

Health Letter

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What Are the Presidential Candidates (And Their Advisors) Talking About? Part II

Last year the Health Letter (August 2007) published a glossary of health care terms that have come up in the Presidential debates. As the debate continues and the candidates' vocabulary broadens, consumers need to keep up with the evolving terminology, which does not lend itself to quick sound bites. Here is Part II of *What Are the Presidential Candidates (And Their Advisors) Talking About?*

Adverse selection: is an insurance term referring to the tendency for an insurance plan to attract those at higher risk, who will have higher claims than the average. Those at lower risk may decide that the insurance is too expensive to be worth their while. When there is adverse selection, pegging premiums to the average will not suffice to cover the anticipated claims, because those who have bought the policy are at higher-than-average risk. And raising the premiums is not a solution, as insurance will then become even less attractive to those at lower risk, thereby exacerbating the problem of adverse selection. Making the purchase of insurance compulsory or, optimally, having government-funded insurance for all, reduces adverse selection because it pools all risks and does not allow those who are healthier and at lower risk to opt out.

Carve out: Used as both a noun and verb, this term describes the services that are excluded from any

service package, or the process of exclusion.

Cherry picking/ Cream-skimming: refers to the process by which insurers try to cover only those who are "good risks." This may occur when an insurer has more information about consumers' expected costs than the consumers themselves, and designs a marketing strategy to primarily enroll those who are healthier. The strategy may also include explicitly excluding those who are unhealthy or at greater risk of becoming unhealthy (see *adverse selection*, above). Cherry picking is a way for insurers to cut their losses and bolster their profits.

Crowd out: is a phenomenon in which a new public program or the expansion of an existing public program prompts some privately-insured persons to drop their private

coverage and benefit from the public subsidy. 'Crowd out' also occurs when public programs act as an incentive for employers to reduce their contributions to employees' health care coverage.

External effects: are benefits or costs that accrue to a person because of someone else's action. If your neighbor plants a beautiful garden that enhances the views from your house and increases the value of your property, you benefit from the external effects of his actions. The health care field is rife with examples of external effects. Immunizations provide external benefits, because they reduce the likelihood that others will get the disease, even if they are not immunized themselves. Some one who gains an external benefit, or benefits from a public good without

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paying for it, is sometimes pejoratively called a free rider (see below).

There are also many cases of external costs — e.g., air-pollution, second-hand smoking, contagious diseases — in which what others do (or refrain from doing) have a negative effect on our health and well-being. External costs often provide the justification for regulation or taxation. Foregoing health insurance has external effects, and imposes costs on others: when an uninsured person goes to an emergency room, or receives care that is uncompensated, other payers make up the difference in the long run. Hospitals

and other health providers may therefore raise their fees to make up for those who fall into their “bad debt and charity pool” because of lack of coverage.

Free riders: are persons who consume more than their fair share of a resource, or shoulder less than a fair share of the costs of its production. In health care, ‘free riders’ are those who do not contribute to the total costs of the services but nevertheless receive the same benefits of those who, in effect, “pay their dues.” Mandates which require everyone to be covered reduce, if not eliminate, the number of free riders. The imposition of mandates therefore appeals to those who feel that mandatory coverage is fairer than asking everyone else to pick up the health care costs of those who choose not to buy it.

Guaranteed issue: is an insurance term that means that an insurer cannot exclude anyone from coverage because of past history or health status. When some plans are allowed to deny coverage and others are required to accept everyone, the

latter are at a disadvantage because of adverse selection against them.

Hidden taxes: refer to external costs that are imposed on the population at large (see *external effects* above). In the health care arena, they refer to the costs that providers impose on covered patients in order to cover the expenses of providing care to the uninsured.

Market-based care: is based on a confluence of consumers and health care providers such that the purchasing power of the former will shape the scope, distribution, and price of the services provided by the former. Market-based care is touted by McCain, who argues that the system needs to be based on consumer choice, personal responsibility, and provider competition. There are good things to be said about each of these in some contexts such as

lower and lower-priced computers, etc, but each runs into difficulties when the “goods” that are being marketed are health services: the public health goal is to prevent disease and avert the need to consume many of these “goods” altogether. Consumers facing a medical problem usually have limited choices, and these are framed and determined by their physician. Once a consumer chooses a provider, it most often is the provider who decides what services the patient needs, and when and where to obtain these. Moreover, choice is often limited by ability to pay, and only those with complete coverage and unlimited resources are in a position to “choose.” “Personal responsibility” is usually a way to blame-the-victim and eschew any control over services provided. And so-called provider competition is limited because consumers are unable

to weigh their options and determine what is best for them.

Penalties/fines: are often imposed on those who opt not to buy health insurance in a health plan in which coverage is mandated. In some cases (e.g., Massachusetts), the initial penalty involves loss of a personal tax exemption; after that, those who do not have insurance face fines for every month that they are without health insurance. This penalty may increase over time, as a disincentive to those who do not buy coverage. During the 2008 presidential primary debate, candidates Clinton and Obama bickered about this. Because the Clinton plan includes an individual mandate and the Obama plan mandates coverage only for children, the former includes penalties and the latter doesn't. Obama has accused Clinton of not having said what the penalties entail, suggesting that these would be an added burden on those who do not get coverage because they cannot afford it.

Purchasing pool: is a device that facilitates more than one employer or group of individuals coming together to collectively purchase health insurance. The assumption is that, by aggregating a large number of smaller purchasers, pools can achieve economies of scale and exert greater leverage in negotiating lower premiums with health plans. The experience with purchasing pools has not been very promising, however. Indeed, pools face a “Catch-22” situation: they need to be large and cohesive in order to be successful in negotiating prices, but they do not become large and cohesive without a good track record insuring at lower prices.

Queueing: results when the demand for a given good or service exceeds its supply, and some customers have to wait to acquire it. In practically all countries including the U.S. (although this is more acute in some than others), transplant patients are placed on waiting lists to obtain scarce organs. In health care,

queueing often takes more “subtle” forms. Thus, for example, you may be sick and need to see a physician today, but you may not be able to get an appointment for another three weeks.

Rationing: is a process by which scarce resources are distributed. Who gets what depends on the system and how it operates. When it comes to health care, few countries can afford to do as much for their populations as is technically feasible. Some services may therefore be rationed because they are considered less necessary than others. Others may be restricted according to medical need, age, or likelihood of success. In cases in which services are sold on the market, services are in effect rationed by price: those who are not able to pay a given price must therefore do without. We therefore have implicit rationing at present.

Much more explicit rationing, unique to the United States — although we spend well in excess of \$2.2 trillion a year on health and can hardly be described as having “scarce resources” — takes the form of the 47 million and counting people who are uninsured.

At least one state has embraced the “luck of the draw” to decide who gets care. The Oregon Health plan, intended for those whose incomes are too high to qualify for Medicaid but too low to afford private health insurance, is using a lottery to decide who is covered. With a few thousand slots available and more than 80,000 registered for the lottery, rationing in this case is simply a matter of chance.

Although food rations mean that everyone gets what he/she needs, “rationing” health care is interpreted as some being deprived of care and is therefore politically toxic. Candidates favoring extending coverage have therefore done careful acrobatics to make the case that their policies would not entail any sacrifices. Instead, they repeatedly state that repealing the Bush tax cuts would provide the revenues needed to expand coverage,

and that a more efficient system (e.g., avoiding unnecessary care, greater emphasis on prevention, control of chronic diseases) would reduce costs in the long run.

“Skin in the game”: sounds like sports jargon, but the phrase has made numerous appearances in the language of health care. The phrase comes from the financial world, where having ‘skin in the game’ means taking an active interest in an undertaking by making a significant investment or financial commitment in it. In the current electoral campaign, Mike Huckabee attributed the health care crisis in the U.S. to the fact that “consumers don’t have much skin in the game” and are therefore not prudent in their decisions. To this, journalist Ezra Klein has replied that “In health care, *all* your skin is in the game” (emphasis added). Like Huckabee, McCain would like health consumers to be more involved by having more of their own resources at stake. He therefore favors tax breaks as incentives to get consumers to open health savings accounts and save for a sickly day. While it is true that Americans now pay a lower share of health expenses than they used to (average out-of-pocket expenses fell from 40 to 15 percent between 1970 and 2005), there is little evidence that greater cost-sharing or having greater “skin in the game” would solve the current problems. Indeed, cost-sharing has been shown to result in the postponement of needed care, especially for those of lower socio-economic means.

Socialized medicine: in its strict definition, this refers to a health care system in which the government funds and manages health care directly, employing providers and owning hospitals and other facilities. At least parts of the British National Health Service (NHS) and the health care systems of Spain and Finland can be called “socialized medicine.” Even in the NHS, which is often seen as the prototypical example of socialized medicine, general

practitioners are independent contractors rather than government employees. In the United States, “socialized medicine” is often used by those enamored of market medicine as a “boo word” or bogeyman, and is part of the inflammatory rhetoric seeking to scare constituents and predispose voters against many types of health care reforms. This election year, Giuliani was particularly quick to brand many proposed changes as “socialized medicine.”

The term is often used incorrectly to describe all publicly-funded health care with universal coverage. Most systems that meet these two criteria do not have socialized medicine, as defined above; instead, the government pays, regulates, and monitors health services but does not operate the production of health care. Medicare is a single-payer system that provides care to part of the population, but it is not socialized medicine: practitioners are not government employees, and hospitals are not publicly owned. The systems of the Veterans Health Administration and of the Department of Defense, however, are examples of socialized medicine, albeit for only a narrow segment of the population.

Because of politicians’ inaccurate or willful misuse of the term in speeches and debates over many years, some people are unsure as to what socialized medicine is. Still, the phrase has lost much of its pejorative connotation. Indeed, a recent (February 2008) national poll conducted by the Harvard Opinion Research Program found that, among those who said they understood the term, 45 percent said that the health care system would be better if the U.S. had socialized medicine; 39 percent said it would be worse.

Macular Degeneration

This article is adapted from a review article in the *New England Journal of Medicine* (June 12, 2008, pp. 2606-17).

Age-related Macular Degeneration (AMD) is the number one cause of permanent vision loss in older adults in the developed world. Among Americans aged 40 and older, it is estimated that 9 percent have any form of AMD and 1.5 percent have the most severe form. These percentages are projected to increase as the population ages. Recent developments in genetics and treatment suggest that we may be entering a new phase in the treatment of this disabling condition.

The eye is composed of three layers. The outermost layer is called the sclera, which in the front portion of the eye forms the cornea. Just inside that is the choroid, which in the front of the eye forms the iris. The innermost layer is the retina, which contains the actual nerve endings that detect light. The portion of the retina with the densest concentration of nerve endings is called the macula, and it is this region of the retina that is responsible for high-resolution vision (e.g., reading and recognizing faces). Behind the photoreceptors (toward the choroid) is the retinal pigment epithelium and between the retinal pigment epithelium and the choroid lies Bruch's membrane.

The basic problem in age-related macular degeneration is that particles of debris, called drusen, are deposited between the retinal pigment epithelium and Bruch's membrane. Drusen are present in all persons over the age of 50 and are considered part of normal aging. But if the deposits are severe, AMD ensues, because the retinal pigment epithelium is damaged, causing chronic inflammation. Initially, these deposits may not cause symptoms (Early AMD), but as the condition progresses to Intermediate AMD

blurred vision, the need for bright lights to read and other symptoms may occur. A more severe form is Advanced Non-neovascular AMD, which is associated with gradually advancing visual loss over months to years. It is distinguished from the more severe Advanced Neovascular AMD by the growth of new blood vessels in the macula. These can lead to retinal bleeding and scarring. Although even Advanced Neovascular AMD is not typically associated with complete blindness, the disability is severe and clinical depression is common.

As noted, the condition is clearly more common in older people and is also more common in whites than blacks, with Asians and Latinos in between. Certain genetic mutations are also strong predictors of the likelihood of developing the disease. Importantly, cigarette smoking, and even exposure to secondhand smoke, have been associated with the risk of contracting AMD. But 20 years after a smoker has quit, he or she is at the same risk for AMD as the general population. Other risk factors include obesity, hypertension and high dietary fat intake.

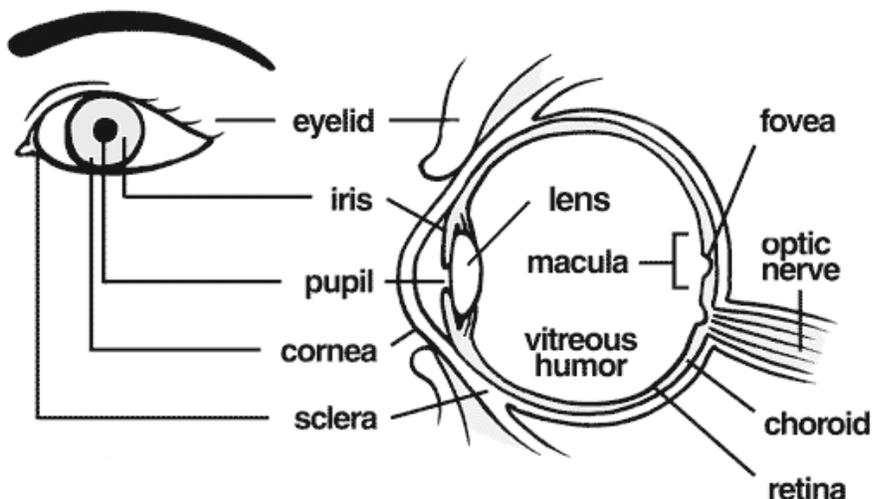
Treatment of AMD

Although there is no evidence for the effectiveness of any drug or vitamin in prevention of AMD, some progress has been made in its treatment.

For any stage of AMD, lifestyle and dietary modifications are recommended. These include quitting smoking, weight loss and blood pressure control. For more advanced disease, combination antioxidant and zinc therapy has been proved to reduce the progression of AMD from the Intermediate to the Advanced stage by 25 percent over five years. The antioxidants administered were vitamins C and E, beta carotene, along with zinc oxide and cupric oxide. The problem is that beta carotene increases lung cancer risk in smokers and vitamin E has been associated with a higher death rate (see May 2005 *Worst Pills Best Pills News*), so the decision to take these antioxidants should be made in consultation with your physician. Obtaining them through the diet in the form of green leafy vegetables, nuts, whole grains and fish, is probably reasonable.

The most common therapies for Advanced Neovascular AMD are two drugs injected into the eye that have

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www.mvrl.org-illustration based upon information from the National Eye Institute/National Institutes of Health

Product Recalls

May 15, 2008 – June 16, 2008

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

DRUGS AND DIETARY SUPPLEMENTS

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

Recalls and Field Corrections: Drugs – CLASS II

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

Name of Drug or Supplement; Problem; Recall Information

Family Dollar Milk of Magnesia Mint Flavor, Magnesium hydroxide 400mg, 12 fl. oz. bottles, 74,314 units of both Family Dollar Milk of Magnesia entries combined Misbranded; dosing instructions for use as a Laxative for children 2 to 5 years incorrectly states 1-3 tablespoons instead of 1-3 teaspoons once a day. Lot #s: 32393, 32394, 32395, 32396, 32711, 32712, 33288, 33289; Aaron Industries Inc.

exp. date 03/31/2009; WE13167, exp. date 04/30/2009; WE13169, exp. date 04/30/2009; WE13248, exp. date 04/40/2009; WE13385, exp. date 04/30/2009; 2) Lots WC11968, exp. date 02/28/2009; WD12368, exp. date 03/31/2009; 3) Lots WB11318, exp. date 01/31/2009; WB11410, exp. date 01/31/2009; WC11699, exp. date 02/28/2009; WD12723; Fresenius Kabi.

Family Dollar Milk of Magnesia Cherry Flavor, Magnesium hydroxide 400mg, 12 fl. oz. Bottles, 74,314 units of both Family Dollar Milk of Magnesia entries combined; Misbranded; dosing instructions for use as a Laxative for children 2 to 5 years incorrectly states 1-3 tablespoons instead of 1-3 teaspoons once a day. Lot #s: 32354, 32355, 32356, 32360, 32361, 32362, 32713, 32714, 33290, 33291; Aaron Industries Inc.

Intralipid 30%, a 30% Fat Emulsion for Intravenous Use, 500 mL flexible plastic container, Pharmacy Bulk Package, sterile, Rx only, each 100 mL contains Soybean Oil 30 g, Phospholipids 1.2 g, Glycerin USP 1.7 g, 235,140 units of all three Intralipid recalls combined; There is an increased potential for port splitting to occur in the administration port. Lot #: WE13010, exp. date 04/30/2009; Fresenius Kabi.

Intralipid 10%, a 10% Fat Emulsion for Intravenous Use, 500 mL flexible plastic container, sterile, Rx only, each 100 mL contains Soybean Oil 10 g, Phospholipids 1.2 g, Glycerin USP 2.25 g, 235,140 units of all three Intralipid recalls combined; There is an increased potential for port splitting to occur in the administration port. Lots WB11179, exp. date 01/31/2009; WD12411, 03/31/2009; Fresenius Kabi.

Levothroid (levothyroxine sodium tablets, USP), 25 mcg, 100- and 1,000-tablet bottles, RX only; NDC 0456-1320-01 (100-ct.) and NDC 0456-1320-00 (1,000-ct.), 17,681/100-tab. bottles and 632/1,000-tab. bottles Levothroid; Subpotent; (8-month and 9-month stability intervals). Lot #s: 050701 (100-tab.) and 050702 (1,000-tab), both from bulk lot HA08207, exp. date 04/2008; Lot #s: 060736 (100-tab.) and 070706 (1,000-tab), both from bulk lot HC13007, exp. date 05/2008; Lloyd Inc.

Intralipid 20%, a 20% Fat Emulsion for Intravenous Use, 100, 250, 500 mL flexible plastic containers, sterile, Rx only, each 100 mL contains Soybean Oil 20 g, Phospholipids 1.2 g, Glycerin USP 2.25 g, 235,140 units of all three Intralipid recalls combined; There is an increased potential for port splitting to occur in the administration port. Lot #s: WB11032, exp. date 01/31/2009; WB11034, exp. date 01/31/2009; WB11163, exp. date 01/31/2009; WC11686, 02/28/2009, WC11688, exp. date 02/28/2009; WC11690, exp. date 02/28/2009; WD12645, exp. date 03/31/2009; WD12649, exp. date 03/31/2009; WD12647,

Multiret Folic 500 Tablets, ferrous sulfate, 525 mg, 6 x 10 film coated tablets, Rx only, Also labeled as Multiret Folic 500 Tablets, Amide Pharmaceutical, 15 lots; 169,433 bottles; Subpotent: Folic Acid. Lot #: 06358A1, exp. date 04/2008; Lot #: 60358A2, exp. date 04/2008; Lot #: 60358A3, exp. date 04/2008; Lot #: 60358A4, exp. date 04/2008; Lot #: 60633A1, exp. date 07/2008; Lot #: 60633A2, exp. date 07/2008; Lot #: 60823A1, exp. date 09/2008; Lot #: 60823A2, exp. date 07/2008; Lot #: 60823A3, exp. date 09/2008; Lot #: 70065A1, exp. date 01/2009; Lot #:

70065A2, exp. date 01/2009; Lot #: 70254A1, exp. date 03/2009; Lot #: 70254A2, exp. date 03/2009; Lot #: 70607A1, exp. date 07/2009; Lot #: 70819A1, exp. date 11/2009; Lot #: 60358A1, exp. date 04/2008; Lot #: 60358A2, exp. date 04/2008; Lot #: 60358A3, exp. date 04/2008; Lot #: 60358A4, exp. date 04/2008; Lot #: 60633A1, exp. date 07/2008; Lot #: 60633A2, exp. date 07/2008; Lot #: 60823A1, exp. date 09/2008; Lot #: 60823A2, exp. date 09/2008; Lot #: 60823A3, exp. date 09/2008; Lot #: 70065A1, exp. date 01/2009; Lot #: 70065A2, exp. date 01/2009; Lot #: 70254A1, exp. date 03/2009; Lot #: 70254A2, exp. date 03/2009; Lot #: 70607A1, exp. date 07/2009; Lot #: 70819A1, exp. date 11/2009; Actavis Totowa LLC.

Paroxetine Tablets, USP, 20 mg, 100 count bottles, 14,256 bottles; Mislabeled; bottle labeled as containing Paroxetine 20 mg Tablets actually contain Warfarin 4mg Tablets. Lot #: MG3179, exp. date 05/2009; Cadila Healthcare Ltd.

Thyro-Tab 0.025mg, 150,000-tablet bulk drums intended for re-packaging, Rx only; 3,820,252 bulk Thyro-Tab tablets; Subpotent; (8-month and 9-month stability intervals). Lot #: HA08207, exp. date 04/2008; Lot #: HC13007, exp. date 05/2008; Lloyd Inc.

CONSUMER PRODUCTS

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

Name of Product; Problem; Recall Information

American Flame Fireplaces. Gas can continue to flow into the fireplace pilot light area after the switch of the Fireplace Gas Valves has been turned "off," posing a fire or explosion hazard to consumers. American Flame Inc., (888) 672-8929 or www.skytechsystem.com.

blowers were previously recalled due to a fire hazard. Shindaiwa Corp., (800) 521-7733 or www.shindaiwa.com.

American Scientific Magnets. Surface paint on the magnets can contain high levels of lead, violating the federal lead paint standard. American Scientific LLC, (866) 518-1665 or www.american-scientific.com.

Bassettbaby Cribs. The space between the spindles on some Wendy Bellissimo Hidden Hills Collection Cribs can fail to meet federal standards and can pose an entrapment hazard to infants. Bassettbaby, (866) 618-5446 or www.bassettbaby.com.

Animal Tracking Explorer Kits. The powder in the Animal Tracking Explorer Kit marked "plaster of Paris" is actually calcium hydroxide, which poses a risk of skin and eye irritation to children using the product. MindWare, (800) 588-1072 or custserv@mindware.com.

Batting Helmets. Surface paint on the Rawlings Junior Batting Helmets contains excessive levels of lead, violating the federal lead paint standard. Rawlings Sporting Goods Co. Inc., (800) 729-5464 or www.rawlings.com.

ATVs. The Polaris All-Terrain Vehicles (ATVs) can have defective Electronic Control Modules (ECM) that overheat, posing a fire and burn hazard to riders. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

Candle Holders. Sunlight passing through the glass portion of the Candle Holders can cause nearby flammable materials to ignite, posing a fire hazard. The Home Depot, (866) 403-5504 or www.homedepot.com.

Backpack Blowers. The Shindaiwa Backpack Blower's impeller (fan) can separate from the base and break apart, causing plastic pieces to be blown out of the machine, and pose a laceration and impact hazard to consumers. The flying pieces also can cause property damage and injury to bystanders. Note: These backpack

Carbon Monoxide/Carbon Dioxide Combination Alarms. The FireX Branded 10000 Series Carbon Monoxide (CO) Alarms and 12000 Series CO/Smoke Combo Alarms can sound a "double chirp"/fault alarm in the presence of CO, prior to going into full alarm. Upon hearing a double chirp, the Owner's Manual instructions recommend a consumer take the alarm out of service, which could expose consumers to hazardous levels of CO and suffer injury or death. Maple Chase Company, (888) 879-3906 or www.firexsafety.com.

CONSUMER PRODUCTS

Ceiling-Mounted Indoor Light Fixtures. A cable that supports the Indoor Ceiling Light Fixtures from the ceiling can fail, causing the fixture to fall and injure nearby consumers. Progress Lighting, (877) 369-4548 or www.progresslighting.com.

Children's Blanket. The Lil' Snugglers™ Children's Blanket's satin edge can come loose, posing a strangulation hazard. Douglas Co., (800) 992-9002 or www.douglastoys.com.

Children's Hooded Jackets. The Squeeze Kids Girl's Corduroy Jackets have a drawstring through the hood, which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (pdf) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Maran Inc., (866) 431-5698 or www.Sqz.com.

Children's Hooded Sweatshirts. The Boy's Hooded Zip Fleece Sweatshirts have a drawstring through the hood, which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (pdf) to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Adio Footwear, (800) 995-6069 or www.adiofootwear.com.

Children's Jewelry. The Children's Jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Daiso Seattle LLC, (866) 768-4620 or www.daisollc.com.

Children's Jewelry. The clasps on some of the Makit & Bakit Jewelry Sets and Suncatcher Sets contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. QuinCrafts, (800) 366-4660 or www.quincrafts.com/recall.

Children's Merry-Go-Rounds. The inner bearing on the Playsafe Spinning Quad Merry-Go-Rounds can fail, causing the seat assembly to suddenly drop to the ground. This poses a fall hazard to children riding the merry-go-round. Pacific Cycle Inc., (877) 564-2261 or www.pacific-cycle.com.

Children's Overalls. The buttons on the shoulder straps of the Infant and Toddler Shortalls can detach, posing a choking hazard to young children. Sara Lynn Togs, (800) 426-9377 or www.saralynntogs.com.

Counterfeit Circuit Breakers. The Counterfeit Circuit Breakers labeled as "Square D" have been determined by Square D to be counterfeit and can fail to trip when they are overloaded, posing a fire hazard to consumers. Specialty Lamp International Inc., (866) 650-3076 or www.ebulb.net.

Crib Mattresses. Some of the Simmons Kids Crib Mattresses can measure smaller than the 27 1/4 inch minimum width requirement for cribs, creating a gap between the mattress and crib side rails, posing an entrapment hazard to infants. Simmons Kids, (800) 810-8611 or www.simmonskids.com.

Cricket "EZ" Cell Phones. A software problem with "Cricket EZ" Cellular Phones causes audio problems with 911 calls. When a call is connected to 911, the operator may not hear the caller or the caller may not hear the 911 operator. Cricket Communications, (866) 441-1577 or www.mycricket.com.

Electric Candle Warmers. The internal heating element of the Candsense Warmers can detach and melt the bottom of its plastic casing, which can in turn ignite or scorch the surface on which the candle warmer is placed, posing a fire hazard to consumers. Provo Craft & Novelty Inc., (888) 306-0132 or www.provocraft.com.

Fireplace Wall Controls. Failure in the IntelliSwitch Fireplace Wall Controls can cause the fireplace to turn on by itself creating a risk of property damage. If the control fails and the consumer has left combustible objects directly in front of an unattended fireplace, there may also be a risk of fire. Hearth & Home Technologies Inc., (800) 215-5152 or www.heatnglo.com.

Floppy Toy Horses. Surface paint on the Floppy Friends Horse Toys contains excessive levels of lead, violating the federal lead paint standard. Toy Investments Inc., (800) 356-0474 or www.toysmith.com.

Fuel Cells. The "Tall Red" Fuel Cells used to power cordless framing nailers can leak fuel, posing a fire hazard. Paslode, (800) 222-6990 or www.paslode.com.

CONSUMER PRODUCTS

Gas Dryers. If the Residential Super-large Gas Dryer is improperly installed, the dryer's internal gas fitting can loosen, posing a risk of gas leaking into the house. Any gas leak that is not detected can cause asphyxiation, a fire or an explosion. Also, one or both of the caps on the internal exhaust duct can become dislodged, which can cause lint to build up and be carried through the gas burner. This poses a risk of fire. Miele Inc., (800) 420-1813 or www.miele.com.

Gel Candles. The Gel Candles can have excessive flame height, posing a fire and burn hazard to consumers. M & A Global Technologies Inc., doing business as Spa at Home, (866) 224-8811 or www.spaathome.com.

Hammer Drills. The Bosch Hammer Drills can continue to operate after the trigger has been released, posing a risk of injury to consumers. Robert Bosch Tool Corp., (877) 472-0007 or www.boschtools.com.

Infant Rattles. The blue plastic end caps of the Tumble Tower Infant Rattles can break, resulting in small parts, posing a choking hazard to young children. Manhattan Group LLC, (800) 541-1345 or www.manhattantoy.com.

Little Rider Toys. Surface paint on the shoe and pants of the Cowboy on a Horse Little Rider Toy contains excessive levels of lead, violating the federal lead paint standard. Master Toys & Novelties Inc., (800) 237-5020 or www.mastertoys.com.

Log Swings. A missing nail connecting the back of the log chair to the seat of the Log Swings can cause the back to separate from the seat while in use, posing a fall hazard to consumers. Far East Brokers and Consultants Inc., (877) 695-8354 or www.fareastbrokers.com.

Outdoor Benches. The Best Value Park Benches can become unstable and break, posing a fall hazard to consumers. Jo-Ann Fabric and Craft Stores, (888) 739-4120 or www.joann.com.

Paint Brushes. Surface paint on the handle of the Yellow Sure Grip Paint Brushes contains excessive levels of lead, violating the federal lead paint standard. Early Childhood Resources LLC, (888) 227-9028 or www.ecr4kids.com.

Pajama Sets. The screen print on the Camouflage Pajama Sets shirts contains excess levels of lead. The Children's Place Retail Stores Inc., (877) 752-2387 or customerservice@childrensplace.com.

Pirates of the Caribbean Sleeping Bags. The surface paint on the Pirates of the Caribbean Sleeping Bags' zipper pull contains excessive levels of lead, violating the federal lead paint standard. Disney Store, (866) 902-2798 or www.disneystore.com.

Remote Control Helicopter Toys. The rechargeable battery contained inside the "Sky Champion" Wireless Indoor Helicopters can catch fire, igniting the helicopter and nearby combustible materials. This poses a burn or fire hazard to consumers. TWIE, (888) 583-4908 or returncopters@aol.com.

Sauna Rooms. The heating unit and fuse of the Infra-Red Sauna Rooms can fail, leading to overheating of the saunas. This defect can result in a serious fire hazard to consumers. Sauna By Airwall Inc., (562) 630-2283 or customersupport@saunabyairwall.com.

Shag Rugs. The large "Remy" Shag Rugs fail to meet federal standards for flammability and could ignite, posing fire and burn hazards to consumers. The small rugs fail to meet federal labeling requirements. Small rugs are not required to meet the federal flammability standard; however, they are required to be permanently labeled with the following statement: "FLAMMABLE (FAILS U.S. DEPARTMENT OF COMMERCE STANDARD FF 2-70): SHOULD NOT BE USED NEAR SOURCES OF IGNITION." Crate and Barrel, (800) 451-8217 or www.crateandbarrel.com.

Shaker Guiro Instruments. Surface paint on the Basic Beat Shaker Guiro Instruments contains excessive levels of lead, violating the federal lead paint standard. Antigua Winds Inc., (800) 397-9378 or service@westmusic.com.

Snowboard Bindings. The cable that links the toe strap to the K2 "Auto" Series Snowboard Bindings, Model Year 2007, could break, posing a fall hazard to snowboarders. K2 Sports, (800) 985-2191 or www.k2snowboarding.com.

CONSUMER PRODUCTS

Snowmobiles. Under extreme cold and dry weather conditions, an explosion could occur in the Ski-Doo Snowmobiles because of sparking in the fuel tank when it is partially filled with gasoline at a low vapor pressure and the engine is left idling. This could cause serious injuries or death. BRP U.S. Inc., (888) 638-5397 or www.ski-doo.com.

Swing Sets. Hangers holding the chains for the gliders of the Adventure Play Sets and Create N Adventure Wooden Play Sets can break, causing a child to fall and suffer injuries. Backyard Leisure LLC, (866) 546-7902 or www.adventureplaysets.com.

Tinker Bell Wands. The paint on the pearl beads in the flowers of the Tinker Bell Wands contains excessive levels of lead, violating the federal lead paint standard. Disney Store, (866) 902-2798 or www.Disneystore.com.

Tomato Planters. The legs on the bottom of the Topsy-Turvy Deluxe Tomato Planters with Stand can detach when the planter is moved or becomes unbalanced. This could cause the planter to fall and injure bystanders. QVC, (800) 367-9444 or www.qvc.com.

Toy Cell Phones. The hinge cover on the Little Tikes Chit 'N Chat Toy Cell Phones can detach from the phone, posing a choking hazard to young children. Kids Station Toys International Ltd., (888) 620-0930 or www.kidsstationtoys.com.

Toy Kitchens. The four pegs supporting the oven shelf and four pegs supporting the refrigerator shelf of the Mini Chef Complete Toy Kitchens can pull out of the wood, posing a choking hazard to children. The toy kitchen unit also can tip over, posing a risk of serious injury to children. eStyle Inc., (877) 378-9537 or www.babystyle.com.

Two-Burner Gas Grills. On the Char-Broil Two-Burner Gas Grills Model 463720108, the main burner does not fit correctly and does not connect properly to the gas valve which could result in a propane leak. This poses fire and burn hazards to consumers. Char-Broil LLC, (866) 671-7988 or www.charbroil.com.

United Scientific Magnets. Surface paint on various magnets contains high levels of lead, which violates the federal lead paint standard. United Scientific, (888) 284-8570 or consumeraffairs@unitedsci.com.

Utility Vehicles. Excessive heat can cause the wiring harness of the Cub Cadet 4x4 EFI Volunteer Utility Vehicles to melt. This defect can result in a fire hazard to consumers. MTD, (888) 848-6038.

Wireless Conference Phone Batteries. The SoundStation2W Wireless Conference Phones with Lithium Ion Batteries can over-heat, posing a fire or burn hazard. Polycom, Inc., (800) 963-7627 or www.polycom.com/2WBattery.

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similar effects upon the immune system: ranibizumab (Lucentis) and bevacizumab (Avastin). Ranibizumab has been shown in clinical trials to prevent the progression of the disease. Inflammation of the inner and middle layers of the eye (endophthalmitis and uveitis, respectively) are rare complications of the drug. Several short-term studies have shown bevacizumab to be about as effective as ranibizumab, with similar toxicities, and it is much less expensive

In sum, AMD is a serious, disabling condition about which more is constantly being learned.

(\$1950 per dose for ranibizumab vs. \$30 for bevacizumab). The catch? Bevacizumab has never been approved by the U.S. Food and Drug Administration for this purpose (it is approved as a cancer drug). The National Eye Institute has initiated a study to compare the two drugs. Other treatments that are less-frequently used include injection of agents that prevent new blood vessel growth directly into the eye and retinal surgery.

In sum, AMD is a serious, disabling condition about which more is constantly being learned. Although there is no known means of preventing the disease, some of the new advances may lead to approaches to partially restore vision or slowing down the progression of a condition that currently has no effective cure.

body than the original compound, and results 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.

Propoxyphene-acetaminophen, or Darvocet, is more dangerous than acetaminophen alone, yet a study has indicated that Darvocet is no more effective in treating post-operative pain than acetaminophen. Reports on propoxyphene dosage suggest addiction can occur at less than the maximum recommended daily dose and unequivocally confirm addiction at just twice the recommended daily dose.

In addition, propoxyphene has been deemed inappropriate for the elderly because of its adverse effects on the central nervous system — such as sedation and confusion — that have been found to increase the likelihood of falls and fall-related fractures. Studies have shown that propoxyphene use is widespread in emergency rooms, and among institutionalized populations and retirement communities.

In addition, propoxyphene has been deemed inappropriate for the elderly because of its adverse effects on the central nervous system — such as sedation and confusion — that have been found to increase the likelihood of falls and fall-related fractures.

U.K. bans drug

As of the beginning of 2008, drugs containing propoxyphene are no longer on the market in the United Kingdom (U.K.).

The U.K. began a phased withdrawal of Darvocet from the British market in 2005, following the recommendation of the U.K. Committee on Safety of Medicines (CSM). In its report, the CSM stated that it could not “identify any patient group in whom the risk-benefit [ratio] may be positive.” The withdrawal was completed at the end of 2007.

We know of no drug with less evidence of any unique benefit that is more dangerous than propoxyphene. Its demise is long overdue.

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Why is Darvon (Darvocet/propoxyphene) Still Around, Hurting People?

Public Citizen has just sued the Food and Drug Association (FDA) to urge the agency to act on our 2006 petition to remove Darvon/Darvocet (generic name propoxyphene) from the market in the U.S.

Public Citizen's lawsuit argues that the FDA is violating the law by not acting on Public Citizen's 2006 petition, thus allowing drugs containing propoxyphene to remain on the market, putting patients at risk.

Thirty years ago we asked the FDA either to ban the drug or acknowledge it was a narcotic and regulate it under the Controlled Substance Act. The agency chose not to ban it but did put some controls on its production and distribution. In 2006, we asked the agency to "immediately begin the phased removal" of the drug due to

"2110 reported accidental deaths in the U.S. from 1981 through 1999."

FDA has known drug is dangerous, addictive

Propoxyphene is physically and psychologically addictive, and is no more effective than safer alternatives, Public Citizen told the FDA in its 2006 petition. Despite the drug's health risks, however, it was one of the 25 most prescribed generic drugs in 2007, with 22 million prescriptions filled in pharmacies in 2007.

Top FDA drug officials, including Center for Drug Evaluation and Research Director Dr. Janet

Woodcock, are well aware that this drug has considerable human toxicity, addiction potential and abuse liability, but very limited therapeutic usefulness. Given this extremely unfavorable ratio of risks to benefits, it is inexcusable that the

Propoxyphene is physically and psychologically addictive, and is no more effective than safer alternatives, Public Citizen told the FDA.

FDA did not take propoxyphene off the market long ago. It is our hope that this lawsuit will force the agency to finally begin this desperately

needed regulatory process. A large proportion of the deaths from propoxyphene occurred because most of the drug is converted into a metabolite that is highly toxic to the heart, lasts longer in the

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