

# Health Letter

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## Hearing Aids: Why Medicare Should Provide Coverage

Unable to enjoy music, hear a buzzer, listen to a physician's instructions, or hold a casual conversation on the telephone, the hearing impaired are often socially isolated and removed from sources of enjoyment and information. Everyday activities that are taken for granted by others are a source of stress and frustration to those who cannot hear. Not surprisingly, hearing loss has been linked to depression, decreased self-sufficiency, anxiety, paranoia and social isolation among the aged.

At the same time, studies have shown that hearing aids can significantly improve quality of life for those with hearing loss as well as for their caregivers and family members. A randomized trial to assess the impact of hearing aids compared those who received the device with a control group who was placed on a waiting list. The study found that, at baseline, 84 percent of the subjects reported adverse effects due to impairment and 24 percent were depressed. Upon follow-up, those who had received hearing aids scored significantly higher than the controls in terms of social and emotional indicators, and communication and cognitive function. The experimental group also reported less depression. Another randomized controlled trial comparing two groups of dependent elders and their caregivers similarly found that all but

one of 63 subjects fitted with a hearing aid reported benefit upon follow-up, as did their caregivers. A national survey of 2,304 hearing impaired persons and 2,090 family members or friends also assessed the impact of hearing aids on the quality of life of users and their kin. More than half (56 percent) of all users reported improvements in relationships at home; family members of the hearing impaired were even more likely to report improvement along practically every dimension studied. After reviewing this topic in more detail, we will outline a plan for Medicare coverage of auditory screening and the purchase of hearing aids.

### Prevalence

Estimates of the size of the US population that could benefit from a hearing

aid or other assistive device vary by the method of assessment (interview vs. audiometric test), the definition used (i.e., the threshold for determining impairment), and the purpose of the estimate.

An Office of Technology Assessment report published 20 years ago relied on 1977 National Health Interview Survey data which found that "about 8 percent of the civilian, non-institutionalized population experienced some degree of chronic hearing impairment." The same survey found a definite age gradient, with prevalence increasing from less than 1 per cent among those under age 17 to more than 38 percent of those over 75. Since then, however, the problem has increased as a result of greater exposure to environmental noise and the aging of the population.

The most recent data indicate that  
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## HEARING AIDS, *from page 1*

31.5 million suffer from hearing loss, and the number is projected to increase to 38.4 by 2020. Among those 65 and older, hearing loss is the third most prevalent treatable disabling condition, following arthritis and hypertension. The fact that the condition is high in prevalence and amenable to treatment suggests that it should be a priority for care and funding. In fact, however, hearing loss has been underdiagnosed, undertreated, and underfunded. It is, in short, an 'orphan' issue with low political salience.

### Estimates of unmet need

Unmet need varies according to the definition of 'need,' the expectation that a hearing aid can effectively address the problem, and an accurate accounting of hearing aids that are actually in use. Not surprisingly, different sources report different numbers.

Nevertheless, there is much evidence that many who would benefit from help are not receiving it. The National Center on Hearing Assessment and Management at Utah State University reports that, while the vast majority of Americans with hearing loss could be successfully treated with hearing aids, only 25 percent currently use them. Among the total hearing loss population the breakdown between users and non-users is as follows:

- Twenty-five percent use hearing aids
- Five percent are potential candidates for, or get, surgical treatment
- Thirty percent can't afford hearing aids
- Thirty-three percent deny or hide hearing loss
- Seven percent are unaware of hearing loss.

Thus, fully 70 percent are either aware of their need but cannot afford hearing aids, or require better diagnosis and follow-up treatment for their condition. The American Academy of Audiology reports that

1.7 million hearing aids are sold every year.

One frequently mentioned hurdle to determining need and efficacy of treatment is the proportion of persons who have hearing aids and do not use them. A market survey that has been carried out seven times over the past two decades found that in 2004 one out of six respondents (16.7 percent) said that they had an "in the drawer" (not used) hearing aid. Although this proportion has fluctuated over time, it nonetheless reflects the lack of follow-up and fine-tuning required in the proper fitting of a hearing aid. Ultimately, success depends not only on the expertise of the hearing-aid specialist in testing the patient and selecting the appropriate instrument, but also on the dispenser's ability to adjust the instrument, prescribe effective rehabilitation if needed, and monitor performance during the period of acclimatization that follows initial use. Increased counseling time and outcome measurement are believed to enhance customer satisfaction. While some audiologists estimate a better than 95 percent probability that hearing aids will work properly when prescribed correctly and worn properly, many users do not routinely take advantage of the follow-up required for satisfactory appropriate use.

### Third-party coverage

Third-party coverage of hearing aids is very uneven, and therefore clearly inadequate. Most private insurers do not cover hearing aids. As a result, 62.7 percent of hearing aid purchases in the US do not involve third-party payers, thereby placing the burden directly on the consumer. (Pets, however, appear to be more welcome clients: the nation's largest carrier of pet health insurance, Veterinary Pet Insurance, covers hearing aids for dogs and cats).

**Medicaid** mandates diagnostic and treatment services, including hearing aids, for children up to age 20 under its Early and Periodic Screening, Diagnosis, and Treatment Program. In addition, 30 states offer some type of

benefit for adults who need hearing aids. Coverage varies widely, with most states imposing restrictions based on one or more of the following criteria:

- **Need**, i.e., hearing loss must exceed a specific decibel threshold
- **Type**, i.e., covering only monaural or excluding ear canal aids and FM units
- **Cost**, i.e., repairs are covered only above a given dollar figure
- **Frequency**, i.e. only every x number of years or per lifetime
- **Type of client** (e.g., only those in state-licensed nursing facilities, or those whose hearing defect is congenital)
- **Purpose** (hearing aids essential for employment).

In addition, some states require co-payments for the devices or their accessories, or for their fitting and repair. Of the 30 states with some hearing coverage under Medicaid, fully 28 reimburse providers on a fee-for-service basis. The exceptions are Minnesota and Wisconsin: both these states buy in bulk from selected contractors.

**Medicare** covers hearing tests only if a physician orders the tests, and the purpose of the test is largely diagnostic, i.e., to select the type of medical or surgical treatment needed for a hearing deficit or other medical problem. But Medicare explicitly excludes "hearing aids or examinations for the purposes of prescribing, fitting, or changing hearing aids."

In contrast, the **Veterans Health Administration** (VHA) has been at the forefront in the coverage of services to its constituents. Between 2000 and 2005, the number of hearing impaired who said they had acquired their hearing aids from the VHA rose from 411,000 to 784,000, an increase of 90.8 percent. The VHA provides hearing aids to those enrolled for VA medical benefits who meet eligibility criteria based on service-related disabilities, income level or other factors. Those who do not meet the criteria are entitled to a hearing aid only if (1) their hearing loss results from another condition for which the veteran is being treated at a VA facility

or results from treatment for such a condition (e.g., ear surgery) or (2) their hearing loss is sufficiently severe that a hearing aid is necessary to permit active participation in their own medical care.

The VHA dispenses over 160,000 hearing aids each year at a cost of over \$50 million. Because it accounts for almost 15 percent of the US hearing aid market, it can therefore exert considerable leverage over costs. The fact that the average hearing aid provided by the VHA costs the government \$313, in contrast with the average \$1500 price tag for hearing aids on the market and the \$1900 spent by the average consumer in 2004, reflects the VA's relative bargaining power. The VHA purchases all devices on the commercial market, negotiating contracts with manufacturers. All types of hearing aids are available through these sources. In addition, veterans are entitled to batteries, spare hearing aids, and a range of assistive devices, with no deductibles or co-payments.

If the VHA's economic clout makes the system affordable, its integrated structure makes it not only feasible but wise: the system has a vested interest in the health of its enrollees, as it reaps any savings that accrue through prevention. Because of its lifetime relationship with its patients, when it comes to health care in general, the VHA "has an investment in prevention and effective disease management. When it does so, it isn't just saving money for someone else. It's maximizing its own resources."

The size and diversity of the population served has allowed the Department of Veteran Affairs to evaluate the efficacy of different types of aids. Assessing the performance of the three types of hearing aid circuits that account for 70 percent of the US market, it found that each provided substantial benefit over unaided listening, but small though statistically significant differences among themselves in terms of different outcomes (e.g., speech recognition, loudness, distortion of sound).

## Political issues

### Cost

The reason most often given for not covering hearing aids is one of cost. Ironically, the high unmet need and fear of "sheer numbers" has been used to justify the current exclusions: the argument is that there are simply too many persons who are hard of hearing and that helping them would be too expensive. At the same time, providers and manufacturers attribute the high per unit cost of hearing aids to the relatively small private market, which precludes the economies of scale that could lower costs. In addition, the market is highly differentiated because of the variety of products that are currently available. It is estimated that there are over 1000 types and models of hearing aids.

Cost estimates include only estimated outlays for services, and do not take into account any benefits that may result from having a healthier, more functional population. A study comparing two groups of hearing loss groups, users vs. non-users of hearing aids, found that "while both treated and untreated hearing loss groups show deterioration in their income as their hearing loss worsens, the income decline is cut in half for hearing aid owners."

Changing technology tends to increase costs, and may be another reason for lack of third-party coverage for hearing aids. Over time, hearing aids have shifted from analog to digital, and from monaural (one-ear) to binaural. Each technology advance has been accompanied by an increase in cost. Complex digital technology is not only more intrinsically costly; it also requires more sophisticated fitting procedures. Payers may therefore be reluctant to commit themselves to underwriting a service in which 'technology creep' makes future costs difficult to predict.

Some, however, believe that the cost of hearing aids is likely to decline over time, and that existing technology has made it possible to develop a high-quality hearing aid at a low cost. Indeed, one expert feels

that "there are a lot of uncomplicated hearing losses in the mild to moderate range that don't require a very sophisticated instrument," and that this could be manufactured and sold over the counter for approximately \$100.

### Low political visibility

Hearing loss does not have the dramatic appeal of other conditions, and does not rally much support among the public at large. In general, conditions that differentially affect children, are potentially lethal, and are preventable or susceptible to dramatic medical intervention, are better able to compete for resources. Moreover, in medical care, cuts and cures invariably command more attention than comfort and care. Because hearing aids clearly fall under the latter rubric, they do not have the political allure of more technology-intensive devices.

### Divided constituents

Coverage of services for the hearing impaired has also been thwarted by cleavages among potential advocates. This has in turn weakened the potential impact of both consumers and providers.

The hearing impaired have multiple points of entry into the health system: who they choose as their provider has implications for what services they receive and how much they pay for them. The three providers of hearing aids are physicians, audiologists, and hearing aid dealers. Each of these has different claims to legitimacy not necessarily recognized by the others. As a result, far from speaking with a single voice, these providers have had competitive and adversarial relationships among themselves. These conflicts have impeded the consensus and closed ranks required for the strong advocacy they could have exerted on behalf of their clients.

Consumers are also divided into the hard-of-hearing and the deaf. While the public may perceive the distinction as one of degree, the two groups are significantly different and perceive

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themselves as such. Any legislation designed to meet the needs of both tends to favor the latter, who, though smaller in numbers, are a more vocal and cohesive group. Unlike the hearing impaired, most of whom consider deafness as a disability to be addressed, the deaf tend to reject a pathological, deficit-oriented interpretation of deafness. Instead, they see themselves as part of a distinct community that is defined by its silence and a largely visual orientation to perception and communication. Thus the deaf share many of the hallmarks of a culture: recognized heroes (e.g., Marlee Matlin, Helen Keller), educational institutions (e.g., Gallaudet University), and a common language (ASL). Those who see themselves as members of the deaf culture reject “audism” and nurture values that prize silence. The culture also favors and promotes marriage within the deaf community, and hopes for deaf children who can more easily take part in their parents’ world and maintain their cultural values.

## European models

Many European countries have devised an array of entitlement schemes to cover hearing aids. Those which have a large public system have nevertheless suffered from long waiting lists, which have prompted other options. The UK’s National Health Service provides free hearing aids to all, but the average waiting period of 47 weeks. It is therefore exploring alternatives to its current system. Finland covers everyone under its public health service, but has waits of between 2 and 24 months. To make the wait somewhat less onerous, there is a priority system in place which favors the young and the employed.

In Denmark, where 90 percent of all hearing aids are fitted in hospitals, the waiting time for a first appointment can reach 84 weeks. In order to address this situation, the Danes have instituted a parallel system of subsidies, through which those who are willing to share the costs are able to ‘jump the queue’ by getting services

privately. Similarly, Ireland provides vouchers and tax credits to those who seek services outside the public health system.

All of these measures provide some relief to consumers and take the pressure off the government, but create a two-tier system: if everyone is assured bread and butter but only some are given jam, the principles of equity and justice which undergird any national scheme are seriously undermined. Moreover, those who are most likely to benefit from the vouchers or tax credits are the better off, who can afford to pay part of the cost of service out-of-pocket. Finally, resources applied to the private sector are siphoned off in fee-for-service payments, and do nothing to solve the under financing of the public sector which creates the long waiting lists in the first place.

## Recent legislative initiatives

The only legislation that Congress has considered in recent years to address coverage of hearing aids is HR 2934, the Hearing Aid Assistance Tax Credit Act of 2001, and even this languished, only to be allowed to die. Like other initiatives based on the “ownership society,” the proposed bill relied on a tax credit and assumed that health care buyers would be able to comparison shop for drugs and devices, exert discretion over their purchase, and have enough available income to pay now and receive a credit or refund later. There is no evidence to indicate that that is the case with the purchase of hearing aids.

The legislation also had significant limitations in terms of beneficiaries and services covered. The bill sought to provide a tax credit of up to \$500 per hearing aid, available once every five years, and covered only those 55 and over and those purchasing a hearing aid for a dependent. While this could have provided some relief to those who met the narrow guidelines and could pay for most of the cost out-of-pocket, it excluded the poor: it did not address the needs of those who do not have substantial tax liabilities, nor did it

do much for the 30 percent who are not able to obtain hearing aids because they are too expensive. The latter would be left facing out-of-pocket costs that would be beyond their means. For them, having 1/5 of the cost of the service covered is tantamount to the often-invoked image of throwing a 10-foot rope to someone in a 50-foot hole.

In addition, tax credits may deflect interests from more comprehensive coverage, and could even drive up prices by raising demand without doing anything to affect supply. Despite these flaws, this legislation had the support of hearing aids dispensers of all types, who expect any kind of subsidy to translate into greater sales. Because the price elasticity of hearing instruments has been found to be 0.6 — that is, a 10 percent reduction in price will result in a 6 percent increase in demand — the proposed credit could result in 12 percent more hearing aids being sold.

## Requirements for proposed coverage

Because hearing aids are statutorily excluded under Medicare, any coverage for Medicare beneficiaries will require amending Title 18 of the Social Security Act. While the details of any legislation are beyond the scope of this paper, we propose the following as guidelines that should inform the drafting of any bill:

- **Elimination of the cost barrier.** Better hearing is not only intrinsically valuable but also instrumental in achieving other societal and individual objectives. Depriving a potential beneficiary of needed care because of cost violates fairness and equity. Surveys of persons with hearing loss who do not use a hearing aid have found that 30 percent do not avail themselves of the device because of cost; point-of-service payments have therefore been shown to act as a deterrent and barrier to care.
- **Inclusion of all Medicare beneficiaries.** This population is not only the one with the highest prevalence of hearing loss, but is also one of the

# Despite New Study, Crestor Should Not Be Prescribed

*Public Citizen's Health Research Group has long warned of the dangers of the cholesterol-lowering drug Crestor. All statins can cause an adverse effect known as rhabdomyolysis, which is a breakdown of muscle tissue that can lead to kidney damage and even death. Yet Crestor causes this effect at a much higher rate than other statins. It also causes unique toxicity to the kidneys that has not been seen with other statin drugs. Read about our concerns with Crestor at <http://www.worstpills.org>. A new study does not change our assessment of this unnecessary drug.*

The study presented recently at a meeting of the American College of Cardiology does not alter our assessment that Crestor has unique risks without evidence of unique benefits, that it should not be prescribed and that it should not have been approved by the Food and Drug Administration (FDA).

The relatively small size and short

duration of the study, coupled with the lack of randomization, preclude any refutation of evidence from larger pre-approval randomized trials (and from post-approval reports) that the rates of muscle and kidney damage in patients who use Crestor

*There still is no evidence that Crestor offers a unique benefit.*

are higher than in patients who use other currently marketed statins.

There still is no evidence that Crestor offers a unique benefit; even the study authors admit that we would probably see the same

improvement in the narrowing of coronary arteries with other statins. Even more important, other statins, unlike Crestor, have been shown to reduce the occurrence of subsequent heart attacks.

The dose used in the study, 40 milligrams, is a dose that the FDA-approved labeling for the drug states should not be used unless patients fail to reduce their LDL cholesterol adequately with lower doses (5, 10 and 20 milligrams). It is unlikely that very many of the generally lower-risk patients in this study would therefore qualify for this high dose.

Finally, even the authors have failed to state that this study should prompt doctors to switch patients to Crestor.

Crestor is associated with an increased rate of rhabdomyolysis (muscle damage) and kidney damage. We repeat our call for the FDA to stop pandering to the pharmaceutical industry and start protecting patients by taking this drug off the market. ■

## HEARING AIDS, from page 4

most vocal. The sifting and sorting of populations that has occurred among those entitled to Medicaid would thus be avoided, thereby reducing administrative costs.

• **Comprehensive coverage of services, from audiological testing to post-fitting adjustment and service.** The effectiveness of hearing aids has been found to be associated with the successful coordination of an array of services, including: audiological assessment to determine hearing loss and how best to address it; procurement of an appropriate hearing aid; initial instruction on how to use and maintain the hearing aid; fitting, and adjustment of the hearing aid; periodic adjustments; and rehabilitation, including counseling, speech reading, and auditory training.

• **Integrated service.** Providers of hearing aids need to assume a longi-

tudinal responsibility for audiological care. The multiplicity of persons involved in the services listed above often results in confusion, fragmentation, and lack of continuity in patient-provider relations. With different providers assuming responsibility for part of the process part of the time, there is no one to orchestrate overall care. Every beneficiary should therefore have an audiological "home," an established point of entry and source of continuing service.

• **Monitoring of safety and efficacy.** Given both the sizeable population eligible for coverage and the constantly changing technology to address hearing loss, it is imperative that data on service cost, utilization, and efficacy be collected. This would allow for evaluation of care, and highlight deficiencies and gaps in care. At present, there are no "best practices" guiding the successful fitting of hearing aids. In the absence

of benchmarks, standards of care vary a great deal, as do the resulting outcomes. Only those hearing aids that meet evidence-based, nationally-set standards for effectiveness should be covered. Similarly, new technologies must be shown to be safe and efficacious before they are included as covered options.

• **Cost controls.** As a major payer and significant player in the health arena, the Medicare program is well positioned to benefit from the economies of scale that accompany the mass purchasing of hearing aids. Its bargaining power has the potential to affect a significant segment of the market, and may have salutary spillover effects for consumers of hearing aids in general. Moreover, value-for-money should be a key criterion in any decision involving public dollars. ■

# Product Recalls

February 15, 2006 — March 15, 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](http://www.fda.gov). Visit [www.recalls.gov](http://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*

**AMO Endosol**, Balanced Salt Solution, Each mL contains: Sodium chloride 0.64%; potassium chloride 0.075%; calcium chloride, dihydrate 0.048%, magnesium chloride, hexahydrate 0.03%; sodium acetate, trihydrate 0.39%; sodium citrate, dihydrate 0.17%, 500mL Glass Bottles and 18mL and 500mL plastic bottles; Failed Pyrogen Test Specifications. Multiple lots; Cytosol Laboratories, Inc.

**Methotrexate for Injection**, USP, 1 Gram, Single Use Vial; Chemical Contamination; product contains low levels of ethylene glycol. Lot #859142, exp. 09/07, Bedford Laboratories.

### 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*

**Campral Delayed-Release Tablets**, (acamprosate calcium), 333 mg; Dissolution failure (12 month stability). Lot #P09190, exp. 08/07; Lot #110437, exp. 08/07, Merck Sante SAS.

U37725A30, U38484B30, U39499A30, K38972A30, K39542A30, U37262A30, U37947A30, U38484E30, K36341R60, Mylan Pharmaceuticals Inc.

**Carbidopa and Levodopa Extended-Release Tablets**, 50 mg/200 mg; The incorrect stability test method was used to assure that the product meets its specifications throughout its shelf life. Lot #4568-5003—5012, Mylan Pharmaceuticals Inc.

**Citalopram Hydrobromide** 20 mg; Mislabeling: incorrect expiration date on the label. Lot 136715D, exp. 12/07, Ivax Pharmaceuticals, Inc.

**Carbidopa and Levodopa Extended-Release Tablets**, 50 mg/200 mg; The incorrect stability test method was used to assure that the product meets its specifications throughout its shelf life. Lot K36341R25, U37262B25, U38484C25, U36886A25, U38484A25, U38484D25, U39499B25; K36341R30, K38972B30, U36886A30,

**Diovan** 80 mg, valsartan; Labeling: labels on a small quantity of bottles may lack the product strength and tablet count information. Lots F0182, exp. OCT 2007; F0183, exp. NOV 2007; F0184, exp. NOV 2007; F0185, exp. NOV 2007; F0185 W1, exp. NOV 2007, Novartis Pharmaceuticals Corp.

**CLASS II Recalls *cont'd.***

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

a) **Dollar General Night Time Original Flavor Multi-Symptom Cold/Flu Relief**, b) **Dollar General Night Time Cherry Flavor Multi-Symptom Cold/Flu Relief**; Misbranding: The identified lots are misbranded in that the Principal Display Panel (PDP) of each of the products' label identifies the Antihistamine contained within the product as Chlorpheniramine Maleate whereas the Antihistamine actually contained within the product as well as identified within the Drug Facts portion of the labeling is Doxylamine Succinate. a) Lot numbers (expiration dates): 2932(08/2007), 22933(08/2007), 3180(08/2007), 24179(10/2007), 24222(10/2007), 24306(11/2007), 24361(11/2007), 24479(11/2007), 24753(12/2007), & 24848(01/2008); b) Lot numbers (expiration dates): 22935 (08/2007), 23183(08/2007), 23496(08/2007), 24129(10/2007), 24224(10/2007), 24308(11/2007), 24484(11/2007), 24608(12/2007), 24689(12/2007), & 24776(12/2007), Aaron Industries, Inc.

**Metformin Hydrochloride Extended-Release Tablets** 500 mg; Subpotent. Lot 142691A, Ivax Pharmaceuticals, Inc.

**Enfamil Gentlease LIPIIL**, a blend of DHA & ARA; Product contains metal particles. Lot GNTLELIP BMJ19, exp 07/07; Mead Johnson Nutritionals.

**Nifediac CC (Nifedipine) Extended-Release Tablets**, USP 30 mg; Superpotent. Lot numbers: 000407T12 exp 05/2006, 000410T15 exp 08/2006, 000412T53 exp 01/2006, 000503T03 01/2007 and 000505T25 exp 02/2007, Biovail Corporation.

a) **Furosemide Tablets**, USP, 40mg; b) **Furosemide Tablets**, USP, 80mg; Mold Growth. a) Lot Nos.: T012J04A, exp 09/06; T013J04A, exp 09/06; T013J04B, exp 09/06; b) Lot Nos.: T009J04A, exp 09/06; T009J04B, exp 09/06, Vintage Pharmaceuticals LLC.

**TriNessa (Norgestimate and Ethinyl Estradiol) Tablets**, Oral Contraceptive; Subpotent: The active Norgestimate component of TriNessa tablets fails stability assay. Multiple lots and expiration dates, OMJ Pharmaceuticals, Inc.

a) **Levothyroxine Sodium Tablets** USP, 50 mcg (0.05mg); b) **Levothyroxine Sodium Tablets** USP, 88 mcg (0.088mg), 100 count bottles; c) **Levothyroxine Sodium Tablets** USP, 100 mcg (0.1mg), 100 count bottles; Subpotent; (21 month stability). Multiple lots, Mova Pharmaceutical Corp.

**Ultane® (sevoflurane) Inhalation Anesthetic**, 250mL bottles; Defective container; bottles may have pinholes which could cause product to leak or evaporate. Lot numbers: 34482DK, 34483DK and 34484DK, Hospira, Inc.

**C O N S U M E R   P R O D U C T S**

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](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; Manufacturer and Contact Information*

**Aquariums.** AquaPod 12-Gallon Aquariums have three power cords, two for the aquarium lamps and one for the air pump. When only one of the two lamp cords is plugged in, the unplugged lamp cord can become energized, posing an electrical shock hazard to consumers. Current USA Inc., (866) 276-8872 or [www.current-usa.com](http://www.current-usa.com).

**Bicycle resistance trainers.** The base of the 2006 Nashbar Bicycle Trainers and 2006 Performance Travel Trac Trainers has a blocking mechanism that can break causing the bicycle to disengage from the stand, posing a fall hazard. Nashbar Direct, (800) 888-2710 or [www.nashbar.com](http://www.nashbar.com); Performance Inc., (800) 553- 8324 or [www.performanceinc.com](http://www.performanceinc.com).

**ATVs.** Certain Suzuki 2005 Eiger model year ATVs were assembled with an improperly manufactured plastic fuel tank. The thin portion of these tanks could develop a fuel leak, posing a fire hazard. American Suzuki Motor Corp., (800) 444-5077 or [www.suzukicycles.com](http://www.suzukicycles.com).

**Cameras.** A defect with the flash circuit in various Olympus-Brand 35mm Film Cameras can cause it to smoke and overheat when the camera is turned on. This poses a possible burn hazard to consumers. Olympus America Inc., (800) 480-1247 or [www.olympusamerica.com](http://www.olympusamerica.com).

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*Name of Product; Problem; Manufacturer and Contact Information*

**Children's game.** The two side poles of Chicken Limbo Electronic Party Game do not fit into their bases properly making the game unstable. This can cause the game to completely fall apart if touched, hitting children playing the game as well as bystanders. Milton Bradley, (800) 245-0910 or [www.miltonbradley.com](http://www.miltonbradley.com).

**Children's jewelry.** The recalled "Girl Favors" Children's Toy Jewelry could break, releasing small beads that pose an aspiration hazard to young children. MTC – Man's Trading Company, (800) 388-7228, [mtcmans@aol.com](mailto:mtcmans@aol.com), or [www.mtcmans.com](http://www.mtcmans.com).

**Conference phone batteries.** Lithium Ion batteries in SoundStation2W wireless conference phone can overheat, which could pose a fire or burn hazard. Polycom Inc., [www.polycom.com/2WBattery](http://www.polycom.com/2WBattery) or (800) 917-5738.

**ElectroPlasma lamps.** There is a burn hazard caused by an electric arc between the metal bottle caps of Coca-Cola ElectroPlasma Lamps and a human contact point. An electric burn is possible if the distance between the metal cap and the contact point is sustained at about 1/8-inch away from the metal cap. Emess Design Group LLC, (800) 678-2579 or [www.emessdesign.com](http://www.emessdesign.com).

**Espresso machines.** The electrical connectors in the C1000 Capresso Automatic Coffee Center espresso machine can erode, posing a fire hazard. Capresso Inc., (888) 406-4440 or [www.capresso.com](http://www.capresso.com).

**Facial cleansing massager.** The cleansing pillows on the Dove™ SkinVitalizer – Facial Cleansing Massager can loosen or dislodge during use and then the SkinVitalizer can cause minor scratches to the skin. Unilever, (800) 896-9479 or [www.dove.com](http://www.dove.com).

**Flashlights.** The light green paint on the Glowin' Dino Animal Flashlights and the brown paint on the Glowin' Doggy Animal Flashlights could contain excess levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. The Little Tikes Co., (866) 765-6729 or <http://littletikes.com>.

**Gas grills.** Turbo Sport Portable Infrared LP Gas Grills have faulty regulators that can release too much gas to the burner causing an excessive burner flame. This also poses a risk of gas leaks, fires and explosions if an ignition source is present. Barbeques Galore Inc., (800) 752-3085.

**Go-karts.** The throttle that controls the Manco Blazer Fun-Kart and Sunright International Go-Karts' engines can fail and not return the vehicle to idle speed, posing a loss of control hazard to the driver. Manco Power Sports Inc., (800) 643-7332 or [www.mancopowersports.com](http://www.mancopowersports.com); Sunright International, (888) 737-7488 or [www.sunright.net](http://www.sunright.net).

**Hooded fleece.** The garments have a drawstring through the hood, posing a strangulation hazard to children. Next Marketing Inc., (866) 871-9978 or <http://www.nextinc.net/productrecalls.html>.

**Hooded sweatshirt.** "U.S. Polo Association" Youth Hooded Sweatshirts with Drawstring have a drawstring through the hood, posing a strangulation hazard to children. Jordache Ltd., (888) 295-3267, <http://www.jcpenney.com>, or [bpalmer@jeans-wear.com](mailto:bpalmer@jeans-wear.com).

**Infant shopping cart seats.** Safe-Seat Plus Model Infant Seats for Shopping Carts can have a white chalky powder or residue on their surface. It is the UV Absorber that has separated from the seat due to a molding defect that affected some seats produced in one or more molding runs. This could cause skin irritation to children who come into contact with the residue. SSC Inc., (800) 448-8945 or [www.seatreplacement.com](http://www.seatreplacement.com).

**Metal charms.** Art Accentz™ Changlz™ Metal Charms contain high levels of lead, posing a serious risk of lead poisoning and adverse health effects to young children. Provo Craft & Novelty Inc., (800) 955-9490 or [www.recall.provocraft.com](http://www.recall.provocraft.com).

**Night lights.** An electrical short circuit in the Forever-Glo Nite Lite™ can cause it to overheat and smolder or melt which can burn consumers or result in a fire. American Tack & Hardware Co. Inc. (AmerTac), (800) 420-751, [www.amertac.com](http://www.amertac.com) or [www.recall-center.com](http://www.recall-center.com).

**Plasma televisions.** Arcing by capacitors inside the left and right side of the back cabinets of Plasma Flat Panel Televisions with Ambilight Feature can pose a safety risk. Philips Consumer Electronics North America, (888) PHILIPS [888-744-5477], PIN 4445 or [www.philips.com](http://www.philips.com).

**Pull-along toy.** BRIO's Pull-along Snail toy is sold with a rattle containing a bell. The rattle can come apart, and the bell poses a small parts choking hazard to young children. BRIO(r) Corp., (888) 274-6869 or [www.brio.net](http://www.brio.net).

**Remote control flying saucers.** The battery charger cord sold with Pro Flying Saucer (Radio Control) can overcharge and cause the toy to overheat, posing a risk of fire. QVC Inc., (800) 367-9444 or [www.qvc.com](http://www.qvc.com).

# Chromium Industry Withheld Data from OSHA

*Public Citizen first petitioned the government to establish a new Permissible Exposure Limit (PEL) over ten years ago. After several missed deadlines and a prolonged court battle, OSHA issued a PEL that will not adequately protect workers from this carcinogenic substance. Shortly before the standard was issued, it was revealed that the chromium industry had concealed data from OSHA that showed a strong correlation between low exposures to hexavalent chromium and lung cancer. Read about Public Citizen's work on hexavalent chromium at <http://www.citizen.org/hrg>.*

**T**he chromium industry – which has fought for years to block a lower federal workplace exposure level for hexavalent chromium – withheld from the government key study data supporting a strict standard for workplace exposure to the potentially deadly metal, Public Citizen said today in a paper published in *Environmental Health*.

The U.S. Occupational Safety and Health Administration (OSHA) is under court order to issue a new standard by the end of this month. The agency has repeatedly requested studies on the health effects of lower exposures to the

metal. Despite having completed just such a study in 2002, the chromium industry did not notify OSHA of the study's existence. In addition, industry-funded researchers manipulated the data to obscure the evidence that hexavalent chromium was carcinogenic at lower exposures.

Public Citizen and the Project on Scientific Knowledge and Public Policy (SKAPP) at the George Washington University School of Public Health and Health Services found evidence of the manipulation in documents that surfaced following the bankruptcy of the Industrial Health Foundation, a chromium industry-funded group.

"The circumstances regarding this study raise troubling questions about the ability of the government to effectively issue rules protecting public health when studies are conducted, controlled and selectively published or provided to the rulemaking agency by the regulated industry," said Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group and report co-author. "Corporate America loves to decry what it calls 'junk science,' but there's no question that the industry was the producer of the junk in this case."

"Polluters and manufacturers of

dangerous products should not be permitted to hide data that are important for protecting the public's health," said Dr. David Michaels, director SKAPP and lead author of the report.

OSHA has estimated that approximately 380,000 workers are exposed to hexavalent chromium, which is used in chrome plating, stainless steel welding and the production of chromate pigments and dyes. Studies dating back to the 1940s have documented that exposure can cause lung cancer.

Public Citizen and the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE), now part of the United Steelworkers, successfully sued OSHA for delaying the promulgation of a new standard. In April 2003, the U.S. Court of Appeals for the Third Circuit ordered the agency to do so by Jan. 18, 2006, but has extended that deadline to Feb. 28, 2006.

After the court ruling, OSHA began its rulemaking process, and, in its proposed rule and again in public hearings that took place in February 2005, actively sought data on exposure to lower levels of hexavalent chromium.

Anticipating that OSHA might attempt to reduce worker exposure

*continued on page 10*

## CONSUMER PRODUCTS *cont.*

### *Name of Product; Problem; Manufacturer and Contact Information*

**Silk tops.** The Victoria's Secret Silk Kimono Tops are made of fabric that fails to meet mandatory standards of fabric flammability in violation of the federal Flammable Fabrics Act. The sheer outer shell fabric of the kimono top can readily ignite and present a risk of burn injuries. Victoria's Secret Direct, (877) 260-8419.

**Snowboard bindings.** The Quechua "Rn'x7FX" snowboard bindings's plastic base can break during use, posing a risk that snowboarders can fall and suffer a serious injury. Decathlon USA, (800) 721-7780 or [www.decathlon-usa.com](http://www.decathlon-usa.com).

**Swing sets.** The connection between the horizontal top beam and the vertical end support post of "Max Play" Single Post and "Kid Builders Arch" Swing Sets can break, posing a risk of injury if the user falls to the ground or is hit by the beam. PlayPower LT Farmington Inc., (800) 265-9953 Ext. 206 or [mike.hayward@ltcps.com](mailto:mike.hayward@ltcps.com).

**Tea light candles.** Harvest Brand Tea Light Candles can burn with a high flame and melt the plastic holders. This poses a fire and a burn hazard to consumers. Big Lots Stores Inc., (866) 244-5687 or [www.biglots.com](http://www.biglots.com).

**Toy mobile phones.** The toy iPlay My First Mobile Phone's yellow antenna can detach, posing a choking hazard to young children. International Playthings Inc., (800) 445-8347 or [www.intplay.com/recall.htm](http://www.intplay.com/recall.htm).

**Vitamins.** Walgreens High Potency Iron Supplements are not in child-resistant packaging as required by the Poison Prevention Packaging Act. Ingesting multiple iron supplements at once can cause serious injury or death to young children. Inverness Medical Nutritionals Group, (888) 698-5032 or [www.walgreens.com](http://www.walgreens.com).

**OUTRAGE, from page 12**

overdose and death. "It has not been possible to identify any patient group in whom the risk-benefit [ratio] may be positive," the British government stated.

In addition, propoxyphene has been deemed inappropriate for prescription for the elderly because of central nervous system-related adverse events — such as sedation and confusion — that have been found to increase the likelihood of falls and fall-related fractures in the elderly. Studies have shown that propoxyphene use is widespread in the institutionalized population, in

emergency rooms and in community-dwelling older people, populations in whom propoxyphene is most dangerous.

Public Citizen is calling for the drug to be phased out, rather than banned immediately, because of its addictive quality.

"The Food the Drug Administration should immediately begin phasing out the use of propoxyphene," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "Millions of people, many of them elderly, are being put at risk when using this drug when there are safer, more effective alternatives available.

We agree with the British government's conclusion that the efficacy of this product 'is poorly established and the risk of toxicity in overdose, both accidental and deliberate, is unacceptable.' "

Public Citizen has a strong track record of identifying dangerous drugs well before federal regulators take action to ban or put warnings on these drugs. For example, Public Citizen warned consumers about the dangers of Vioxx, ephedra, Bextra, Rezulin, Baycol, Propulsid and many other drugs years before the drugs were pulled from the market. ■

**CHROMIUM, from page 9**

to hexavalent chromium, in 1997 the industry commissioned a study that would combine the mortality data at four sites – two in the United States and two in Germany. The study, completed in 2002, showed a significantly elevated risk of lung cancer death when workers were exposed to lower levels of hexavalent chromium. The study protocol explained that multiple study sites were necessary to gain sufficient statistical power. The industry never published this four-site study, not did it provide the findings to OSHA. Public Citizen did so in June 2005.

But the industry did split the results in two, reducing its statistical vigor. A paper about the two U.S. plants was published in the *Journal of Occupational and Environmental*

*Medicine* just weeks before OSHA's comment period was scheduled to end. The published paper, based on only three lung cancer deaths and limited follow-up, inappropriately concluded that reductions in exposure to hexavalent chromium may have reduced the incidence of lung cancer. The industry then highlighted the study in comments to OSHA.

In the second paper, describing the two German sites, the industry-funded researchers combined the results from the "intermediate" and "high" exposure groups, obscuring the fact that in the full four-site study, the risk of lung cancer death was elevated at even the intermediate level – a level close to that considered by OSHA for a new exposure limit. Together, these two papers were intended to prevent OSHA from promulgating a stricter

exposure limit.

Public Citizen recommends that parties in regulatory proceedings be required to submit all relevant data in their possession to the public record and that they disclose the true sponsorship of the study. In addition, parties in regulatory proceedings should be required to disclose whether the studies they submit were performed by researchers who had the right to present their findings without the sponsor's consent or influence. Industry-funded researchers should be required to make their data available for analysis by other researchers, the way publicly funded researchers do.

A copy of the paper is available at [http://www.ehjournal.net/imedia/1517239368845801\\_article.pdf?random=672770](http://www.ehjournal.net/imedia/1517239368845801_article.pdf?random=672770) ■

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# Darvon and Darvocet: What Are They Thinking?

*Public Citizen first petitioned the FDA to remove propoxyphene, the active ingredient in painkillers Darvon and Darvocet, in 1978. Since that time, thousands of accidental deaths have been reported that are attributable to this drug. We renew our call for it to be removed following the British Committee for the Safety of Medicine began a phased withdrawal of Darvocet as a result of the high number of accidental deaths associated with the drug in that country paired with its low efficacy in treating pain. To read the full petition, visit <http://www.worstpills.org>.*

Public Citizen has petitioned the U.S. Food and Drug Administration (FDA) to immediately begin to phase out the widely prescribed pain reliever propoxyphene (Darvon, Darvocet and generic

versions) from the market because the drug has been associated with more than 2,000 accidental deaths, is physically addictive and is no more effective than safer alternatives.

Data from the Federal Drug Abuse Warning Network, which provides autopsy information from medical examiners in the United States, has found that 5.6 percent of all drug-related deaths were related to propoxyphene during the past 19 years. In 2004, 23 million prescriptions for propoxyphene were filled, making it the 12th most commonly prescribed generic drug in the United States. Four companies account for more than 91 percent of U.S. prescriptions.

Propoxyphene has been associated with 2,110 reported accidental deaths in the United States since 1981. A large proportion of these deaths occur

because most of the drug is converted into a metabolite that is highly toxic to the heart and lasts longer in the body than the original compound, resulting in cardiac depression. Adverse cardiac events associated with propoxyphene include an interruption of heart transmission of electrical impulses, slowed heartbeats and a decreased ability of the heart to contract properly.

"The number of deaths involving propoxyphene in the U.S. alone is striking," says the petition, filed by Public Citizen and two Swedish experts on propoxyphene, Drs. Ulf and Birgitta Jonasson. The entire petition can be viewed at [www.worstpills.org](http://www.worstpills.org).

Last year, the British government announced a phased withdrawal of the drug because of its negligible effectiveness and the high risk of

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