Fuller Disclosure  
What is Comparative Effectiveness Research, and Why is it Being  
Badmouthed?  
Intro to Comparative Health Systems  
OUTRAGE: A Coalition of the Scared

## July 2009, V25#7

Q&A on the Current Health Debate: What Does a 'Public Plan  
Option' Mean and Why Does Public Citizen Oppose it?  
Hospitals Drop the Ball on Physician Oversight  
A Dictionary of Health Policy Terms, Part III  
OUTRAGE: Language Matters: Poor Communication Can Mean Poor  
Health Care

## August 2009, V25#8

Dr. Sidney Wolfe's Testimony before Subcommittee on Health at  
Hearing on Health Insurance  
Dr. Steffie Woolhandler's Testimony before Health Subcommittee at  
Hearing on Health Insurance  
Letter to the Editor of the Washington Post Regarding the Coverage  
of the Recent Congressional Hearing on Single-Payer  
Ineffectual Medical Treatments Misleadingly Produce "Good" Results  
OUTRAGE: Medical Publisher Offers Bribes for Writing Favorable  
Book Reviews

## September 2009, V25#9

Obama Administration Must Make Disciplinary Records of Nurses,  
Health Workers Available to Hospitals, Nursing Homes  
Letter Urging Secretary Sebelius to Provide Hospitals and Nursing  
Homes Access to Names of Disciplined Nurses and  
Other Health Workers  
A Call to Action: Why We Need Medical Resident Work  
Hour Reform  
Are We Now Twice as Sad? The Drug Industry and Doctors  
Think We Are!  
OUTRAGE: Ghostly Prescriptions

## October 2009, V25#10

The Uninsured in the United States: What the Rise to 46.3 Million  
Means  
Public Citizen Proposes Basic Patient Safety Reforms that Would  
Save 85,000 Lives and \$35 Billion a Year  
A Review of Homeopathy  
Health Debate or Health Charade?  
OUTRAGE: Drug Company Inducements to Doctors:  
Not Par for the Course

## November 2009, V25#11

Health Reform: Where Will the Money Come From?  
Product Recalls  
Harvard Study Finds Nearly 45,000 Excess Deaths Annually Linked  
to Lack of Health Coverage  
OUTRAGE: AHIP's Actuarial Acrobatics

## December 2009, V25#12

What Happened in Health Care in 2009  
The Price We Pay for Uninsurance  
Analysis of USPSTF 2009 Revised Breast Cancer Screening  
Recommendations  
OUTRAGE: The Case of Neurontin: Skewed Research  
in the Service of Selling



# Opposition to Prophylactic Removal of Third Molars (Wisdom Teeth)

*The following is a policy statement from the American Public Health Association released on their website Oct. 28, 2008. For direct access to the APHA website database file and a complete list of references for this statement, visit [www.apha.org/advocacy/policy/](http://www.apha.org/advocacy/policy/).*

Excessive health care in the United States has been documented by numerous studies. It results in waste of limited funds and harm to millions of people, not excluding death, because even the safest treatment is not without risk. The obvious solution, when effectively applied, is "evidence-based practice," which minimizes unnecessary procedures and reduces costs. The public is already aware that some surgical procedures, such as tonsillectomy, are no longer routinely performed in the absence of infection to prevent future infection. Yet, there are procedures such as the prophylactic removal of third molars that result in injury to tens of thousands of people at a cost of billions of dollars, about which the public is ill informed and thus subject to the risks of unnecessary surgery.

Accordingly, the American Public Health Association (APHA) calls for dental care, like all aspects of health care, to be evidence based. APHA encourages the collection, review, dissemination and policy applications of knowledge supporting or negating the efficiency and cost-effectiveness of specific forms of dental care ... encourages dental professionals, consumers, private and public health care financing agencies, and state licensing authorities to adopt an evidence-based approach to dental services, in order to rationally control costs, help assure quality and favorable outcomes and extend more affordable dental care to a wider public.

All health-related organizations should promote evidence-based

practice and discourage treatment that is of questionable value and that has the potential to cause significant injury to the public.

No one questions the removal of third molars, or any other tooth, where there is evidence of pathological changes such as infections, nonrestorable carious lesions, cysts, tumors, and damage to adjacent teeth. But the contention by many dentists, including oral surgeons, that retaining third molars, whether or not impacted, will likely lead to sufficient harm does not justify removing all third molars.

The main arguments for prophylactic removal of third molars are as follows: eruption is unpredictable; adjacent teeth could be damaged; the teeth may harbor pathogenic bacteria that may cause periodontal disease and may contribute to low infant birth weight and other diseases such as diabetes, cardiovascular disease, and stroke; eruption may cause crowded or crooked teeth; and they are easier to extract and cause less morbidity when extracted in adolescence.

None of these contentions is sufficient to support prophylactic extraction of third molars. Unpredictability of eruption is not valid because most wisdom teeth erupt, and only a small percentage of those that remain unerupted or partially erupted cause problems that warrant extraction. All periodontically diseased teeth harbor pathogenic bacteria and require treatment by general dentists, dental hygienists, and periodontists, whose goal is to retain, not extract, them. Presence of third molars in conjunction with systemic diseases represents association, not causation.

Because the rationale to remove all third molars to reduce morbidity or prevent cysts and crowding of anterior teeth does not meet the evidence-based test, the current

emphasis on third molars as a potential cause of periodontal disease and other debilitating or life-threatening conditions warrants more detailed analysis. Since the 1990s, the American Association of Oral and Maxillofacial Surgeons has been a major sponsor of research exploring periodontal disease in third molars. The few studies of long-term retention of impacted teeth have shown little risk of harm. In one large study, in which 3702 "neglected" impactions (96 percent third molars) were retained for an average of 27 years, only 0.81 percent showed dentigerous cystic changes. Further, any type of pathological change can be expected eventually in approximately 12 percent of an impacted third-molar population and 1.8 percent of the general population, including those with impacted teeth. Accordingly, the authors questioned routine removal of impacted third molars.

A similar panoramic radiograph study of 1418 women found 16 percent had "moderate" pathological conditions, consisting "in most cases of a slightly widened follicle or resorption of the crown. A new examination 12 years later revealed unchanged conditions in 85 percent of the cases." The 12 percent incidence of pathology referred to previously does not include pericoronitis or inflammation and infection of the gum tissue around a tooth as it erupts, which is distinguishable from normal "teething." Estimates range from 6 percent to 10 percent. Adding an average of 8 percent raises the potential for third-molar pathology to 20 percent. Also, it has been reported that as many as one third of the population may experience some discomfort at one time or another associated with wisdom teeth; thus, there is likely need for, at most, one third of the extractions currently being done.

Third-molar surgery is not without



risk of injury. The most common injury is temporary and permanent paresthesia, which has been documented by numerous studies. Incidence of permanent paresthesia of the mandibular nerve varies from a low of 0.33 percent to a high of 1 percent. There is also injury to the temporomandibular joints (TMD/TMJ), which has been reported at 1.2 percent for patients aged 15 to 20 years. The nearly 6000 oral and maxillofacial surgeons account for 94 percent of the 10 million third-molar extractions in the United States annually, averaging 52.7 cases a month. Thus, an estimated 3.8 million people experience 5 million mandibular third-molar extractions each year. As a consequence, as many as 17,000 to 50,000 people have some degree of permanent mandibular nerve paresthesia and tens of thousands experience TMD/TMJ injuries, an unknown number of which also become permanent. Furthermore, patients experience an average of 2.7 days, more than 10 million days in aggregate, of discomfort and disability pain, swelling, bruising, and malaise and absence from school and loss of work and income after uncomplicated third-molar extractions. Other risks include inadvertent fractures of the jaws, damage to the maxillary sinus, damage to adjacent teeth, and occasional deaths attributed to general anesthesia.

In a literature review of 40 studies involving third-molar extractions, the authors concluded that, "In the absence of good evidence to support prophylactic removal, there appears to be little justification for the removal of pathology-free impacted third-molars." A similar Cochrane Review on interventions for treating asymptomatic impacted wisdom teeth advised that watchful monitoring may be a more appropriate strategy. "Prudent decision-making, with adherence to specified indicators for removal, may reduce the number of surgical procedures by 60 percent or more."

A further review of the literature

on third-molar extraction by an oral pathologist concluded, "third molars without associated pathology or developmental conditions are sacrificed, usually in adolescents and young adults, like no other human tissue, in the name of preventive dental care ... in more than 98 percent of cases, there is no apparent benefit to prophylactic third-molar extraction in adolescents. The concept that all third molars (functional or nonfunctional) should be extracted prophylactically should be abandoned."

Consequently, the National Health Service in Great Britain adopted the policy that, "The practice of prophylactic removal of pathology-free impacted third molars should be discontinued.... There is no reliable evidence to support a health benefit to patients from the prophylactic removal of pathology-free teeth." In the United States, millions of mostly young people continue to have prophylactic extraction of their wisdom teeth in the belief that it is necessary. This practice is not evidence based and needs to be discouraged by providing the public with information essential to making an informed decision.

The 2000 U.S. Surgeon General's report, *Oral Health in America*, and *Healthy People 2010* emphasize the role of public health and health care providers, educators, and researchers in improving the public's health literacy. The American Dental Association defines oral health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate oral health decisions." Improvement in health literacy requires more than exposure to information, much of which can appear to the public as confusing if not contradictory; it also requires provision of "clear, understandable science-based health information to the American people," including health care providers. It requires assistance in interpretation by public health organizations, educational

institutions, and agencies with no financial or personal interests one way or the other.

Accordingly, the American Public Health Association:

1. Recommends that public education about the removal of third molars (wisdom teeth), like the removal of any teeth, should be based on evidence of diagnosed pathology or demonstrable need;

2. Opposes prophylactic removal of third molars, which subjects individuals and society to unnecessary costs, avoidable morbidity, and the risks of permanent injury;

3. Recommends that the Agency for Healthcare Research Quality and the National Institutes of Health, agencies of the U.S. Department of Health and Human Services, and other independent researchers call for convening an expert panel that considers evidence-based research on the effectiveness and appropriateness of prophylactic removal of third molars and generates a consensus statement;

4. Recommends that oral health researchers and funding agencies include in their research agendas support for the application of evidence-based dental practice, to include issues such as the prophylactic extraction of third molars and how to most effectively translate evidence-based science into the practice of dentistry;

5. Urges all public health agencies and dental professional organizations to disseminate information explaining why prophylactic removal of third molars is not recommended, in keeping with their dedication to improving the health literacy of the public and its consequent ability to make informed health care decisions. ♦



# Product Recalls

*November 19, 2009 – December 18, 2009*

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

## DRUGS AND DIETARY SUPPLEMENTS

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

### Recalls and Field Corrections: Drugs – CLASS I

*Indicates a problem that may cause serious injury or death*

**S-DROL tablets**, 60 tablets per bottle, UPC 8 272386 000376, 1688 bottles; Marketed without an approved NDA/ANDA: Product contains desoxymethyltestosterone, an anabolic steroid, making it an unapproved new drug. Lot #: 810481, exp. date 01/2012; Nutracoastal Trading, LLC.

**Stamina Rx, Maximum Sexual Stimulant**, Dietary Supplement, 550 mg proprietary blend herbal ingredients, sold in 10, 30 and 40 tablet bottles and in 2 and 6 tablet blister packs; 18 million tablets; Unapproved new drug; product contains benzamidenafil. All lot numbers; Hi Tech Pharmaceuticals.

### Recalls and Field Corrections: Drugs – CLASS II

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

*Name of Drug or Supplement; Problem; Recall Information*

**Motrin IB/Ibuprofen Tablets**, 200 mg/650 mg, 8 count Coated Caplets, NDC 50580-110-68; 88,104 tablets; Failed USP Dissolution Specifications; 3 month stability test interval. Lot #: SHC003, SHC004; Recalling Firm: McNeil Consumer Products, Co.

undeclared anhydrous lactose and tartaric acid. Lot #: 46182, 55485, 57950, 54082, 58319, 59996 and 48196; McKesson Packaging Services.

**Phentermine Hydrochloride**, USP, 37.5 mg, 100 count bottle, Rx only; 28,309 bottles; Super Potent Single Ingredient Drug: The manufacturer received a product complaint of large tablet thickness for 2 tablets. The manufacturer's investigation determined that tablets contained 136.1% more active ingredient than as specified on product label. Lot #: T058E09A, exp. date 05/2012; Vintage Pharmaceuticals LLC DBA Qualitest Pharmaceuticals.

**Apotex Inc.**, Ontario, Canada announced by letter on August 28, 2009 a firm initiated recall for the following 73 products due to current good manufacturing practices (CGMP) Deviations (the products were manufactured in a facility with significant cGMP deficiencies). The company reports that 4,578,203 bottles and boxes are affected. Contact your pharmacist to find out if yours is one of the affected lots.

**Senna-Time Micro-Coated Clear Tablets**, Sennosides 8.6mg, NDC 63739-431-10, packed in 100 and 750 tablet blister pack, unit dose containers; Product may contain undeclared anhydrous lactose and tartaric acid. Lot #: 57536, 56922, 54816, 51962, 46183, 48214 and 51943; McKesson Packaging Services.

**Allopurinol Tablets**; Amlodipine Besylate Tablets; Benazepril Hydrochloride Tablets; Benazepril Hydrochloride Tablets; Benazepril Hydrochloride Tablets; BuPROPion Hydrochloride Tablets (multiple strengths); Carvedilol Tablets (multiple strengths); Cefprozil Tablets (multiple strengths); Cetirizine Hydrochloride Tablets; Cimetidine Tablets (multiple strengths); Ciprofloxacin Tablets; Citalopram HBr Tablets; Clonazepam Tablets (multiple strengths); CycloSPORINE Capsules (multiple strengths); Diclofenac Potassium Tablets; DILT-CD (diltiazem hydrochloride) Extended-Release Capsules (multiple strengths); DILTZAC (diltiazem hydrochloride) Extended-Release Capsules (multiple strengths);

**Senna-Time S Film Coated Orange Tablets**, Natural Vegetable Laxative Plus Softener, NDC 63739-432-10, packed in 100 and 750 tablet blister pack, unit dose containers; Product may contain



Divalproex Sodium Delayed-Release Tablets; Eplerenone Tablets (multiple strengths); Etodolac Tablets (multiple strengths); Fosinopril Na Tablets (multiple strengths); Gabapentin Capsules (multiple strengths); Gemfibrozil Tablets; Lithium Carbonate Capsules; Meloxicam Tablets; Metformin Hydrochloride Tablets (multiple strengths); Omeprazole Delayed-Release Capsules (multiple

strengths); Oxaprozin Tablets; Oxcarbazepine Tablets (multiple strengths); Paroxetine Tablets (multiple strengths); Quinapril Tablets (multiple strengths); Ranitidine Tablets (multiple strengths); Ranitidine Syrup (Ranitidine Oral Solution); Terbinafine Hydrochloride Tablets; Topiramate Tablets; Torsemide Tablets; Tramadol Hydrochloride Tablets; Zolpidem Tartrate Tablets (multiple strengths).

## CONSUMER PRODUCTS

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

### *Name of Product; Problem; Recall Information*

**Alpine Ski Bindings.** The toe component of the ski bindings could fail to fully secure the ski boot to the ski binding, causing the binding to release unexpectedly. This could cause the skier to lose control or fall and suffer injuries. Salomon USA, (877) 789-5111 or [www.salomon.com](http://www.salomon.com).

**Amby Baby Motion Beds.** The side-to-side shifting of the hammock can cause infant to roll and become entrapped or wedged against the hammock's fabric and/or mattress pad, resulting in a suffocation hazard. Amby Baby USA, (866) 544-9721 or [www.ambybaby.com](http://www.ambybaby.com).

**Blenders.** The blade assemblies of the blenders may come apart or break, posing a laceration risk. Haier America Trading, L.L.C., (866) 327-6147 or [www.haieramerica.com](http://www.haieramerica.com).

**Boy's Velour Warm-up Sets.** The sweatshirts have drawstrings through the hoods, posing a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated in to an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. KT Group Inc., (212) 947-2223 or [www.fashionoptions.com](http://www.fashionoptions.com).

**Children's Hooded Sweatshirts with Drawstrings.** The sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Sunsations Inc., (800) 786-9044 or [www.sunsationsusa.com](http://www.sunsationsusa.com).

**Children's Metal Pendants.** The recalled children's pendants contain high levels of lead. Lead is toxic if ingested by young chil-

dren and can cause adverse health effects. Team Work Trading, (213) 680-4489.

**Cooks Outdoor® BBQ Grills.** The drip pan on the grill does not allow for adequate drainage, posing fire and burn hazards to consumers. JCPenney Purchasing Corp., (888) 333-6063 or [www.jcp.com](http://www.jcp.com).

**Electrolux ICON and Kenmore Pro 30" Gas Ranges.** An incorrect part allows more fuel to pass to the range's oven than can be burned efficiently, causing incomplete combustion and the release of carbon monoxide. This poses a risk of carbon monoxide poisoning to consumers. Electrolux Home Products Inc., (888) 360-8557 or [www.gasrangeorifice.com](http://www.gasrangeorifice.com).

**Evenflo ExerSaucer® 1-2-3 Tea for Me™ Activity Learning Centers.** The candle flame attached to the top of the cake toy can detach, posing a choking hazard to young children. Evenflo Co. Inc., (800) 233-5921 or [safety.evenflo.com](http://safety.evenflo.com).

**Girl's Hooded Sweatshirts.** The sweatshirts have a drawstring through the hood, which can pose a strangulation hazard to young children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as sweatshirts. Allura Imports Inc., (800) 695-4510 or [www.burlingtoncoatfactory.com](http://www.burlingtoncoatfactory.com).

**"Hello Kitty" Zip Up Hoodie Sweatshirts.** The sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets or sweatshirts. NTD Apparel, (866) 317-3974.



## CONSUMER PRODUCTS

**LED Rocketship PalPODzzz™ Portable Nightlights.** The bottom plastic cover on the recharging base of the portable nightlight can break, exposing internal electrical components. This poses an electric shock hazard to consumers. OSRAM SYLVANIA Products Inc., (877)-423-3772 or [www.sylvania.com](http://www.sylvania.com).

**Little Miss Matched Girls Pajama Sets.** The sleepwear fails to meet the federal children's sleepwear flammability standard posing a risk of burn injury to children. Little Miss Matched Inc., (877) 649-4386 or [www.littlemissmatched.com](http://www.littlemissmatched.com).

**Log Splitters.** The control handle of the log splitter could fail to automatically return to the neutral position as it should and could fail to stop the splitting wedge from moving forward, posing a risk of amputation to consumers' hands and fingers. MTD Products Inc., (888) 848-6038 or [www.mtdproducts.com](http://www.mtdproducts.com).

**Model Year 2010 Can-Am® ATVs.** The dynamic power steering can fail, resulting in the sudden loss of steering control. This poses a risk of injury to riders. BRP U.S. Inc., (888) 638-5397 or [www.can-am.brp.com](http://www.can-am.brp.com).

**"Molly" and "Betsy" Cribs.** The cribs have cut-outs in the end panels that can allow young children to get their heads entrapped, which can pose a strangulation hazard to infants and toddlers. LaJobi Inc., (800) 266-2848 or [www.Lajobi.com](http://www.Lajobi.com).

**Monday the Bullfrog Plush Books.** The plastic eye on the frog can detach, which may pose a choking hazard to young children. Simon & Schuster Inc., (800) 732-9531 or <http://kids.simonandschuster.com>.

**Packaged Terminal Air Conditioner/Heat Pump (PTACs) Units.** The power cords on the PTACs can overheat, posing a burn or fire hazard. Goodman Company, LP, (800) 366-0339.

**Snap Beads.** The tip of the snap bead peg may break off under repetitive pressure, posing a choking hazard to small children. Edushape Ltd., (800) 404-4744 or [www.Edushape.com](http://www.Edushape.com).

**Stainless Steel Cookware.** The handles on the cookware can break, posing a burn hazard to consumers. Cost Plus Inc., (877) 967-5362 or [www.worldmarket.com](http://www.worldmarket.com).

**Super Rigs Play Sets.** The toy truck's surface coating contains high levels of lead, violating the federal lead paint standard. Variety Wholesalers Inc., (800) 678-7776 or <http://www.vwstores.com>.

### OUTRAGE from page 12

There is evidence that oseltamivir has a modest effect in reducing some minor flu symptoms and contagiousness in otherwise healthy adults by about one day, but this is probably not the main reason most

doctors are prescribing the drug for their patients. This less important benefit may well be offset by the risks of the drug.

We therefore strongly agree with the statement that in healthy adults, oseltamivir should not be used in

routine control of seasonal influenza.

In addition, we support the call for more independent review of all of the raw data from company-funded clinical trials, something that has been missing in the case of oseltamivir and many other drugs. ♦

Editor.....Sidney M. Wolfe, MD  
Managing Editor.....Kate Resnevic  
Contributors.....Sidney M. Wolfe, MD

Proofreader..... Kate Resnevic

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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Robert Weissman

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# Tamiflu? More Like Scamiflu!

Millions of healthy people and their doctors have flocked to use the anti-flu drug Tamiflu (oseltamivir) in the hope that it will prevent death or other serious complications of the flu. In October, record numbers of prescriptions, 2.5 million for Tamiflu, manufactured by Roche, were filled in the U.S. This is more than 70 times higher than the 35,000 prescriptions filled in October, 2008. For the last 12 months, there were 6.8 million prescriptions filled, compared with 4.3 million the previous 12 months.

The problem with this hopeful picture — and an explanation for the astounding sales — is that Roche appears to have put a positive spin on the data supporting Tamiflu's ability to reduce the likelihood of serious complications of the flu.

But a joint investigation by the

*British Medical Journal* (BMJ) and British TV Channel 4 published in the BMJ on Dec. 8 concluded that in otherwise healthy adults they "have no confidence in claims that oseltamivir reduces the risk of complications and hospital admission in people with influenza" and believe it should not be used in routine control of seasonal influenza. There was also concern about under-reporting of side effects of the drug.

In contrast, according to the BMJ, Roche has stated in media briefings that oseltamivir reduced hospital admissions by 61 percent; secondary complications (including bronchitis, pneumonia, and sinusitis) by 67 percent in otherwise healthy individuals and lower respiratory tract infections requiring antibiotics by 55 percent.

BMJ editor Dr. Fiona Godlee, said "claims that oseltamivir reduces complications have been a key justification for promoting the drug's widespread use. Governments around the world have spent billions of pounds on a drug that the scientific community has found itself unable to judge."

*continued on page 11*



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