PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Q&A on the Human Papilloma Virus Vaccine Gardasil

Heard the one about the right-wing Southern governor who ignored required legislative procedures and ordered 11-year-old girls to be vaccinated against a sexually transmitted disease? Here's the punchline: it actually happened.

Yes, Texas Governor Rick Perry, successor in fact and in small-government philosophy to President George W. Bush, actually signed an Executive Order requiring sixth grade girls in Texas to be vaccinated against the human papilloma virus (HPV), the cause of most cases of cervical cancer. In so doing, he cast aside the concerns of his political base that the vaccine would unleash a torrent of unfettered sexual activity among teens otherwise preoccupied with HPV.

Here's a hot tip: whenever you see apparently incongruous political behavior, the first question you should ask is "Where's the money?" Turns out that simple line of inquiry would have solved this erstwhile mystery. For starters, Perry's former chief of staff Mike Toomey has found a new (and presumably more lucrative) lease on life with Merck, manufacturer of the HPV vaccine Gardasil. And on the very day that Perry's staff met with Merck about the Executive Order, a $5,000 check from the company made its way into the governor's coffers. Add to that Merck funding of a group of female state legislators called Women in Government, many of whom introduced mandatory vaccination bills in their respective states, and you have all the ingredients for a sordid political stew.

But just because self-interested corporate behavior is at the root of an initiative does not prove that the initiative is not worthwhile. Cervical cancer takes the lives of some 3,700 American women each year. Preventing these deaths is obviously an end worth pursuing. In this article we provide a Q&A on the HPV vaccine that is based on questions about the vaccine we have received at the Health Research Group.

Why do we need a vaccine when cervical cancer is rare and actually declining?

It is true that cervical cancer is becoming less common in the US. This is probably the result of increased condom use, due to concern about HIV/AIDS, and improved access to pap smears. But in 2006, there were still 9,710 cases of cervical cancer and 3,700 deaths. Even the majority of patients who are cured have to endure years of treatment and anxiety about recurrence. Certainly, the fact that a deadly disease is becoming less common is not a convincing argument to downplay it, and few parents hesitate to vaccinate their children against chicken pox, which takes considerably fewer lives than cervical cancer.

Can't pap smears prevent cervical cancer? If so, why is the HPV vaccine necessary?

Pap smears are one of the great medical innovations of the 20th century, having saved the lives of tens of thousands of women. The problem is that this effective intervention is underutilized, particularly among poor Americans with limited access to health care. It is in this

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HPV VACCINE, *from page 1*
group that the HPV vaccine will have the greatest benefit.

Is the HPV vaccine effective in preventing cervical cancer?

The FDA approved the HPV vaccine primarily on the ground that the vaccine reduced the rate of new cases of cervical cell abnormalities called dysplasia. Experts agree that dysplasia is a necessary precursor of cervical cancer (although some cases of dysplasia resolve spontaneously) and that any intervention that reduces dysplasia should reduce cervical cancer rates. In the context of clinical trials, which only last a few years, cervical cancer is quite rare, so it is difficult to demonstrate a decrease in new cases of cancer that is statistically credible. That's why the researchers examined the impact of the vaccine on dysplasia, which is considerably more common than cervical cancer.

Will the HPV vaccine prevent all cases of cervical cancer?

The current HPV vaccine is designed to protect against HPV subtypes 16 and 18, which are responsible for 70 percent of cases of cervical cancer, and HPV subtypes 6 and 11, which cause 90 percent of genital warts. It is not known to be effective against any of the other HPV subtypes.

How effective was the HPV vaccine in reducing the rate of dysplasia?

Among women who had not been exposed to the relevant HPV subtypes and who received all three shots in the vaccination series, the vaccine prevented between 95 percent and 100 percent of cases of cervical dysplasia. Not surprisingly, effectiveness rates were lower (39 percent to 46 percent) if one combined the data from women with and without HPV exposure at the beginning of the study and included women who may not have completed the vaccination series. This provides an argument for earlier vaccination in that people who have not initiated sexual activity are unlikely to be infected with HPV. Importantly, the HPV vaccine does not treat existing cases of cervical cancer, dysplasia, or genital warts.

Does the HPV vaccine protect against other forms of cancer?

Certain strains of HPV have been linked to cancers of the anus, female external genitalia, penis, vagina, throat, and mouth. Researchers are studying both women and men to determine whether the HPV vaccine is effective in preventing cancers due to HPV infection in these areas. However, the vaccine is currently only approved for the prevention of cervical cancer.

Here's a hot tip: whenever you see apparently incongruous political behavior, the first question you should ask is "Where's the money?"

Won't the HPV vaccine cause women to not get their pap smears?

This question has not been studied and is a legitimate subject for future research. But there would have to be large numbers of women foregoing pap smears before the benefits of the vaccine in women not exposed to HPV would be exceeded. Women who have received the HPV vaccine should continue to have pap smears just as frequently as before they were vaccinated.

Won't the HPV vaccine cause an increase in teen sexual activity?

While this has also not been studied, this seems very unlikely to us. Of all the factors young women (and men) take into consideration when deciding whether to have sex, a vaccination, years previously, against an infection they may not have heard of seems unlikely to rank high.

Why can't the vaccine be made voluntary instead of being required?

Studies show that mandatory vaccination programs, usually linked to school attendance, have much higher participation rates. Moreover, outbreaks of meningitis, measles, and much more have resulted from refusals to participate in vaccination programs. All of the HPV vaccination programs proposed allowed some exception for parental refusal but varied in the breadth of that exemption.

Why do the proposed vaccination programs involve girls so young (and why only girls)?

Merck's data show much lower effectiveness rates when the patient is already infected with HPV, so it is important to vaccinate young women before they become infected, ideally before they begin sexual activity. The fact is 60 percent of high school seniors are already sexually active. Because early studies focused on dysplasia prevention in women, the effects of the vaccine on men and boys are not yet known, but studies are ongoing.

Is the HPV vaccine effective in younger teens?

The primary studies of the vaccine involved women aged 16-26 years, yielding the results noted previously. In additional studies of women aged 9-15 years, similar antibody levels were seen as in the older age group, and so the effectiveness in young women was inferred. (Antibodies are chemicals made by the body in response to exposure to outside stimuli such as vaccines or infections and frequently correlate with vaccine effectiveness. It is common in the vaccine field to use antibody data to explore vaccine effectiveness.) Cervical dysplasia (let alone cervical cancer) is too rare for investigators to see enough cases in a study of young women to prove that the vaccine reduces new cases.

Is it true that the HPV vaccine is the first for a sexually transmitted disease?

No; hepatitis B is also spread by

sexual contact (as well as by drug injection, hospital needlesticks, and from mother to infant) and the vaccine is now administered to babies before they leave the hospital after birth.

Is the vaccine safe?

Studies of the vaccine show that toxicity was limited, usually restricted to pain and tenderness at the injection site (84 percent and 25 percent respectively). There are, however, few data on long-term toxicity due to the limited length of the trials conducted. This leaves many questions unanswered. The FDA recommends against use in pregnant women, though there is no evidence that it is toxic to the developing fetus.

Do we know whether the vaccine will work in the long term?

The longest study of the HPV vaccine was four years long. Such study durations are common for newly approved vaccines. Some patients who have received the vaccine will be followed to see if their antibody levels decline and thus if they (and others) would require a booster injection.

This vaccine is very costly. How am I supposed to pay for it?

At $360 for the full three-injection series, that is certainly so. Some states' proposals inappropriately required vaccination, but did not provide for funding. In other states, some funding was provided. If we had a national health insurance program in this country, the vaccine could be added to those covered and the problem of lack of funding would be more manageable.

Among women who had not been exposed to the relevant HPV subtypes and who received all three shots in the vaccination series, the vaccine prevented between 95 percent and 100 percent of cases of cervical dysplasia.

Isn't it true that the studies were funded by a drug company and so the results are suspect?

It's true that the studies were funded by Merck itself, but this is standard practice in the drug and vaccine industries. We have advocated that drug companies be required to pay into a pool and that neutral scientists should conduct and analyze drug and vaccine studies. But until this proposal is accepted, most studies of new products will be conducted by their sponsors. While this should always make one skeptical of the results reported, one cannot simply dismiss studies solely on the basis of who is their sponsor. To do so would lead to refusing to take almost all drugs.

This vaccine has been the subject of inappropriate lobbying by the manufacturer. Shouldn't I mistrust any legislative requirement that may ensue?

We certainly agree that the lobbying for this product has been unseemly. In its greed to maximize profit and its desire to gain a solid foothold before another HPV vaccine is approved, as is expected, Merck opted for the hard sell. It is unusual for a vaccine to be mandated so early in its lifespan. A better course would have been to wait for more safety data to accumulate and then sell the vaccine on its scientific merits, rather than by heavy-handed lobbying.

Will people in the developing world ever have access to the vaccine?

The vast majority of cervical cancer cases occur in the developing world; lack of access to pap smears is a major contributor to the 233,000 annual deaths from this disease. At present, however, there is little evidence that this vaccine will be made available at prices affordable to those in the developing world. This is a tragedy, as it represents a major lost opportunity to save the lives of women worldwide. ■

Editor.....*Sidney M. Wolfe, MD*
Managing Editor.....*Kate Resnevic*
Contributors.....*Peter Lurie, MD, MPH*
Annette Ramírez de Arellano, DrPH
Kate Resnevic
Proofreader.....*Shiloh Stark*
Production Mgr......*Kristy I. Jackson*
President.....*Joan Claybrook*

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

May 23, 2007 — June 23, 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 II

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

Recall Note

A misbranding incident at Heartland Repack Services, LLC, has resulted in a recall of multiple drugs. There is the possibility of multiple product packaging mix-ups. An over-the-counter drug, prescription drug, or nutritional supplement other than what is indicated on the product labeling may be inside the packaging. Ask your pharmacist to find out if your sample is part of the recalled batch.

Acetaminophen 325mg, Acetaminophen 500mg Caplet, Gelcap and Tablet, Acetaminophen/cod#3 300/30mg, Acetaminophen/cod#4 300/60mg; Acetazolamide 250mg; Albuterol Sulfate 2mg and Albuterol Sulfate 4mg; Allopurinol 100mg and Allopurinol 300mg; Alprazolam 0.25mg, Alprazolam 0.5mg, and Alprazolam 1mg; Amantadine 100mg; Amiodarone 200mg; Amitriptyline 100mg, Amitriptyline 25mg, and Amitriptyline 50mg; Aspirin 325mg; Aspirin Buffered 325mg; Aspirin Chew 81mg; Aspirin ec 325mg and Aspirin ec 81mg; Atenolol 100mg, Atenolol 25mg, and Atenolol 50mg; Azathioprine 50mg; Baclofen 10mg and Baclofen 20mg; Benzonatate 100mg; Benztropine 0.5mg, Benztropine 1mg, and Benztropine 2mg; Bisacodyl 5mg; Bumetanide 0.5mg, Bumetanide 1mg and Bumetanide 2mg; Bupropion 100mg and Bupropion 75mg; Buspirone 10mg, Buspirone 5mg, and Buspirone 7.5mg; Captopril 12.5mg; Captopril 25mg and Captopril 50mg; Haloperidol 0.5mg, Haloperidol 10mg, Haloperidol 1mg Tablet, Haloperidol 2mg, and Haloperidol 5mg; Hydralazine 25mg, Hydralazine 50mg; Hydrochlorothiazide 12.5mg and Hydrochlorothiazide 25mg; Hydrocodone/Apap 5/500mg, Hydrocodone/Apap 7.5/500mg; Hydroxyzine 25mg; Ibuprofen 200mg, Ibuprofen 400mg, Ibuprofen 600mg, and Ibuprofen 800mg; Imipramine 10mg, Imipramine 25mg, and Imipramine 50mg; Indomethacin 25mg; Isoniazid 300mg; Isosorbide Dinitrate 10mg, Isosorbide Dinitrate 20mg, Isosorbide Dinitrate 30mg, and Isosorbide Dinitrate 5mg; Isosorbide Mononitrate 10mg and Isosorbide Mononitrate 20mg; K-Tab 10meq; Labetalol 100mg, Labetalol 200mg, and Labetalol 300mg; Lisinopril 10mg, Lisinopril 2.5mg, Lisinopril 20mg, Lisinopril 30mg, and Lisinopril 40mg; Lisinopril/Hctz 10/12.5mg and Lisinopril/Hctz 20/12.5mg; Loperamide 2mg; Loratadine 10mg; Lorazepam 0.5mg and Lorazepam 2mg; Lovastatin 10mg and Lovastatin 40mg; Meclizine 12.5mg and Meclizine 25mg; Metformin 1000mg and Metformin 500mg; Methazolamide 50mg; Methocarbamol 500mg, Methocarbamol 750mg, Methyldopa 250mg; Metoclopramide 10mg and Metoclopramide 5mg; Metoprolol Tartrate 100mg, Metoprolol Tartrate 25mg, and Metoprolol Tartrate 50mg; Metronidazole 250mg; Metronidazole 500mg; Minocycline 100mg; Minoxidil 2.5mg; Multivitamins, Ther W-Minerals Tablet; Multivitamins, Therapeutic Tablet; Naltrexone 50mg; Naproxen 250mg, Naproxen 375mg, Naproxen 500mg; Nifediac Er 30mg, Nifediac Er 60mg and Nifediac Er 90mg; Nifedipine 10mg; Nitrofurantoin 100mg; Nortriptyline 10mg, Nortriptyline 25mg, Nortriptyline 50mg, and Nortriptyline 75mg; Oxybutynin 5mg; Oyster Shell 500mg.

Name of Drug or Supplement; Problem; Recall Information

Armour Thyroid (thyroid tablets, USP), 3 grain (180 mg); Printing error on bottle label incorrectly states 144 mcg Levothyroxine (T4) per tablet. Label should state 114 mcg Levothyroxine (T4) per tablet. Lot #s: 010711, exp. date 06/2008; 030714, exp. date 07/2008; 030723, exp. date 08/2008; Forest Pharmaceuticals Inc.

Recalls and Field Corrections: Drugs — CLASS II *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

Cooldent-Coolmint Ice Toothpaste & Toothpaste/Brush Combo, 6.4 oz tubes, labeled ingredients include Sodium Monofluorophosphate 0.5% and Diglycol. UPC barcodes: 8-40929-03901-5 & 8-40929-03903-9; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). Item Numbers: S3901(toothpaste with toothbrush) & S3903 (toothpaste only); Goldcredit International Enterprises.

Cooldent-Fluoride Toothpaste & Toothpaste/Brush Combo, 6.4 oz tubes, labeled ingredients include Sodium Monofluorophosphate 0.5% and Diglycol. UPC barcodes: 8-40929-03907-7 & 8-40929-03908-4; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). Item Numbers: S3907 (toothpaste only) & S3908 (toothpaste with toothbrush); Goldcredit International Enterprises

Cooldent-Spearmint Toothpaste & Toothpaste/Brush Combo, 6.4 oz tubes, labeled ingredients include Sodium Monofluorophosphate 0.5% and Diglycol. UPC barcodes: 8-40929-03904-6 & 8-40929-03906-0; Toothpaste from China contains the poisonous chemical diethylene glycol (DEG). Item Numbers: S3904 (toothhpaste only) & S3906 (toothpaste with toothbrush); Goldcredit International Enterprises.

Levothroid (levothyroxine sodium tablets, USP), 25 mcg, 100- and 1,000-tablet bottles; Product may not maintain potency throughout shelf life. Lot #s: 020652, 020653 exp. date 02/2007; 040601, 040623 exp. date 03/2007; 060602, 060603 exp. date 05/2007; 060641, 060642, exp. date 06/2007; 070627, 070628, exp. date 07/1007; Lloyd Inc.

Levothroid (levothyroxine sodium tablets, USP), 50 mcg, 100- and 1,000-tablet bottles; Product may not maintain potency throughout shelf life. Lots #: 020655, 020654, exp. date 02/2007; Lloyd Inc.

Levothroid (levothyroxine sodium tablets, USP), 137 mcg, 100- and 1,000-tablet bottles; Product may not maintain potency throughout shelf life. Lot #s: 110545, 110544, exp. date 03/2007; Lloyd Inc.

Levothroid (levothyroxine sodium tablets, USP), 50 mcg, 100- and 1,000-tablet bottles, RX, NDC 0456-1321-01 (100 tablets) and 0456-1321-00 (1,000 tablets); Product may not maintain potency throughout labeled shelf life. Lot #s: 040602, 040603, 040624, exp. date 03/2007; 050606, 050608, exp. date 04/2007; 060607, 060613, exp. date 05/2007; 060643, 060644, 060658, 060660, 070610, exp. date 06/2007; 070629, 070631, 070632, 070641, 070642, exp. date 07/2007; 080648, 080655, 080660, 080661, exp. date 08/2007; 090641, 090642, exp. date 09/2007; Lloyd Inc.

Miracle II, by Tedco, Miracle Neutralizer, Nature's Miracle for the Total Body, Sopi' H20, Biodegradable, 22 oz (638 mL), 1 gal, 5 gal, 15 gal, and 55 gal; This is an extension of a recall initiated in January 2006 due to microbial contamination. Because these products have no code number, but have similar labeling, they cannot be distinguished from product having microbial contamination. Recall includes all product without a code number distributed between January 3 and April 7, 2006; Tedco, Inc.

Miracle II, by Tedco, Neutralizer Gel, Nature's Miracle for the Total Body, Sopi' H20, Biodegradable, 8 oz (232mL), 22 oz, 1 gal, 5 gal, and 15 gal; This is an extension of a recall initiated in January 2006 due to microbial contamination. Because these products have no code number, but have similar labeling, they cannot be distinguished from product having microbial contamination. Recall includes all product without a code number distributed between January 3 and April 7, 2006; Tedco, Inc.

Miracle II, by Tedco, Neutralizer Gel, Nature's Miracle for the Total Body, Sopi' H20, Biodegradable, 7X, 8 oz (232mL), 22 oz, and 1 gal; This is an extension of a recall initiated in January 2006 due to microbial contamination. Because these products have no code number, but have similar labeling, they cannot be distinguished from product having microbial contamination. Recall includes all product without a code number distributed between January 3 and April 7, 2006; Tedco, Inc.

Miracle II, by Tedco, Neutralizer, Nature's Miracle for the Total Body, Sopi' H20, Biodegradable, 2X, 22 oz (638 mL) and 1 gal; This is an extension of a recall initiated in January 2006 due to microbial contamination. Because these products have no code number, but have similar labeling, they cannot be distinguished from product having microbial contamination. Recall includes all product without a code number distributed between January 3 and April 7, 2006; Tedco, Inc.

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Recalls and Field Corrections: Drugs — CLASS II *cont'd.*

Name of Drug or Supplement: Problem: Recall Information

Miracle II, by Tedco, Neutralizer, Nature's Miracle for the Total Body, Sopi' H20, Biodegradable, 3X, 22 oz (638 mL) and 1 gal; This is an extension of a recall initiated in January 2006 due to microbial contamination. Because these products have no code number, but have similar labeling, they cannot be distinguished from product having microbial contamination. Recall includes all product without a code number distributed between January 3 and April 7, 2006; Tedco, Inc.

Thyro-Tab (levothyroxine sodium tablets), 0.050mg, 150,000-tablet bulk drums intended for repackaging; Product may not maintain potency throughout labeled shelf life. Lot #s: HA05206, HB05206, HC05206, HA08606, HB11406, HC11406, HB14306, HC14306, HD14306, HA17806, HB17806, HC17806, HB20206, HC20206, HB23606; 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: Manufacturer and Contact Information

ATVs. The Polaris "Outlaw 525" ATVs may have a loose fuel valve within the fuel tank, which could cause a fuel leak and pose a fire hazard to riders. Polaris Industries Inc., (800) 765-2747 or www.polarisindustries.com.

ATVs. The Polaris Model Year 2006 Hawkeye 2x4 and Hawkeye 4x4 ATV's front bearing carrier can fail due to an insufficient amount of material thickness in the area where the lower a-arm and ball joint are attached which can result in a loss of control and a crash and/or serious injury to the operator. The steering posts can break in the area where the handlebar attaches to the steering post. This can result in loss of steering control resulting in a crash and/or serious injury to the operator. Polaris Industries Inc., (800) 765-2747 or www.polarisindustries.com.

Bicycles. Bicycles with Carbon Cranksets' crankset could break, posing a fall hazard to user. Cannondale Bicycle Corp., (800) BIKEUSA (245-3872) or www.cannondale.com.

Birthday Party Hats. Foil fringe glued to the bottom edge of the Children's Party Hats can detach, posing a choking hazard to young children. Creative Expressions, (800) 428-5017 or www.ceg4party.com.

Ceramic Cooktops. The Thermador® Brand Ceramic Cooktop can come on by itself when switched off, creating a potential fire hazard if flammable items are left on the cooktop. BSH Home Appliances Corp., (800) 758-1001 or www.thermador.com.

Children's Jackets. The zipper pull can detach from the Pine Peak Blues Children's Jacket zipper, posing a choking hazard to young children. Nordstrom Inc., (800) 933-3365 or contact@nordstrom.com.

Children's Jeweled Sandals. The jewel decorations on the Calypso Sandals can detach, posing a choking hazard to young children. Nordstrom Inc., (888) 282-6060 or www.nordstrom.com.

Children's Jewelry. Children's Metal Jewelry contains high levels of lead which can cause adverse health effects and is toxic if ingested by young children. Tween Brands Inc., (800) 934-4497, www.limitedtoo.com, or www.justicejustforgirls.com.

Children's Necklaces. The metal clasp on the Butterfly Necklaces contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. GeoCentral, (800) 231-6083 or www.geocentral.com.

Cribs. The assembly instructions provided with the Nursery-in-a-Box Cribs incorrectly instruct consumers how to attach the crib's drop side. If improperly installed, the drop side can disengage from the crib, posing fall and entrapment hazards for the child. Additionally, the metal locking pins on the drop side can pop off, presenting a choking hazard. Simplicity Inc., (800) 784-1982 or www.simplicityforchildren.com.

Dishwashers. An electrical component in the Asko DW95 Model Series Dishwashers can overheat, posing a fire hazard to consumers. AM Appliance Group Inc., (866) 309-9921 or www.askousa.com.

Dry Fire Sprinklers. The Globe Model J Series Dry Fire Sprinkler heads can deteriorate over time and fail to operate in a fire. Globe Fire Sprinkler Corp., (800) 248-0278 or www.globesprinkler.com.

CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Fireworks. 300 Shot Saturn Missiles Battery Fireworks can travel in an unexpected and dangerous direction, which could pose eye and other injury hazards to bystanders. Far East Imports, (800) 766-1277 or www.fareastimporting.com.

Fireworks. The tubes on March or Die Mine/Shell Fireworks Devices could become loose, making the devices unstable during use. If the device tips over during use, it could pose burn and injury hazards to bystanders. Jakes Fireworks Inc., (800) 766-1277 or www.jakesfireworks.com.

Flashing Eyeball Toys. The Floating Eyeballs contain kerosene, which if broken, presents a chemical hazard to children. Gemmy Industries Corp., (800) 231-6879 or Davidm@gemmy.com.

Gas Ranges. GE Monogram® Professional Gas Ranges have a design flaw that can cause an electrical arc between the wiring and griddle gas supply tube, posing a fire hazard. GE Consumer & Industrial, (877) 546-0116 or http://geappliances.com.

Generators. The Stationary Natural Gas and Propane Fueled Generator's fuel shut-off valve can fail to close, resulting in a gas leak from the unit. This poses a risk of fire and burn injuries to consumers. Cummins Power Generation Inc., (800) 888-6626.

Glassware. Blue/Green Dual Glassware Pieces can crack or break unexpectedly, posing a laceration hazard to consumers. Pier 1 Imports, (800) 245-4595 or www.pier1.com.

Infant Long Johns. The metal snaps on the Red Baby Long Johns can loosen and detach, posing a choking hazard to young children. Personal Creations, (888) 627-3283 or www.personalcreations.com.

Infant Swings. Infants can shift to one side of the Rainforest Open Top Take-Along™ Swing and become caught between the frame and seat, posing an entrapment hazard. Fisher-Price, (888) 303-5631 or www.service.mattel.com.

Kayak Paddle Floats. The plastic tubes used to inflate the paddle float could break and deflate, posing a drowning hazard to consumers. NRS, (877) 677-4327 or www.nrsweb.com.

Laptop Computer Batteries. Gateway Lithium Ion Battery Packs can overheat, which could pose a fire hazard to consumers. This is not an internal battery cell defect. Gateway Inc., (800) 292-6813 or www.gateway.com/battery.

Mountain Bicycles. The Mountain Bicycles with Lefty Speed SL and Lefty Speed DLR Forks can break during use causing the rider to lose control of the bicycle, fall and suffer serious injuries. Cannondale Bicycle Corp., 800- BIKEUSA (245-3872) or www.cannondale.com.

Pine Cone Candles. The Vivre Royale Pine Cone Candle's exterior coating and beads can ignite and catch fire. The fire resulting from the coating and beads on the exterior of the candle could ignite nearby combustibles. Royal Products Inc., (800) 693-1199 or www.royalproducts.com.

Silver Stud Earrings. "Accessories" Silver Stud 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.

Ski Bindings. Skiers can unintentionally displace a lever at the rear of the Marker M1 Demo Ski Binding which is used for fitting adjustment by ski technicians. If it is fully displaced, it can result in the unexpected release of the binding and possibly cause the user to fall. K2 Sports, (888) 546-3754.

Sleigh Round Cribs. The assembly instructions included with the Sleigh Round Cribs direct consumers to assemble the crib with the mattress support in the highest position and do not indicate that the mattress support can be moved to a lower position. This poses a fall hazard to children who are able to sit or stand up in the crib. Song Lin Industrial Inc., (888) 589-0088 or www.songlinfurniture.com.

Snow Throwers. When the Briggs & Stratton OHV Snow Thrower Engines are primed, excess fuel can overflow into the carburetor and ignite, posing fire and burn hazards to consumers. Briggs & Stratton Corp., (866) 478-7855 or www.briggsandstratton.com.

Toy Drums. The red paint on Eli's Small Drums and Liberty's Large Drums contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. The Boyds Collection Ltd., (877) 772-3277 ext.2179, e-mail safety@boydsstuff.com, or www.boydsstuff.com.

Wooden Railway Toys. Surface paints on Various Thomas & Friends™ Wooden Railway Toys contain lead. Lead is toxic if ingested by young children and can cause adverse health effects. RC2 Corp., (866) 725-4407 or recalls.rc2.com.

Organ donations: What price, the priceless?

We don't think about our individual body parts until one of them is weakened, sick, or non-functional. But for those needing to replace an organ, obtaining an essential body part is a matter of overwhelming concern. Taken collectively, those who need organs represent a potent force for re-thinking how we distribute scarce resources, especially when these can make the difference between life and death.

The US, like most other countries, has a waiting list of patients awaiting organs, most frequently hearts and kidneys. At present, this list is calculated at 96,000. It is estimated that, in 2006, approximately 16 persons died each day because the number of available organs was not sufficient to meet the needs of those awaiting transplantation. And the gap between organ supply and demand is likely to grow, with the number of persons needing an organ growing five times as fast as the number of donors.

Organ sales are prohibited in the US. This policy has been denounced by some, who argue that paying for hearts or kidneys would create an incentive for potential donors to come forward, thereby reducing or even eliminating the shortage of organs. But there are compelling arguments against allowing organs to be bought and sold like other commodities, and these need to be examined. Given varying pressures and circumstances, different countries have adopted different policies with respect to organs. These are also worth studying, particularly because there is a global market in organs and this may undermine what any individual country allows or restricts.

Current options

Currently in the US, those who need an organ have three main choices. They can receive a cadaver organ, although these are distributed according to need and there is a queue for these limited organs. Another choice is to obtain an organ from a friend or relative. For many this is the preferred alternative: it draws on existing ties and avoids the uncertainties of a queue. A third choice is to appeal to the kindness of strangers. Some solicit organs through mass media in the hope that an altruistic person will be moved to give an organ to an unknown recipient.

Each of these approaches has its limits. Cadaver donations, which account for some 65 percent of transplanted kidneys in the US, hinge on potential donors having signed donor cards allowing their organs to be harvested for transplantation after death. They also depend on family members having knowledge of this and complying with the wishes of the deceased. But many families refuse to allow organ recovery from a recently deceased loved one. Some hospitals and other health care institutions, however, have instituted active organ procurement policies and have achieved good results. They have therefore been able to obtain consent for deceased organ donation from more than 70 percent of potential donors or their families, thus cutting back the waiting time for those awaiting organ transplants.

The second option, donation from a known living donor, involves delicate negotiations, and is inaccessible to some with small or far-flung families or restricted social networks. Moreover, it places the potential recipient in an uncomfortable situation: asking for a donation may be interpreted as coercive, while waiting for a spontaneous offer may prove ineffectual.

Making a public appeal for an organ from a stranger has become increasingly popular. Both the Internet and television have been marshaled towards the end of encouraging donors and bringing them together with needy persons awaiting organs. Thus the actual billboard has been replaced by virtual billboards which list the needs, traits, and urgency of the potential recipient. The results, while legal, may verge on the tasteless. More important, they may run counter to ethical principles of justice. In the US, for example, MatchingDonors.com is a nonprofit organization and website designed to connect patients in need of organs with those willing to be donors. Potential recipients pay a $295 fee to register for a 30-day posting on the web. This includes their photograph, clinical information, and personal narrative. Potential donors also register for a fee; they can then browse the data on potential recipients and select the individuals to which they are going to donate organs. As of the end of May 2007, the site has amassed a roster of 4116 potential donors, and has matched 45 donors with recipients; another 40 surgeries are pending. While the site complies with existing laws, it is considered only borderline ethical by some: it favors those who can pay the registration fee and can present a more compelling story, and permits potential donors to choose recipients on the basis of personal preferences and ethically irrelevant factors such as sex, physical attributes, and estimated value to society.

"Transplant tourism"

Given current organ shortages in the US and elsewhere, some are choosing to travel to countries where organ sales are allowed and the market is largely unregulated. Key destinations in this trade are Bangladesh, Brazil, China, India, and Turkey, where organ sales are permitted if not necessarily promoted. Not surprisingly, the trade in human organs has led to accusations of theft, abuse, and outright plundering of bodies, often unbeknown to donors and their families. While data on these activities are not available, there is at least a mechanism by which this trade is documented. Organs Watch, an independent human rights organization, investigates allegations of medical abuse in the harvesting, distribution, and transplantation of organs. The organization, founded by medical anthropologist Nancy Scheper-Hughes, has documented cases of widespread abuse through-

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Taming the Giant Corporation

In early June, a group of concerned citizen activists wearing well-worn suits or faded jeans and t-shirts bearing slogans like "Paz y justicia" and "Give peace a chance" congregated at the Carnegie Institute in Washington, D.C.

These activists had gathered for Taming the Giant Corporation: A National Conference on Corporate Accountability. The conference was the first of its kind to be held in the past 15 years, put on (not surprisingly) by Ralph Nader and the Center for Study of Responsive Law, a consumer advocacy group that engages in a broad range of issues related to civic responsibility and corporate power. Panelists were the not-so-silent soldiers of consumer activism, experts in their fields who have dedicated their careers and their talents to creating a fairer, safer, more consumer-friendly country.

The conference was defined by the respectable shabbiness of nonprofit organizations; rooms pulsed with impassioned commitment as Ivy League-educated advocates traded stories and strategies: What have we done well? What can we do better? What is our overarching vision?

Conversation floated seamlessly from one topic to the next: ways to reclaim language and shape dialogue; the challenges posed by deep-pocketed corporate lobbyists; strategies to displace the corporations; how to reclaim "the commons," including the airwaves and health knowledge. At the core of it, though, the three ways to transfer power from corporations to the public resonated as a theme throughout the conference: government regulation and legislation, civil litigation, and arming the public with accurate information.

Public Citizen presents...

Dr. Sidney Wolfe, director of Public Citizen's Health Research Group (HRG), summarized the group's achievements over the decades. As a brief history, in 1971 Dr. Wolfe and Ralph Nader together filed their first petition urging the Food and Drug Administration (FDA) to remove Red Dye No. 2 (a food color additive) from the market. The petition (and its eventual success) marked the beginning of Public Citizen, which has grown to become a national consumer advocacy group representing more than 100,000 consumers.

HRG continues to fill an important niche in American consumer safety at a time when only 7 percent of the population thinks pharmaceutical companies are trustworthy. There are over 2 million adverse drug reactions (ADRs) every year, and roughly 100,000 deaths related to ADRs. That makes serious ADRs the 4th-6th highest-ranked cause of death in this country.

Regulation and legislation, litigation,

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ORGAN DONATIONS, *from page 8*
out the world. Scheper-Hughes summarizes her experiences as follows:

> Organ transactions today are a blend of altruism and commerce; of science, magic, and sorcery; of voluntarism and coercion; of gift, barter, and theft. In general, the organs flow from South to North, from poor to rich, from black and brown to white, and from female to male bodies. Today, affluent transplant tourists can travel to select medical sites ... in search of transplants that they cannot arrange quickly or safely enough at home.

Not surprisingly, the World Health Organization condemns these practices and opposes payment for organ donation regardless of the circumstances. Yet the shortage of organs in many countries is driving this trade, with practically no nation able to meet its own needs for transplantable organs. Even Iran, which has a regulated system of living kidney sales, has not been able to completely eliminate its waiting list for kidneys.

Some possible strategies

Even without allowing market forces to intervene in the allocation of organs, there are some measures that nations have taken to promote organ donations and reduce the number of persons awaiting transplants.

The first of these is instituting a policy in which everyone is considered a potential donor unless he or she explicitly "opts out" of the system. This would turn around the current default policy of assuming no one is a donor unless he or she explicitly states so. The US's present system of "opting in" requires potential donors to specifically consent to donating their organs at the time of death. In contrast, several European countries – including Austria, Belgium, France, Spain, and Italy – have switched to a policy of presumed consent in which all citizens are expected to donate their organs unless they say no. Nevertheless, some of these countries ask for family consent, and the wishes of the next-of-kin are always respected.

As an adjunct to this policy, some countries such as Spain have increased organ donation by developing an integrated transplantation coordination network based at the site of organ donation. In fact, the director of Spain's National Transplant Organization credits the coordination of services at the national, regional, and hospital level rather than its policy of presumed consent with its success in procuring organs and reducing the number of those on the waiting list. As a result, Spain has had a sustained increase in organ donation during the past 17 years, its donation rate now reaching 35.1 per 1 million inhabitants (versus 25.5 per million in the US). In addition, Spain has trained health professionals in the techniques of donor detection and management, approaching families, and in the legal, logistical, and organizational aspects of organ donation and transplantation. ■

HRG, *from page 9*
and information have been the triple-angle strategy for HRG (and many other research-based advocacy groups). HRG's team of doctors, pharmacists, a pharmacologist, and public health scholars collect and analyze data to estimate the risks posed by certain drugs and medical devices. This expert analysis is compiled in formal petitions and letters to government agencies (e.g., the FDA, OSHA) or published in major reports released by Public Citizen. In the past year, HRG sent five formal letters and four petitions to the FDA, and also produced three original reports.

Regulation and legislation translate research findings into policy and ensure that corporations are held accountable to the rules laid out by governing bodies. As Dr. Wolfe said, "laws enable governmental regulatory agencies, ***theoretically*** acting on behalf of the public, to hold industries accountable by means of standards, approval processes, and criminal or civil penalties and other sanctions for noncompliance." Public Citizen blows the whistle on businesses that fail to comply with rules and regulations by appealing to the Occupational Safety and Health Administration (OSHA) and the FDA with petitions and formal letters. One of the letters HRG sent to the FDA in the past year epitomizes the successful use of regulations to protect consumers against misleading or false claims. Five companies were illegally promoting laser therapy for smoking cessation. The medical device used was FDA-approved for laser acupuncture but had never been approved to help people quit smoking. Thus the promotion of this expensive and unconvincing type of therapy was categorically illegal. A well-researched letter to the FDA alerting the agency to this regulatory violation was followed by three of the five companies in question changing their online advertising of the therapy for smoking cessation within a month.

Civil litigation is the method through which injured people or families can seek financial redress from producers of goods and services that have killed or harmed them. For HRG, litigation against the government is supplementary to regulation and legislation. When petitions filed with the FDA or OSHA are ignored or the allotted time for internal review has lapsed and no action has been taken, HRG will file suit against the agency in question to achieve the desired results. Public Citizen also sometimes resorts to litigation in order to obtain data through the Freedom of Information Act.

Accurate information is the third instrument of change HRG uses to counteract misguided, often dangerous corporate power. Information influences choices made by members of the public individually and collectively. HRG asserts itself as a source of information, and regularly publishes two newsletters: ***Health Letter*** and ***Worst Pills, Best Pills News*** as well as WorstPills.org. The group has also published books, including ***Worst Pills, Best Pills***, and many reports. In the past year, HRG put out a report ranking the performance of state medical boards' Web sites, a national report ranking state Medicaid programs, and a report ranking the disciplinary rates of state medical boards (all available on www.citizen.org/hrg). Reports also put public pressure on government agencies to improve: no one wants to be called inadequate, and states make honest efforts to better their programs when deficient areas are identified.

Power to the people

Perhaps the most inspiring aspect of the Taming the Giant Corporation conference was the timing. It's not an election year, or the marker of a new decade; it's not the beginning of the year and Congress isn't even in session. There is no strategic reason to say "we are in dire need of change right now." But that's what defines the tamers of giant corporations: the recognition that the need for change is ongoing, not limited to the swings of a political cycle. More important, the conference served to remind the audience of several principles and tenets of activism and the fight for change:

- Corporations are only as powerful as we allow them to be.
- Victories, including small ones, are important to raise morale. They can be harnessed in future fights.
- People have to stop thinking that they are powerless. In the words of Ralph Nader, activism "needs the equivalent of ***American Idol***." ■

OUTRAGE, *from page 12*
User fees have left behind a trail of banned drugs – and patients who have been needlessly killed or injured by them.

User fees have undermined working conditions at the FDA

The strict review deadlines imposed by PDUFA have had a deleterious effect upon staff morale. The 2002 GAO report cited above also documented that staff turnover is higher among FDA scientists than among scientists in other government agencies. Indeed, the former head of the agency's drug center has conceded that PDUFA has "create[d] a sweatshop environment that's causing high staffing turnover."

The user fee program has demonstrably failed. In a recent open letter, 22 drug regulatory experts, including six former senior FDA staff and four authors of the Institute of Medicine's drug safety review, opposed the continuation of user fees and concluded that "User fees may appear to save taxpayers money, but at an unacceptable cost to public health." Although the almost-$400 million in user fees now sought in some PDUFA reauthorization bills is critical to the agency, it is not a sum that would make much of a dent in the federal budget. We urge Congress to return the agency's funding source to those to whom the agency is supposed to be accountable: the American taxpayer. ■

PDUFA: Buying Votes, Selling Unsafe Products

In May 2007, Public Citizen wrote a letter to Congress opposing the Prescription Drug User Fee Act (PDUFA) which is currently up for Congressional renewal. PDUFA is a policy under which pharmaceutical and biotechnology companies pay fees that fund the Food and Drug Administration (FDA) with the intended effect of quickening the movement of prescription drugs and biological products (medical devices) to the market. Public Citizen has long had serious concerns with this act.

User fees have created an untenable conflict of interest in which the FDA is literally in hock to the industry it is supposed to be regulating. The result has been a decline in safety standards at the FDA, with a resultant record number of drug withdrawals for safety reasons.

Federal agencies should be funded by the federal government

The FDA has reviews all prescription drug applications. A poor review can result in patients being denied effective medicines or in the release of needlessly dangerous products. Such a delicate balancing act should be performed only by an agency that is totally objective – one that has the public's interest at heart and is not swayed by the business concerns of companies seeking product approval.

Yet the user fees do just that: the agency has become dependent for its funding upon the very industry over which it has regulatory authority. This is an unacceptable conflict of interest, with the predictable consequences we describe below.

User fees have been associated with an unprecedented number of drug withdrawals

With the agency continually looking over its shoulder so as not to endanger its funding stream (fully one-fifth of the overall FDA budget in current proposals would come from user fees), there has been a fundamental change in the atmosphere within the agency such that pharmaceutical companies are increasingly seen as stakeholders, customers, or even clients. This has been followed by a rash of drug withdrawals; over a dozen drugs have been withdrawn from the market since 1997.

In 2002, the General Accounting Office (GAO) found that "a higher percentage of drugs has been withdrawn from the market for safety reasons since [PDUFA] was enacted."

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