PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Public Citizen Petitions FDA to Ban Third-Generation Oral Contraceptives

For more than a decade, the Food and Drug Administration (FDA) has knowingly allowed a form of birth control pill that has twice the risk of life-threatening blood clots as other, safer alternatives to remain on the market, putting hundreds of thousands of women at unnecessary risk. These pills, called third-generation oral contraceptives, contain desogestrel, an ingredient not included in other birth control pills. On February 6, 2007, the consumer advocates at Public Citizen filed a petition with the regulatory agency demanding that it immediately ban third-generation oral contraceptives containing the drug desogestrel.

Between November 2005 and October 2006, American women filled an estimated 7.5 million prescriptions for third-generation oral contraceptives. Banning the pills could save hundreds of women a year from developing venous thrombosis, or blood clots, which have disabling and sometimes fatal consequences. Blood clots typically form in a patient's legs. The danger of these blood clots is that they can travel through the veins and block blood flow at another location, causing a condition known as venous thromboembolism. Blood clots that travel to the lungs, for instance, can cause pulmonary embolism, which can be fatal.

Combination oral contraceptives contain synthetic versions of both estrogen and progestins. The difference between second- and third-generation oral contraceptives is the progestin component. All third-generation contraceptives in the United States contain desogestrel, while second-generation contraceptives contain norgestrel, levonorgestrel or norethindrone. Third-generation birth control pills were developed in the 1980s in an unsuccessful attempt to create an oral contraceptive with fewer adverse effects than the previous versions.

The labels of all third-generation birth control pills contain a submerged warning about this increased risk of venous thrombosis, an acknowledgement by the manufacturing companies of the greater risk of blood clots associated with third-generation oral contraceptives compared to the second-generation ones.

Oral contraceptives have had a tremendously positive impact on the lives of millions of women worldwide. The development of these pills has given women the ability to control their reproductive lives, an important precursor to a woman's ability to plan other areas of her life. Although all birth control pills come with a certain risk level, the benefits generally far outweigh the slight chance that a woman will suffer any harm from taking birth control pills.

Third generation oral contraceptives, however, put women at twice the risk of blood clots as second generation oral contraceptives without

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protecting women any better against pregnancy. The increased risk is unnecessary and does not bring with it any additional therapeutic advantages and, for that reason, the risk is unacceptable.

Worse, the FDA has known about this increased risk since 1995 and has not taken any actions to take these drugs off the market. Although there is a warning on third-generation OC labels, Public Citizen thinks that this is not enough. The presumption that any risk is acceptable so long as there is informed consent is misguided. Women can enjoy the same benefits of birth control pills without putting themselves at risk of any unnecessary life-threatening conditions.

In December 1995, three independent studies showing the dangers associated with third-generation birth control pills appeared in *The Lancet*, concluding that these contraceptives had about twice the risk of venous thrombosis compared to second-generation pills. Many additional studies since then have confirmed this elevated risk. "The FDA must ensure the well-being and safety of women in the U.S. and ban third-generation oral contraceptives containing desogestrel," the petition says. "Women should discuss with their doctors alternative methods of birth control, such as the second-generation oral contraceptives, and how to safely switch contraceptive methods."

Along with Health Research Group director Dr. Sidney Wolfe, the petition was co-authored and signed by Jay Parkinson, MD, MPH and Sylvia Park, MD, MPH, both research analysts for Public Citizen. Another signer was Frits Rosendaal, MD, of Leiden University in the Netherlands, who has published hundreds of papers and conducted ongoing studies of thrombosis, particularly in connection with oral contraceptives.

Banning the pills could save hundreds of women a year from developing venous thrombosis, or blood clots, which have disabling and sometimes fatal consequences.

The third-generation oral contraceptives containing desogestrel are: Desogestrel and Ethinyl Estradiol (Duramed/Barr and Watson Pharmaceuticals), Desogestrel and Ethinyl (Duramed/Barr), Desogen (Organon), Velivet (Duramed), Kariva (Duramed/Barr), Mircette (Duramed/Barr), Apri-28 (Duramed/Barr), Ortho-Cept (Ortho-McNeil), Reclipsen (Watson) and Cyclessa (Organon).

YouTube Can Make Your Voice Heard

In addition to the petition sent to the FDA, Public Citizen initiated an online, grassroots effort to open a dialogue on the importance of safer birth control pills and the dangers of third-generation oral contraceptives.

This effort includes a video on YouTube in which women explain why safer birth control is important to them and a place where people can sign on to the citizen's petition to the FDA regarding the subject. It is the first time the advocacy organization has used the Internet in this way to generate grassroots support of an official legal petition directed at a government agency.

The video is housed on its own website, www.NotMyPill.org, where visitors to the site can also read the full petition; send comments to the FDA voicing their opinions on Public Citizen's initiative; submit their own YouTube videos about why the FDA should ban third-generation oral contraceptives; or tell a friend about the campaign.

The online initiative has already enjoyed a great deal of success. Within a month of its launch, the YouTube video had been viewed well over 6,500 times, and roughly 10,000 people had sent comments to the FDA in support of Public Citizen's effort to ban these drugs. ■

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Product Recalls

January 20, 2007 — February 27, 2007

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

DRUGS AND DIETARY SUPPLEMENTS

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

Recalls and Field Corrections: Drugs — CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

NASUTRA Herbal Supplement for Men, proprietary blend of ten chinese herbs, 300mg, Unapproved New Drug; Product contains undeclared acetildenafil, an analogue of sildenafil. Lot #s WP-505, WP904, WP1005, WP106, WP206, WPNA506 and WPNA706, Bactolac Pharmaceutical, Inc.

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

Alesse-28 Tablets Clinical Packs, levonorgestral 0.10mg and ethinyl estradiol 0.02mg, 28 tablet blister packs, 50 count box; Impurity (18 month stability). Lots # A66651 exp. date 12/2006, and A66652 exp. date 01/2007; Wyeth Pharmaceuticals Company.

Compressed Gas, Oxidizing, N.O.S., Medical Gas Mixtures, UN 3156, 20% Carbon Dioxide, 80% Oxygen, Size 44 Steel Cylinders; Product was fitted with incorrect CGA valve connection. Correct valve is CGA 500, but product was fitted with CGA 280. Lot # 0826BG06, Specialty Gases of America Inc.

GlipiZIDE 5mg Tablets USP, 100 count Unit Dose packages and 100 count bottles; Exceeds impurity specification. Lot # 138020A exp. date 02/2007, Lot #138020U exp. date 02/2007; Ivax Pharmaceuticals, Inc.

Levothroid (levothyroxine sodium tablets, USP), 25 mcg; Subpotent (6-month stability). Lot 050604 (100 ct.) and Lot 050605 (1,000-ct.), exp. date 04/2007; Lloyd Inc.

Tizanidine HCl Tablets, 2 mg, packaged in 150 tablet plastic bottles; Failed dissolution test requirements. Lot # 9694 exp. date 09/2007. Alphapharm Pty, Ltd.

Levothyroxine Sodium Tablets USP, multiple strengths; Subpotent. Multiple lots, Mova Pharmaceutical Corp.

Thyro-Tab 0.025 mg, packaged in 150,000-tablet bulk drums intended for repackaging; Subpotent (6-month stability). Lot #HA08306, exp. date 04/2007; Lloyd Inc.

Systane® free Lubricant Eye Drops Liquid Gel, (polyethylene glycol 400, 0.4% and polyethylene glycol 0.3%), 3mL (sample size) and 10mL, Sterile; Mold Contamination (Curvularia sp and Alternaria sp). 3mL size lot #s 63722F, 114115F, 60907F, 63239F, 121916F, 120742F, 122349F, 114984F, 120081F, and 121936F; 10mL size lot #s 63190F, 61410F, 113575F, 113576F, 115267F, 115809F, 115808F, and 115268F; Alcon Laboratories, Inc.

CONSUMER PRODUCTS

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

Name of Product; Problem; Manufacturer and Contact Information

All-Terrain Vehicles. The front suspension arm ball joints of Honda Model Year 2006 TRX450ER/R ATVs could have been contaminated during production, resulting in rapid wear of one or more of the ball joints and possible ball joint separation. If the ball joint separation occurs while riding, the operator could lose control of the ATV. American Honda Motor Corp. Inc., (866) 784-1870 or www.powersports.honda.com.

Battery Packs for Toy Vehicles. The lithium-ion polymer Battery Packs for Toy Vehicles can ignite while charging, posing a fire hazard. JAKKS Pacific Inc., (877) 875-2557 or battery@jakks.net.

Bicycles. The front wheel forks on Mirraco Bicycles could have been welded improperly. This poses a risk that the weld could fail, and the rider could lose control and fall. Mirraco LLC, (888) 431-7653 or www.mirrabikeco.com.

Boiler Controls. "Erie Boiler Boss" Operating and Reset Controls can fail, causing water temperature to rise to the high temperature limit. Should the high temperature thermostat or external safety limit devices also fail, consumers could suffer scalds from unexpectedly hot water during use or system piping damage can result. TAC LLC, (866) 692-1110 or www.tac.com.

Boilers. The boiler assembly is not properly sealed. Exhaust and carbon monoxide (CO) of Model 80, 88, 94, and LGB Packaged Commercial Boilers can leak during operation and accumulate, posing a risk of poisoning. Weil-McLain Co., (219) 879-6561 or www.weil-mclain.com.

Children's Bracelets. Children's "Ultra Gear" Bracelets contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. DM Merchandising Inc., (800) 548-6784 or www.dmmerchandising.com.

Children's Hooded Sweatshirts/Windbreakers. Children's Hooded Sweatshirts and Windbreakers with Drawstrings have a drawstring through the hood, posing a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Basix U.S.A., (800) 236-8150.

Children's Jackets. The snap closures on the Heavyweight Outerwear Jackets contain excessive amounts of lead, which poses a lead poisoning hazard. Samara Brothers LLC, (800) 985-9975 or www.samarajacketrecall.com.

Children's Jewelry. Children's "Kidsite" Necklace and Earring Sets contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Crimzon Rose Accessories, (800) 659-7026 or www.kmart.com.

Children's Rings. "Claudia Jublot" Children's Rings contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Lari Jewelry Co., (866) 524-0024 or www.biglots.com.

Children's Rings. Children's "Rachael Rose Kidz" Rings contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Shalom International Corp., (800) 359-8162 or www.familydollar.com.

Curling Irons. The handle of the Curling Iron can come apart exposing its line cord, posing a shock or electrocution hazard to consumers. Conair Corp., (800) 687-6916 or www.conair.com/ironrecall.html.

Decorative Trunks. Home Decorators Collection Leather Suitcase Trunks have an exterior clasp that can lock unexpectedly when the trunk lid closes. If a child climbs inside the trunk, he/she may not be able to open the trunk from the inside. This poses an entrapment and suffocation hazard to children. Home Decorators Collection, 800 464-0164.

Dishwashers. Liquid rinse-aid can leak from Maytag(r) and Jenn-Air(r) brand dishwasher's dispenser and come into contact with the dishwasher's internal wiring which can short-circuit and ignite, posing a fire hazard. Maytag Corp., (800) 675-0535 or www.repair.maytag.com.

Easy-Bake Ovens. Young children can insert their hands into the Easy Bake Oven's opening and get their hands or fingers caught, posing an entrapment and burn hazard. Easy-Bake, a division of Hasbro, Inc., (800) 601-8418 or www.easybake.com.

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Electric Oil Lamps. The power cord of Electric Oil Lamps is not polarized and is undersized. The power cord is not correctly secured and there is no strain relief on the switch housing. Additionally, the switch housing is not flame-retardant. As a result of these issues, the lamps pose shock and fire hazards. Hong Teng Trading (USA) Inc., (866) 435-3915.

Electronic Control Boards. Incoming and outgoing messages to and from Gamewell-FCI Electronic Control Boards by Honeywell can interfere with each other, preventing it from sending a message to the command center in the event of fire. Gamewell-FCI, (800) 633-1311 or www.gamewell-fci.com.

Flojet VAC Pumps. A manufacturing defect of Flojet duplex II 115 VAC Pump, a component of the LeBleu Automatic 50 Gallon Bottled Water Systems can cause consumers to receive an electric shock when the metal housing is touched. Flojet Division of ITT Corp., (714) 628-8113 or www.flojet.com.

Floor Lamps. The light socket of Thomasville Table and Floor Lamps has a defect, which poses electrical shock and fire hazards. Currey & Company, (866) 577-6430 or www.curreyco.com.

Gel Candles. The Gel Candles can have excessive flame height, posing a fire and burn hazard to consumers. M & A Global Technologies, (866) 224-8811.

Hair Dryers. Travel'N Baby Mini Hair Dryers are not equipped with an immersion protection plug to prevent electrocution if the hair dryer falls into water. Electric shock protection devices are required by industry standards for all electric hand-held hair dryers. If the hair dryer falls into water during use and is not equipped with this safety device, it can pose a shock and/or an electrocution hazard to consumers. Metropolis Beauty, Inc., (800) 871-6824 or www.metropolisbeauty.com.

Infant Booties. A small metal zipper tab on Faux-Shearling Infant Booties can detach posing a choking hazard to young children. L.L. Bean, (800) 555-9717 or www.llbean.com.

Inflatable Bounce Houses. The fan and the plastic housing surrounding the fan can break apart during use of the inflatable bounce house, posing a risk of impact injury to consumers. Sportcraft Ltd., (800) 511-0675 or www.sportcraft.com.

Low Pressure Cookers. Hot food under pressure can be expelled from Bella Cucina Brand "Zip Cooker" Low Pressure Cookers causing burn injuries. HSN LP, (800) 837-0372 or www.hsn.com.

Mason Jar Candles. The wick of Old Williamsburgh Mason Jar Candles, sizes 3.5 to 5.0 oz., can move from the center of the jar to the side causing the glass to overheat and possibly crack or shatter. Exposure to broken glass and molten wax poses laceration and burn hazards to consumers. Old Williamsburgh Candle Corp., (866) 564-1500 or www.oldwilliamsburgh.com.

Oscillating Tower Fans. Electrical arcing in Holmes(r) Oscillating Tower Fans' wiring can cause a fire hazard. The Holmes Group, (800) 524-9204 or www.holmesfanrecall.com.

Remote Controls. If the batteries are placed backwards in the Remote Control Sold With Insignia 100W DVD Compact Shelf System with the positive and negative sides improperly switched, overheating can result and present a burn hazard. Best Buy Co. Inc., (888) 809-7022 or www.BestBuy.com.

Sake Warmers. These sake warmers can unexpectedly spray hot sake on consumers during use, posing a risk of serious burns. Tap Machine Inc., (888) 556-0703 or www.sakewarmer.com.

Septic Pumps. The plug on Zoeller Brand Septic Pumps with a 20-foot black cord with a plug could have a grounding problem that could pose an electrical shock hazard to consumers. Zoeller Pump Co., (800) 928-7867 or customercare@zoeller.com.

Sippy/Tumbler Cups. The impact of being dropped or banged can cause the Sippy/Tumbler Cups to break into pieces, resulting in sharp or jagged edges that pose a laceration hazard to children. Mead Johnson Nutritionals, (800) 222-9123 or EnfamilResourceCenter@Enfamil.com.

Tankless Water Heaters. Components inside the Power Vent tankless water heaters may shift during transit, causing an air filter door switch to operate improperly. If the switch fails and the air filter door is out of place, the water heater could continue to operate and dust and lint could build up, posing a carbon monoxide poisoning hazard. Water Heating Division of Rheem Sales Company Inc., (866) 369-4786 or www.tankless-recall.com.

Tea Light Candles. Tea Lights Sold with Votive Candle Holders have a clear, plastic shell that can melt or ignite, posing a fire or burn hazard to consumers. Sally Foster, Inc., (866) 723-0925 or www.sallyfoster.com.

Toddler Pants. The zipper pull on the jacket of Toddler Pants Sets can detach, posing a choking hazard to young children. G & W Industries Inc., (212) 736-4848.

Adverse Reactions to Cough and Cold Meds Sent 1500 Babies to the Emergency Room in 2004, 2005

The Centers for Disease Control and Prevention (CDC) has found that children under age 2 are at risk for illness or even death if they are given prescription or over-the-counter cough and cold medicine.

More than 1,500 children under two were treated in emergency rooms across the United States for overdoses and other adverse reactions associated with the use of cough and cold products in 2004 and 2005, according to a new CDC report, published January 12 in the agency's weekly newsletter, *Morbidity Mortality Weekly Report*. The CDC report is available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.

In the report, the CDC made the following recommendations about administering cough and cold medications to children under 2 years of age:

> Caregivers and clinicians should be aware of the risk for serious illness or fatal overdose from administration of cough and cold medications to children aged [less than] 2 years. Caregivers should only administer cough and cold medications to children in this age group when following the exact advice of a clinician. Clinicians should be certain that caregivers understand 1) the importance of administering cough and cold medications only as directed and 2) the risk for overdose if they administer additional medications that might contain the same ingredient. Caregivers should always inform their health-care providers of all medications they are administering to a child.

In response to this report, the CDC and the National Association of Medical Examiners (NAME) investigated and identified three deaths in infants under six months of age. Coroners or medical examiners determined that the cause of death in the three infants was ingestion of cough and cold preparations.

The three infants who died ranged in age from 1 to 6 months. They all had high levels of the nasal decongestant pseudoephedrine (Sudafed) in their blood. (We list pseudoephedrine as a Do Not Use drug for children and adults because it can raise heart rate and blood pressure.)

Two of the infants received a single pseudoephedrine-containing drug, one prescription and one over-the-counter. The third infant had been given both a prescription and an over-the-counter cough and cold combination drug – each containing pseudoephedrine – at the same time.

Both of the infants who had been given a prescription had ingested a drug containing the antihistamine carbinoxamine.

There were also detectable blood levels of the cough suppressant dextromethorphan and acetaminophen (Tylenol), the popular pain and fever reducing drug, in the two infants who received over-the-counter medication.

The CDC made its estimate of emergency room visits with a national tracking system called the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS-CADES). This system was developed by the CDC, the Food and Drug Administration and the Consumer Product Safety Commission to estimate the number of patients who visit emergency rooms annually because of adverse drug reactions.

Experts: Cough and cold medicines could put kids at risk

These findings shouldn't come as a total surprise – there have been multiple official statements regarding

CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Toy Bunnies. The pink pompom nose of "Laugh and Learn" Learning Bunny Toys can detach, posing a choking hazard to young children. Fisher-Price, (866) 447-5003 or www.service.mattel.com.

Vases. The base of PARODI Glass Floor Vases can break off unexpectedly, posing a laceration hazard to consumers. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Water Coolers. A water leak inside Contact Hot and Cold Water Coolers can create an electrical arc, posing a fire hazard. DS Waters of America Inc., (800) 480-1434 or www.water.com/ContactRecall.

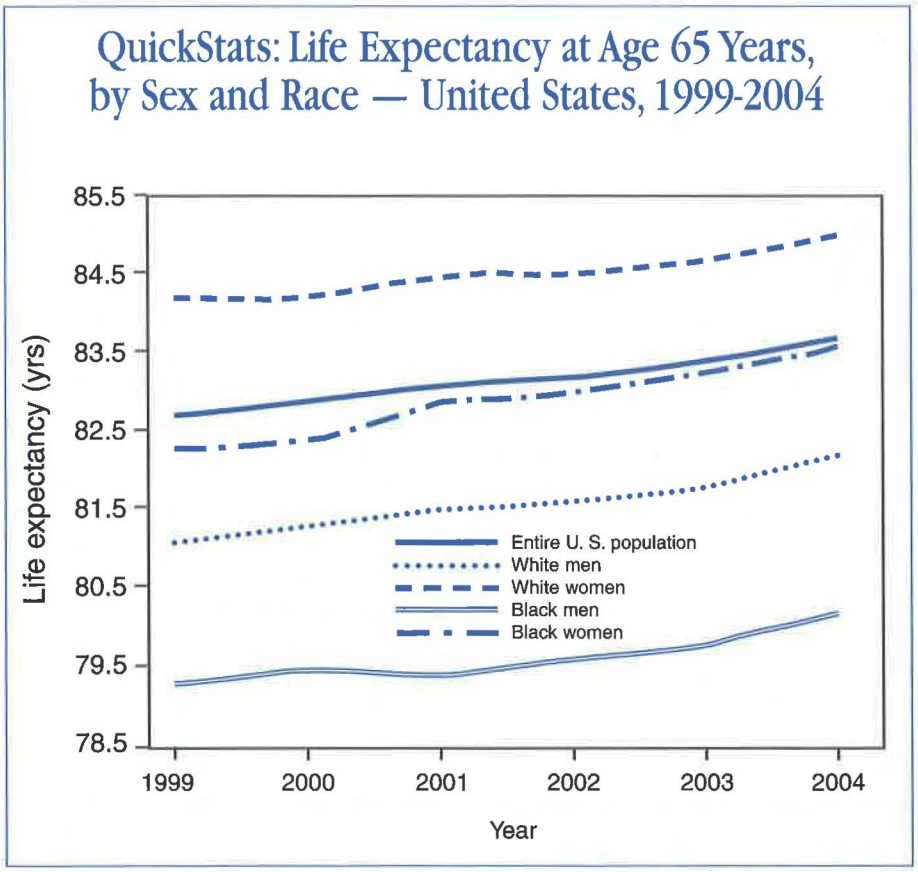
Youth Model ATVs. On the Arctic Cat 90cc DVX and Utility model All-Terrain Vehicles (ATVs), the handlebar base mounting bolts, tie-rod ends and tie-rod adjustment locking nuts may not have been tightened to the proper torque during the production process. Operating an affected ATV could cause components to loosen resulting in loss of steering control. This condition could result in loss of vehicle control which could result in injury or death. Arctic Cat Inc., (800) 279-6851 or www.arctic-cat.com.

American Life Expectancy On the Rise

On February 23, 2007, the Centers for Disease Control (CDC) released statistics in Morbidity and *Mortality Weekly Report* showing an average 1.0 year life expectancy increase for Americans from 1999 to 2004.

The graph above demonstrates the life expectancy trend. If you were a 65 year-old person in the year 2004, you could, as of 2004, expect to live, on the average, to be 83.6 years old, a year older than you would have if you had been 65 in 1999. White men can expect to live 1.1 years longer, white women can expect 0.8 years, and black men can expect 0.9 more years. More gains, between 1999 and 2004, have been made in the life expectancy for black women than for other groups, with an expected increase of 1.3 years for people in this group.

To find this information online, visit the CDC online at http:// www.cdc.gov/mmwr/preview/mmwrhtml/mm5607a5.htm?s_cid=mm5607a5_e. ■



COUGH AND COLD MEDS, *from page 6*

cough and cold management for children during the past decade.

In 1997, the American Academy of Pediatrics issued a policy statement advising that parents should be told that efficacy of the cough suppressants codeine and dextromethorphan in young children was unproven, and that there is a potential for adverse drug reactions.

In 2004, a systematic review done by the highly regarded Cochrane Collaboration, an international organization that reviews healthcare interventions, examined of controlled clinical trials of over-the-counter cough and cold products. It found them no more effective than a placebo in reducing acute cough and other symptoms of upper respiratory tract infection (such as a cold).

Two years later, the American College of Chest Physicians advised health professionals to stop recommending cough suppressants and other over-the-counter cough medications for young children because of associated adverse effects and the possibility of death.

Children are not little adults, and they may handle drugs differently.

Small children require different doses of medications

No FDA-approved over-the-counter products have dosing recommendations for children under 2 years old. Consumers are advised to consult their doctor for this age group.

Clinicians and health professionals commonly extrapolate a dose based on the patient's age or weight for children younger than 2. Such an extrapolation is based on assumption – which may not be true – that the effects of drugs are similar in adults and children. Children are not little adults, and they may handle drugs differently.

What You Can Do

The common cold is a mild, self-limiting condition that will resolve in about seven days whether it is treated or not. Colds are caused by a virus and antibiotics do not work against viruses; antibiotics should therefore not be used to treat colds.

Prescription and over-the-counter cough and cold medications should not be used in children younger than 2 years of age. ■

Colds: How to Treat Them

This article was originally printed in the February 1993 edition of Health Letter. *We are reprinting it again to help cold-sufferers best treat their ailments.*

What largely seasonal complaint sends Americans to their pharmacies in droves this time of year? There are probably several answers. But the one we have in mind is none other than the common cold. Believe it or not – and despite all the advertising suggesting otherwise – this all-too-familiar problem is usually best treated with little use of most of the products that pharmacies have for sale.

For one thing, no drug has rigorously been shown to kill rhinoviruses, the cause of common colds, so the many non-prescription products available for colds, at best, temporarily relieve their symptoms. For another, some of these products contain ingredients that are not appropriate even for symptomatic relief.

Non-Drug Measures

The best way to treat a cold is to let it run its course, being sure at the same time not to smoke, to get enough rest and to drink at least three to 10 full glasses of non-alcoholic liquids a day. Warm or hot beverages including water tend to be more soothing than those that are cold.

It is also important for people with colds to try not to touch their eyes, mouths and noses and, out of consideration for others, to wash their hands with soap and hot water frequently and thoroughly. Studies have shown that the viruses that cause colds are more readily spread by contaminated hands than through the air.

The hand-washing habit, incidentally, is also a good one to develop to minimize the chances of catching a cold from someone else. So is avoiding cigarettes. Smokers are more susceptible to colds than their non-smoking counterparts because smoking paralyzes the cilia or hairlike cells in the nasal passages which serve to keep the nasal passages clean.

Stuffy Nose

If your nose starts running when you have a cold, it's best to grin and bear it, if possible. As inconvenient and uncomfortable as that may be, it's the body's way of removing the offending virus and correcting the inflammation it has caused. Unless things get to the point where instead of "running," your nose is stuffed-up, especially so much so that you can't breathe or sleep at night or your ears are affected, it's best to leave well enough alone. Under those circumstances, a nasal decongestant in the form of nose drops, spray inhalers or nasal sprays may be worthwhile.

Drugs Not to Use

While we're on the subject of nasal decongestants, do not share the containers with anyone else; doing so can spread the infection.

And before buying any of these products, check to he sure what's in them. For instance, some contain chlorpheniramine maleate, an antihistamine. Studies have shown that antihistamines are not useful in treating cold symptoms.

Other products to avoid are those that contain so-called anticholinergics such as belladonna alkaloids or atropine sulfate. According to the Food and Drug Administration (FDA), their property of drying up runny noses is the very reason they should be avoided. They may cause coughing in the process or the formation of plugs of nasal secretions that block air passages and so interfere with proper functioning of the lungs. These drugs also can cause constipation, dry mouth, sleeplessness, excitement, confusion, rapid heartbeat and blurred vision and, for people with glaucoma, can be downright dangerous.

Moreover, more often than not, over-the-counter (non-prescription) cold remedies containing an antihistamine or an anticholinergic also have other ingredients. This is true, in fact, of most cold remedies. Among the many reasons not to use these combinations is that not all of those ingredients are likely to be well suited to relieving your symptoms. Even if all of them were suitable, each is present in a fixed amount. Chances are that to get enough of one ingredient that is really useful you would have to overdose on another. (Incidentally, the same is true of all non-prescription remedies whether for colds or not.)

Safe & Effective Drugs for Stuffy Noses: What Products Are Appropriate?

The answer – though it means reading the fine print ingredient labeling of prospective purchases – is to stick to products containing a chemical found safe and effective for the purpose by an FDA scientific advisory panel. Specifically, the panel found acceptable for use in sprays, drops or inhalers ephedrine preparations and naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride and xylometazoline hydrochloride.

However, Public Citizen's Health Research Group does not recommend one of these drugs – naphazoline hydrochloride – because one dose of it can cause rebound congestion (an increase in nasal stuffiness) after the medication wears off and delay recovery from a cold. In addition, the panel endorsed for nasal decongestant inhalers only (not for nose drops or nasal sprays) propylhexedrine and l-desoxyephedrine – either alone or in combination with aromatics (chemicals that give off a vapor) such as camphor, methylsalicylate, bornyl acetate and lavender oil. Note, however, that these aromatics – while pleasing to some people and offensive to others – do not in themselves generally do anything useful for a cold. Be careful not to use any of these products for more than three days at a time. Otherwise, you risk "rebound congestion." As seriously, longer use can lead to dependence on these products which can be very difficult to break.

Oral Decongestants

In general, it is best to avoid oral decongestants for an illness as short-lived as the common cold because safer and faster relief usually can be obtained from a nasal spray, an inhalant, or nose drops. Among other things, the relatively high doses (compared to the amounts in sprays or nose drops) of decongestant in oral products can increase blood pressure even in people with low blood pressure.

These oral formulations are potentially dangerous for everyone, especially those with high blood pressure, heart disease, thyroid disease or diabetes. They are also contraindicated for people given so-called monoamine axidase (MAOI inhibitors) – such as Marplan, Nardil or Parnate – to help them battle depression.

A further disadvantage of oral decongestants is that they may contain an ingredient that is safe and effective when applied to the nose, but has not gotten this endorsement when taken by mouth. Ephedrine sulfate is an example of such an ingredient. To be sure, a health professional may occasionally recommend an oral decongestant in the treatment of an illness that persists longer than the typical cold. In such cases, however, a single-ingredient product is preferable and it is important not to exceed the recommended dose. Additionally, if symptoms do not improve within a week, a health professional should be consulted before a cold sufferer continues to take any of these drugs.

Fever

Fever, headache, and muscle aches are sometimes fellow travelers of the common cold. They are best treated without drugs – in other words, with rest and adequate fluids – or with plain aspirin or acetaminophen. *However, never give a feverish person who is less than 40 years old aspirin because he or she may have influenza, rather than a cold. There is strong evidence that young people who take aspirin when they have flu (or chicken pox) have a greatly increased risk of later getting Reyes Syndrome, a rather rare but potentially fatal disease that often leaves its victims impaired for life, if they survive.*

In addition, a fever over 103°F (39.4°C) or 100°F (38°C) that lasts for more than four days calls for consulting a health professional. In either of these situations, the patient probably doesn't have a cold.

Cough

Your lungs clean themselves constantly in order to maintain efficient breathing. Mucus normally lines the walls of the lungs and captures foreign particles such as inhaled smoke and infecting virus particles. Hair-like cells push this out of the lungs. Coughing adds an additional, rapid-fire means of removing unwanted material from the lungs.

A cough is beneficial as long as it is bringing up material such as phlegm from your airways and lungs. This is called a "productive" cough. A dry, hacking, "non-productive" cough, on the other hand, can be irritating and keep you awake at night. You should seek out medical advice if your phlegm becomes greenish, yellowish, or foul smelling; if your cough is accompanied by a high fever lasting several days; if coughing or breathing deeply causes sharp chest pain; or if you develop shortness of breath-you may have pneumonia. Anyone who coughs up blood should consult a health care professional.

Treating a Cough

A *productive cough* is useful in helping you recover from cold or flu and you should do what you can to encourage the clearance of material from your lungs by "loosening up" the mucus. This is the purpose of an expectorant, which thins secretions so that they can be removed more easily by coughing (or "expectoration"). The best expectorant is water, especially in warm liquids such as soup, which thins the mucus and increases the amount of fluid in the respiratory tract. A moist environment also helps this effort. You should drink plenty of liquids and, if you can, moisten the air with a humidifier or plain water steamed by a vaporizer. A pan of water on the radiator can help in the winter.

A *non-productive cough* – a dry cough bringing up no mucus – may be treated with a cough suppressant, also called an antitussive. A cough which keeps you up at night or is extremely exhausting may also call for the use of one of these agents. Cough suppressants should be used in a single-ingredient product. Rest and plenty of fluids are also in order.

Over-the-Counter (OTC) Products for Cough

OTC products to treat a cough contain either an expectorant or an antitussive (a cough suppressant). Of these products, the only type we recommend is a single-ingredient cough suppressant to treat a dry, non-productive cough.

Expectorants

Many OTC cough remedies contain ingredients called expectorants, which are supposed to promote clearing of mucus from the lungs. In theory, this is a wonderful idea. Unfortunately, an FDA advisory panel review of the marketed expectorants found that all OTC expectorants lack evidence of effectiveness. This includes ingredients in many widely marketed and sold products.

Some expectorants which lack evidence of effectiveness are guaifenesin, sodium citrate, ammonium chloride, eucalyptus oil, menthol, terpin hydrate preparations and spirits of turpentine Some ingredients, such as ipecac fluid extract (in *Cerose DM*), lack evidence of safety as well.

Cough Suppressants

For the occasional bothersome, non-productive cough, a variety of ingredients and combinations of cough suppressants are available. Of these, we recommend a single ingredient. The FDA advisory panel reviewed all of the cough suppressants in OTC products and classified only two as safe and effective: dextromethorphan hydrobromide and codeine.

Dextromethorphan should be your choice if you need an over-the-counter medicine to stop a non-productive cough. If you can, use a product which contains it as a single ingredient to avoid the unpleasant side effects and expense of additional ingredients.

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COLDS, *from page 9*
Unfortunately, this effective product is not readily available in the necessary dosage in many drugstores. We recommend that you buy a generic or store brand product if available: some more expensive brand name products with dextromethorphan include *Hold, St. Joseph s Cough Syrup for Children* and *Sucrets Cough Control Formula.*

Dextromethorphan acts on the cough center in the brain to suppress cough. It is a highly effective, non-narcotic drug with few side effects. Overdosing can slow breathing so carefully judge the amount needed. Read the label to find the concentration of the product. A proper dose is 10 to 20 mg every four hours for adults, 5 to 10 mg for children 6 to 12 years and 2.5 to five mg for children 2 to 6 years. Children under 2 should not be treated with drugs for cough without medical supervision.

If you are unable to find any plain, single-ingredient dextromethorphan-containing products, and you need a cough suppressant, it may be necessary to use a combination product. If this is the case, try one with guaifenesin such as *Cough Culmers* or *Robitussin PM*, or a less expensive generic or store brand equivalent; ask your pharmacist to stock a generic, single ingredient dextromethorphan product in the future.

Diphenhydramine hydrochloride (in *Benylin Cough Syrup*) was approved by the FDA in September 1981 as an OTC antitussive, separate from their OTC review process. Diphenhydramine is an antihistamine also sold as a sleep aid. (It is the sole active ingredient in *Compoz*, *Nytol* DPH and *Sominex Formula 2.*) It has a strong sedative effect, and other antihistamine side effects.

Diphenhydramine should not be used in situations where mental alertness is required or when a drying effect (of the nose, throat, and mouth) may be unwanted as is often the case with a cold. Because of its sedative effect, it shouldn't be used with any tranquilizers, sedatives or alcohol (which is five percent of Benilyn Cough Syrup). We cannot recommend the use of this product. In our opinion, dextromethorphan is a safer alternative.

Lozenges containing menthol are widely marketed for sore throats (which are discussed in the next section). An FDA advisory panel found that these products lack evidence of effectiveness as cough suppressants. The FDA has started the process of reclassifying menthol in lozenges as safe and effective as a topical (on the surface) cough suppressant. Menthol acts locally in the throat, rather than centrally in the bran, as do other cough suppressants. Don't take more than one menthol lozenge an hour. If you find them ineffective and are still bothered by a cough, try a medicine with dextromethorphm. Menthol-containing lozenges include *Halls Mentholyptus*, *Nice* and *Victors*: a number of generic and store-brand products are also available. For a mild cough related to a dry throat, sucking on a hard, sour candy may do as well.

Chest rubs containing menthol, camphor, eucalyptus oil, thymol, oil of turpentine, cedarleaf oil, and myristica oil (the combination in *Vicks Vaporub*) were found by an FDA advisory panel to lack effectiveness. Based on studies of artificially-induced cough, in normal, healthy people (rather than of people with cough from colds), the FDA started the process of reclassifying the ingredients in *Vaporub* as safe and effective as an antitussive. Nevertheless, we do not recommend the use of chest rubs like *Vaporub*. A chest rub can neither soothe the throat as a sour candy does nor affect the cough center in the brain as dextromethorphan does.

Combination products for cough are not recommended to treat your ailment. When you are unable to find the plain ingredient you are looking for, the only combination product you should consider is one which contains the single ingredient you need (such as dextromethorphan) along with a safe though ineffective ingredient (such as guaifenesin). Ask your pharmacist to stock good single-ingredient products so that you take only the medicine you need. Examples of combination cough remedies which should not be used under any circumstances include *Robitussin CF*, *Robitussin PE*, and *Triaminic Expectorant*. They all contain additional ingredients that we do not recommend. ■

OUTRAGE, *from page 12*
posed by their diseases? Or is the purpose to make them dissatisfied enough that they will seek treatment?

The film is nothing more than an attempt to blur the line between art and commerce. And the enterprise depends entirely on subterfuge. If not, why would Remicade not be mentioned at all and the sponsor's name be squirreled away in the credits? Last time we looked, Warner Brothers didn't do it that way. And if the film truly was not intended to promote Remicade, however indirectly, why didn't the filmmakers follow some patients with diseases the drug doesn't treat?

These sorts of quasi-commercials have another advantage: they can evade meaningful oversight from the FDA, which would require an ad mentioning both Remicade and rheumatoid arthritis, for example, to list the drug's major side effects such as increased susceptibilities to tuberculosis and certain cancers. Another little detail the drugumentary fails to disclose: the week before the Oscars, Centocor received a subpoena related to its pricing practices for Remicade. And the Service Employees International Union has filed a class action lawsuit against the company related to the same practices.

A movie about fraud in the pharmaceutical industry: now that's a drugumentary we'd like to see. ■

And the Oscar for the Best Drugumentary Goes to ...

Is it just us, or does the annual Academy Awards hypefest seem a little shopworn? How much longer can we be expected to endure acceptance speeches thanking high school teachers or winks directed at kids who ought to be in bed anyway? And what exactly is "art direction"? Come to think of it, couldn't we just have some new award categories to keep us awake till "Best Picture"?

Seems that very question has crossed the minds of execs in the drug industry. With growing signs that the public has overdosed on direct-to-consumer ads that seek to convince us that our arteries are too hard or our erections too soft, the industry needs a new outlet. Lo and behold ... the drugumentary!

The first entry into this new cinematic category is a 60-minute "documentary" called InnerState, paid for by Centocor, a branch of Johnson & Johnson that produces Remicade (infliximab). Remicade is approved by the Food and Drug Administration (FDA) to treat rheumatoid arthritis, Crohn's Disease and psoriasis. It has been reeling from competition from similar drugs that, unlike Remicade, do not have to be injected in a doctor's office.

The film follows three patients who suffer from the three aforementioned diseases. It highlights the impact of these diseases on the patients' overall quality of life, thus emphasizing the need for patients to seek medical attention. Missing, though, is any mention of Remicade, and disclosure of Centocor's involvement appears only at the tail end of the credits. It will be rolled out in movie theaters in fourteen cities starting with the film industry-standard "premiere" in New York City.

Screenings will be free and the guest lists will include members of patient advocacy groups such as the National Psoriasis Foundation and the Crohn's & Colitis Foundation of America. In a kind of perfect storm of marketing manipulation, both foundations accept financial support from Centocor.

"This is definitely not a 60-minute infomercial," said Michael Parks, a Centocor spokesperson who doubles as the film's Executive Producer, "The intent is really to educate patients in a meaningful way." Really? Do patients who belong to patient advocacy groups need to be educated by a drug company about the hardships

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