

Health Letter

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The Changing Dynamics of C-Sections in the United States: Cesarean Delivery on Maternal Request *Part 2*

Last month in Health Letter, we described recent trends in cesarean sections in the United States. Here, we summarize the major findings of an NIH conference on the topic. This article is the second in a two-part series.

Last March, the National Institute of Child Health and Human Development (NICHD) and the Office of Medical Applications of Research convened a panel of experts and held a State-of-the-Science Conference on “Cesarean Delivery on Maternal Request” to look into the following questions:

1. What is the trend and incidence of cesarean delivery over time in the United States and other countries?
2. What are the short-term (under one year) and long-term benefits and harms to mother and baby associated with cesarean by request versus attempted vaginal delivery?
3. What factors influence benefits and harms?
4. What future research directions need to be considered to get evidence for making appropriate decisions regarding cesarean on request or attempted vaginal delivery?

Although the initial question referred to overall c-section trends

over time, the focus was on cesareans on maternal request. Over the course of two days, however, it became evident that the data are spotty, many studies are not amenable to comparisons, and there are no easy algorithms or decision trees to provide reliable guidance to patients and physicians. Although *The Washington Post's* report on the conference was headlined “NIH panel finds no extra risk in cesarean section,” the discussions reflected a more complicated reality.

The idea of “maternal request” is actually misleading. Despite a few high profile celebrities who have said they want to deliver by cesarean section, there is limited evidence that women actually request a particular type of delivery. Instead, their choice is

usually constrained by physician practices and preferences, and the information women receive. The National Center for Health Statistics uses the term “cesarean with no medical indication,” thereby focusing on the apparent lack of a health rationale rather than on the women’s choice; others use “no medical risk cesarean” for the same reason. But the acronym CDMR (cesarean delivery on maternal request) has already entered the medical literature, and the conference’s title and the ensuing report may give additional legitimacy to this nomenclature. Although the final report states that CDMR “is not readily identifiable in any existing studies or U.S. national databases, either currently or historical-
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ly,” and that there is “little confidence in the validity of estimates” suggesting that CDMRs represent four to 18 percent of all c-sections, the report assumes that a growing proportion of c-sections are driven by medical need. The only survey to directly gauge the incidence of CDMR was sponsored by Childbirth Connections and conducted by Harris Interactive. This study, which interviewed women who gave birth in 2005, found that less than 0.4 percent (1/252) of the respondents who had a primary cesarean initiated a planned cesarean without medical reason. Two other women with a primary c-section said that the procedure was scheduled ahead of time without medical reason and initiated by a health professional.

The medical literature, though growing, does not provide much guidance for practitioners. In preparation for the conference, NICHD commissioned a literature review comparing cesarean delivery on maternal request with planned vaginal delivery. The review found that the existing studies lack consistent definitions of routes of delivery and are therefore difficult to compare. In addition, most focus on the actual route of delivery rather than on what was planned. Not surprisingly, the final conference report concludes that “there is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed.”

In fact, those reviewing the litera-

ture found only three instances in which there was at least *moderate* evidence of maternal and neonatal outcomes favoring one modality over the other. There was a lower frequency of postpartum hemorrhage with planned cesarean delivery than with planned vaginal delivery or unplanned cesarean delivery. But two other

There is limited evidence that women actually request a particular type of delivery. Instead, their choice is usually constrained by physician practices and preferences, and by the information women receive.

outcomes — maternal length of hospital stay and neonatal respiratory morbidity — favored planned vaginal delivery over c-section. Evidence concerning the association of neonatal respiratory morbidity with c-section is particularly strong and consistent for

babies delivered prior to 39 or 40 weeks of gestation. As a result, one of only two practice guidelines included in the report’s conclusions state that “cesarean delivery upon maternal request should not be performed prior to 39 weeks of gestation or without verification of lung maturity, because of the significant danger of neonatal respiratory complications.”

There is a reluctance to adopt any “ideal rate” of cesarean delivery as a goal. The conference panel rejected that option, which the World Health Organization and other organizations have espoused. In the absence of benchmarks, women and practitioners will therefore lack a legitimate yardstick to assess the labor practices of particular physicians and hospitals. This may eventually be reflected in the nation’s *Healthy People* objectives when they are revised.

The data may very well become more muddled over time. Despite calls for more targeted, better-designed studies and more funding for research, it is unlikely that any clear guidance will come from this source. The gold standard for medical evidence — the randomized clinical study — presents a number of difficulties. First, it would probably be unethical to randomize women to a planned cesarean delivery versus a planned vaginal birth, nor would many women be willing to consent to such randomization. In addition, the study would have to be very large

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Patients without Borders: The Emergence of Medical Tourism

Part 2

In the July issue of Health Letter, Public Citizen wrote about the rapidly emerging phenomenon of medical tourism. The article described a kind of “patients without borders” whereby more and more Americans are traveling beyond national boundaries to receive medical care. Here, Public Citizen expands on this topic. This article is the second in a two-part series.

A growing number of U.S. patients are turning to other countries for surgical and other care. The lure of “first-class services at third-world prices,” as tantalizingly portrayed in the electronic and other media, is attracting those who want to combine their care with a vacation, are seeking alternative therapies, or are simply enticed by the lower prices of most procedures. In the previous article, we provided a summary of some of the international and local implications of the trends for the countries

involved. Here, we will present some of the trade-offs the U.S. consumer is making when opting for medical tourism, and some of the issues that should inform this decision.

How good is the care?

For Americans going abroad, the possibility of trading off quality care for affordability may be of vital importance. And the choice consumers face between “suffering with a health problem or facing significant damage to their finances” may not be easy.

The short answer to the question concerning quality is: it depends. As with health services in the United States, the quality of the product can vary widely, and patients are often not in a position to judge what they are getting. In the absence of standards, the obvious trappings of care — physical facilities, size and cleanliness of rooms, availability of staff, physician attentiveness — often take precedence over medical skill and accountability. It is therefore not

surprising that hospitals seeking to attract foreign patients have taken pains to provide the amenities that ensure patient approval. Many have therefore invested an inordinate amount of resources to create posh facilities combining high-technology medicine with resort attractions.

In addition, some hospitals designed for a foreign clientele have adopted Western standards of care, and sought and obtained accreditation from the international arm of the Joint Commission for the Accreditation of Healthcare Organizations. They also capitalize on the fact that some of their physicians were trained in the West. And, because they are in the hospitality business, they tend to have a high staff-to-patient ratio and stress gracious care.

What does this mean for the U.S. consumer?

American medical consumers who are able to travel see the expanding global market as another option enabling them to get care at affordable prices. Because pay scales are lower and service volumes higher in a number of developing countries, their medical “products” may be significantly cheaper. In some cases, surgical procedures may cost a fifth and even a tenth of what they would cost in the United States. With few or no restrictions concerning length of stay, patients may appreciate relief from drive-by surgeries and difficult convalescences at home. And the promise of “peaceful relaxation in complete anonymity” may appeal to those who want to avoid prying eyes and uncomfortable questions. For the more adventurous, the possibility of exploring another culture and environment may be seen as a bonus. Moreover, the Internet has greatly eased the process of getting information about far-flung hospitals, bridg-

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in order to pick up rare but serious complications affecting the woman and her child. Finally, the study population would have to be followed up on for a number of years in order to detect effects on subsequent deliveries and other long-term sequelae. This would increase the likelihood of women being lost to follow-up, make the study very costly, and run the risk of introducing additional threats to validity, including history and maturation.

If the current trend goes unchecked and the rate of cesarean delivery increases, more low-risk women will undergo surgical delivery and the outcomes for this will be more favorable. As a result, the statistics are likely to show decreasing risks, and hence less of a difference

in birth outcomes between women having a c-section and those having vaginal births. This may in turn increase the tendency to opt for a cesarean, running the risk of having the trend become self-sustaining.

As a “snapshot in time” of the state of knowledge on cesarean delivery, the presentations and final statement of the NIH conference therefore reflect an uneasy state of “clinical equipoise” in which there is genuine uncertainty about what to recommend. Most of the conclusions of the conference address the current lack of data rather than the need for clinical direction. Women who are contemplating childbirth are therefore advised to discuss the risks and benefits of vaginal and surgical delivery with their physicians, remembering that chance fights on the side of the prudent. ■

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ing distances and making the exotic deceptively familiar. Some businesses specialize in orchestrating both the travel and medical arrangements, easing the process by providing Destination Program Managers (DPM) to help the patient navigate the new system upon arrival in the new setting. "All you really need is an air ticket!" pledges one enterprising company.

Nevertheless, there are a number of factors to which the potential consumer should be alert. While seemingly ancillary to medical care, they can greatly influence, if not determine, the efficacy of treatment and the success of the experience.

1. Travel may be contraindicated.

Unless the patient is getting an elective procedure (which may very well be unneeded and risky), he or she may have a condition that is exacerbated by airplane travel. A 10-hour plane trip can be stressful, and being strapped in a seat confined to a small space, with limited mobility, for a long time may trigger deep-vein thrombosis (DVT), more commonly called "coach class syndrome." This rare but possibly lethal condition is a risk of long-distance travel. The combination of immobility, dehydration, and seat pressure on veins at or below the knees increase the risk of blood clot formation and hence of a pulmonary embolism. Undiagnosed in 80 percent of cases, DVT is nevertheless associated with a wide range of risk factors, including varicose veins, pregnancy, recent surgery, autoimmune disorders, Type A blood, cancer/chemotherapy, clotting disorder, congestive heart failure, elevated cholesterol, inflammatory bowel disease, and elevated platelet counts. As a result, many potential medical travelers may be unwittingly placing themselves at risk and possibly worsening the condition for which they are seeking care in the first place.

2. Insurance coverage may be

spotty. While it is mostly the uninsured who seek health services outside the United States, some insured individuals may also opt to undergo elective surgery abroad. In the latter case, it is important for consumers to verify beforehand that they will be covered or reimbursed for expenses incurred abroad. Each insurance plan has specific requirements governing coverage. Aetna, for example, covers routine care outside the U.S., but only for certain beneficiaries: those not in closed-panel HMOs. In most cases, insurers exclude cosmetic and other elective surgery. In addition, even when care is covered by insurance, there may be other hurdles to coverage. For example, pre-certification may be required. In addition, some insurers cover complicated transplant procedures only if these are performed in specific medical centers that meet established quality standards and other criteria for care. As incentives for patients to choose these "centers of excellence," some insurers may offer travel and lodging reimbursement. Patients should read the small print and get information in writing before making a final decision concerning where to get care.

3. Continuity of care can be compromised.

In-hospital service represents a small part of the continuum of care. Longitudinal responsibility for a patient's care fosters accountability and reciprocity on the part of both patients and providers. Even if the patient remains in the country following treatment, long-term follow-up may be difficult. While proximity is neither necessary nor sufficient for continuity of care, it certainly facilitates it. Patients traveling for a procedure should take their medical records, including test results and x-rays. In addition, they should inform their providers at home of their plans in order to ensure easy access to medical data

and consultation.

4. Problems of communication may arise.

Many medical errors are the result of poor communication. Misunderstandings and gaps in information often occur when a provider speaking medical jargon is face-to-face with a nervous patient. Adding linguistic, cultural, and class barriers to the mix further complicates the situation. Additionally, religious and gender nuances and taboos may increase the probability of missed cues or misconstrued messages.

5. An adequate support network will most likely be missing.

Most patients require help during convalescence. In the event of a prolonged recovery, the patient/tourist may feel stranded with limited help. There is no "mustering the troops" when the patient is alone or has a single companion. There are occasions when the familiar is comforting and broader resources may be needed. Illness can be isolating, and a foreign environment can only make a difficult situation more onerous.

6. "Alternative" treatments may not be the right alternative.

Some countries attract patients seeking treatments that are routinely performed elsewhere but are not approved in the United States (e.g., robot-assisted joint replacement). Whatever the deficiencies of the current U.S. regulatory systems, they are designed to limit procedures to those that meet standards of safety and efficacy. More likely than not, there are valid reasons for not approving certain therapies.

7. "Natural" does not mean "safe."

Most toxic substances are found in nature; that does not make them any less dangerous. Patients equating "natural" with "harmless" run the risk of taking products that may have intrinsic adverse effects or cause bad reactions when taken with other drugs and medications.

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The “Ultimate Prize” for Big Tobacco: Opening the Chinese Cigarette Market by Cigarette Smuggling

The following article was written by Thomas E. Novotny, a Professor in Residence at the Department of Epidemiology and Biostatistics at the University of California, San Francisco, in California. It originally appeared in the Public Library of Science (PLOS), a free, web-accessible journal on science and medicine (www.plos.org).

The Prize

China has long been identified as the most important international cigarette market, now and in the future — O’Sullivan and Chapman called China the “ultimate prize” among the world’s emerging tobacco markets. Almost two-thirds of Chinese men (63

percent), and 3.8 percent of Chinese women, are smokers, giving a total of 350 million smokers in China, with more on the way. Young Chinese women are likely to be an important target group for growth for Big Tobacco.

According to a 1998 survey, among Chinese adolescents aged 11–20 years, almost half (47.8 percent) of the boys and 12.8 percent of the girls surveyed were experimenting with tobacco. This survey would surely warm the cold heart of any multinational tobacco company executive. Robert Fletcher, regional public affairs manager for the tobacco company Rothman, said that “thinking about Chinese

smoking statistics is like trying to think about the limits of space”.

China has been a member of the World Trade Organization since 2001, and this membership may reduce barriers to market entry through lowered tariffs on imports by transnational tobacco companies (TTCs). Thus, it is important to understand how these markets will be entered by the TTCs, as market entry also means globalizing the imagery, advertising, and health effects of smoking. Market entry into China also means that with greatly increased numbers of smokers, the burden of non-communicable diseases attributable to smoking will

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Moreover, even some seemingly innocuous products may be combined with other ingredients that are potentially toxic. One study of Ayurvedic medications published in 2004 found that, of 70 over-the-counter remedies, 14 (20 percent) contained mercury, lead, or arsenic at levels that could be harmful.

8. Travel ‘frills’ can eclipse medical care. Patients are well-advised to separate their medical requirements from other aspects of the health travel “package.” If you want cosmetic surgery and are convinced that Argentina is the best place for you, your decision should not be contingent on whether or not the package includes the services of “a personal assistant who will help direct you to ...Señor Tango, one of the hottest tango halls in Buenos Aires.”

9. Environmental conditions may not be equal to those of more developed countries. Even if the hospital is impeccable, quality of air

and water, noise, and sanitary conditions outside the premises may affect the salubrity of the environment. Similarly, a blood transfusion can be either a life-saver or a major threat, depending on how the blood supply is screened and managed. There are a number of blood-borne diseases, and many countries lack adequate means for their surveillance and prevention. According to a World Health Organization study, 11 percent to 21 percent of cities surveyed had inadequate screening of blood donations for the infectious agents associated with malaria, HIV, and hepatitis.

10. The “rules of the game” may be quite different. The Centers for Disease Control warns that systems outside the United States may operate differently from those in the U.S. and are not subject to the same rules and regulations. Procedures regarding informed consent, advanced directives, and guardianship, for example, may not be in place. Similarly, hospitals and other health care facilities may maintain discrimi-

natory prices that would not be acceptable in the United States. For example, one company in the health travel business advises potential clients that the charge for a particular surgical procedure may be 30 percent more than the regular rate if the patient is HIV positive.

11. There may be no legal recourse if needed. In the event of an adverse effect, resorting to a legal process may be difficult or simply not available. Some countries have malpractice laws that limit damage awards, thereby protecting physicians and hospitals from litigation.

Summing up

U.S. consumers may be well advised to separate their medical needs from their vacations. The lower cost of care abroad, however important a motivator, has to be weighed against other intangibles that can make the difference between success and failure in health outcomes. ■

Product Recalls

July 19, 2006 — August 21, 2006

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

DRUGS AND DIETARY SUPPLEMENTS

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

CLASS I — Recalls and Field Corrections

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Tacrolimus Bulk Powder; Subpotent. Lots TA1210 pack letters A-F (Batch 031002); Lots UD1060 pack letter A (Batch 20050323), UF0298 pack letter A-B (Batch 20050323), UL0964 pack letter A (Batch 20051129), & VB0031 pack letter A-B (Batch 20051129), Spectrum Laboratory Products Inc.

CLASS II — Recalls and Field Corrections

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

Comfort Shield Personal Cleansing Perineal Care Washcloths, Dimethicone 3%; Microbial contamination; *Burkholderia cepacia*. Reorder #7503 - Lot 1999; reorder #7503-M - Lots 1702 and 1995; reorder #7403 - Lots 1301, 1312, 1457, 1651 and 1677; reorder #7408 - Lot 1848; reorder #7905 - Lot 1766; reorder #7524 - Lots 2070 and 2086, Sage Products, Inc.

Extra Strength Super Troche DM, 15 mg Benzocaine and 10 mg Dextromethorphan HBr; Drug Facts label on back of the bottle does not list Dextromethorphan HBr as an active ingredient and lacks the warning not to use the product if taking a monoamine oxidase inhibitor. Lot 06039A1, exp. date 07/2008, Weeks & Leo Co., Inc.

FDG F-18 Fluorodeoxyglucose Injection, 20 mCi/mL; Pharmaceutical for injection was out of specification for endotoxin levels. Lot 140718061, exp. date 7/18/2006, Cardinal Health Inc.

Fexofenadine Hydrochloride, 60 mg tablets; Packaging mix-up- The outer packaging is labeled as Fexofenadine Hydrochloride 60 mg tablets, but the unit dose blister strips inside the box may contain and be labeled Hydralazine Hydrochloride, 100 mg. tablets. Lot K43240R30, exp. date 12/12/2006, Lot K43240R25, exp. date 12/12/2006, Heartland Repack Services LLC.

Cilostazol, 100 mg tablets; Packaging mixup; The outer package is labeled as Cilostazol, 100 mg tablets, but the unit dose strips inside the outer packaging may contain and be labeled as Benztropine Mesylate, 0.5 mg tablets. Lot K43243R30, exp. date 12/13/2006, Lot K43242R25, exp. date 12/13/2006, Heartland Repack Services LLC.

Flumazenil Injection, 1 mg/10 mL (0.1 mg/mL); Mispackaging: Some of the boxes of Flumazenil Injection may contain vials of Levothyroxine Sodium for Injection. Lot 200324, exp. date 04/2007, Abraxis Pharmaceutical Products.

Hydralazine Hydrochloride, 100 mg tablets; Packaging mix-up- The outer packaging is labeled as Hydralazine Hydrochloride, 100 mg tablets, but the unit dose blister strips inside the outer packaging may contain and be labeled as Benztropine Mesylate, 0.5 mg tablets. Lot K43263R30, exp. date 12/13/2006, Lot K43263R25, exp. date 12/13/2006, Heartland Repack Services LLC.

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

Name of Drug or Supplement; Problem; Recall Information

Levothyroxine Sodium Tablets, USP, 100 mcg (0.1 mg), 125 mcg (0.125 mg), 137 mcg (0.137 mg), 200 mcg (0.2 mg); Subpotent. Lot C04T1921A / 04T14200 / 04T14210; Lot C05T0441A / 05T1130 / 05T1140, Lot C05T0111A2 (05T7060), Lot C05T0471A / 05T2250 / 05T2260; Lot C05T0221A4 / 05T7140, Lot C05T0701A3 / 05T2960, Lot C05T0711A / 05T3010; Lot C05T0131A2 (05T7330), Lot C05T0801A2 (05T11190), Lot C05T0721A / 05T3070 / 05T3080 / 05T3090, Lot 05T3051A, Lot 05T3061A, Lot 05T3101A, Lot 05T3111A, Lot 05T3201A, Mova Pharmaceutical Corp.

Triphasil, Packages of 3 Dial Packs; Presence of Foreign Substance; phenol. Lots: A36954, A36955, A63687, A67660, A67664, A67671, A67680, A86544, A88644, A92651, A93846, A97336, A97337, B15552, B22428, B24181, B31843, B32893, B40792, and B47404, Wyeth Pharmaceuticals.

Lorazepam Tablets, 2 mg; Lorazepam 1 mg tablets packaged and distributed as Lorazepam 2 mg tablets. Lot 452E0622, exp. date 4/30/2007, Sandoz, Inc.

Zosyn for Injection (Piperacillin and Tazobactam for Injection), 2.25 gram, 3.375 gram, 4.5 gram; Lack of Assurance of Sterility; possible damage to the breakaway cap. Multiple lots, Wyeth Pharmaceuticals.

Synthroid Tablets, (levothyroxine sodium tablets, USP, 25 mcg (0.025 mg), 200 mcg (0.2 mg), 100 tablet; Failed Impurity Specification. Lot 0000354304 exp. date 09/2006, Lot 0000354314 exp. date 09/2006, Abbott Laboratories.

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 mounting brackets used to secure the left-front suspension arm to the Suzuki 2006 Model Year Eiger ATV's frame may not have been welded completely and could break off during riding. If this occurs the rider could lose control of the ATV and crash, posing a risk of serious injury or death. American Suzuki Motor Corp., (800) 444-5077 or www.suzukicycles.com.

Children's Lamp. The Hampton Bay® Transitional Collection Fire Truck and Bulldozer Accent Lamp with Night Lights have a red toy fire truck or yellow toy bulldozer base that sits on a 6-inch wide by 9.75-inch long hand-painted wood base. SKU No. 167-367 is printed on the bottom of the base of the fire truck lamp and SKU No. 167-939 is printed on the bottom of the bulldozer lamp. The fire truck and bulldozer have glass windows. The overall assembled dimensions are about 12 inches wide by 20.5 high. "Made in China" is printed on the bottom of the lamps. Hampton Bay® is printed on the box only. Emess Design Group LLC, (800) 678-2579 or www.emessdesign.com.

Cage Bell Instruments. If the bell inside the Cage Bell Musical Instrument for Babies is damaged during manufacturing, the bell can be pulled out of the instrument, posing a choking hazard. Kindermusik International Inc., (800) 628-5687 or cagebell@kindermusik.com.

Coffeemakers. The Bunn® home coffeemaker's plastic pour-in bowl and lid can melt or ignite due to an electrical failure, posing burn and fire hazards to consumers. Bunn-O-Matic Corp., (800) 385-2652 or www.regcen.com/bunnrecall.

Children's Cooking Sets. The glass pot lids can break, posing a laceration hazard to children. Panline USA Inc., (800) 666-2539 or recall@alextoys.com.

Computer Batteries. Dell-branded lithium-ion batteries made with cells manufactured by Sony can overheat, posing a fire hazard to consumers. Dell Inc., (866) 342-0011 or www.dellbatteryprogram.com.

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Name of Product; Problem; Manufacturer and Contact Information

Counterfeit Extension Cords. The 6-foot Power Xtension counterfeit extension cords could have undersized wire and substandard insulation, which can cause overheating, resulting in a possible shock hazard. Greenbrier International Inc., (800) 876-8077 or www.dollartree.com.

Dimming Ballasts. Tu-Wire® ballasts used with dimmable compact fluorescent lights, if not properly grounded in accordance with the National Electrical Code, can present a risk of electric shock to persons who come in contact with the ballast or with a light fixture that incorporates the ballast, such as when a consumer changes a fluorescent lamp bulb. Lutron Electronics Co. Inc., (866) 793-4270 or www.lutron.com.

Electric Hair Dryers. “Monica” and “Turbo 1200” Hand-Held Hair Dryers are not equipped with an immersion protection plug to prevent electrocution if the hair dryer falls into water. Such electric shock protection devices are required by industry standards for all electric hand-held hair dryers. Style Tronics Inc., (888) 266-9272 or www.styletronic.net.

Electric Lawnmowers. An electrical component in the Black & Decker and Craftsman Brand Cordless Electric Lawnmowers can overheat, posing a fire hazard. Black & Decker (U.S.) Inc., (866) 229-5570 or www.blackanddecker.com.

ElectroPlasma Lamps. Arcing between an object and the removable cover of the Mars Lightning ElectroPlasma Lamps can pose a fire hazard. Spencer Gifts LLC, (800) 762-0419 or www.spencersonline.com.

Engines. The plastic fuel tanks of Generac GTH410 and GTH220 Engines with Plastic Fuel Tanks can leak. If an ignition source is present, a fire or explosion can occur. Generac Power Systems Inc., (800) 320-1143 or www.generac.com.

Floor Stripper. 5-gallon sizes of “Zep Industrial Purple Cleaner & Degreaser,” and “Zep Heavy Duty Floor Stripper” can unexpectedly crack and leak from the base, posing a risk to consumers due to the corrosive nature of these products. Acuity Specialty Products Group Inc., a subsidiary of Acuity Brands Inc., (888) 591-5053 or www.zeprecall.com.

Folding Chair Beds. Fingers can become caught in the folding mechanism of the LYCKSELE Chair Bed and Sofa Bed, posing a laceration and/or amputation hazard. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Folding Picnic Tables. The legs on the Folding Picnic Tables can buckle or break during use, causing the table to collapse or fold unexpectedly. Atico International USA Inc., (877) 546-4835 or www.aticousa.com.

Fun Express Children’s Toys. The paint on the Fun Express Bendable Dog and Cat Toys contains excessive levels of lead, which is banned under federal law. Lead is toxic and if ingested by young children can cause adverse health effects. Fun Express Inc., a subsidiary of Oriental Trading Company Inc., (800) 723-6155 or www.funexpress.com.

Gas Controls. Robertshaw FS Flame Switches and FM Automatic Safety Valves (installed in commercial cooking appliances) are designed to prevent gas from flowing when the pilot light is out. The recalled controls can remain on after the pilot light is extinguished. If this happens, gas can continue to flow to the main burner of the appliance, which poses a risk of a gas explosion and fire. Robertshaw Controls Co., (800) 232-9389 or www.robertshaw.com.

Glass Candleholders. The glue connecting the Clear Glass Candleholders could fail causing the candleholder to fall apart. This poses a fire and laceration hazard to consumers. Meijer, (866) 280-8419 or www.Meijer.com.

Hooded Sweatshirts. A drawstring of Hide & Seek Hooded Sweatshirts is threaded 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. Quiksilver Inc., (877) 246-7257 or channels@quiksilver.com.

Lamps. The lamp’s electrical circuit board can spark and overheat due to an electrical problem, posing a fire hazard to consumers. J.C. Penney Corporation Inc., (888) 333-6063 or www.jcpenney.com.

Light Fixtures. The reflector/trim pieces of Gotham 8-inch APR/APRH Down Lighting Fixtures may not be properly attached to each other. The lower portion of the reflector/trim assembly could detach and fall from the ceiling striking consumers. Gotham Architectural Lighting division of Acuity Lighting Group Inc., (800) 315-4982 or www.gothamlighting.com.

Light-Up Backpacks. The Cool Blue Backpack’s battery pack can overheat causing the battery case to melt, presenting a burn hazard if touched. Lands’ End, (800) 200-6212.

Name of Product; Problem; Manufacturer and Contact Information

Lounge Pants. Quiksilver and Roxy Girl lounge pants fail to meet the children's sleepwear flammability standards, posing a risk of burn injury to children, due to the possible ignition of the garment. These garments were not labeled or marketed as sleepwear, but because they are children's loungewear, they must meet the children's sleepwear flammability standards. Quiksilver Inc., (800) 576-4004 or channels@quiksilver.com.

Plastic Hardware Covers. The small cam lock of Homeroom Bedroom Collection hardware covers on children's furniture can be easily removed, presenting a choking hazard to young children. Hold Everything, (800) 840-2849.

Potted Candles. The packaging or holder of Toulon Potted Candles can ignite, posing a fire hazard to consumers. Ballard Designs Inc., (800) 367-2810 or www.ballarddesigns.com.

Scooters. The handlebars, wheels and wheel brakes of Firestreet Scooters can break and detach, causing the rider to lose control, fall and possibly suffer injuries. Triple Win Sports, (800) 440-0680 or www.target.com.

Snowthrowers. The plastic fuel tank of Toro Snow Commander and CCR Single Stage Snowthrowers can crack and leak gasoline, posing a risk of fire and injury. The Toro Company, (800) 689-8671 or www.toro.com.

Speed Buckle Harnesses. The Speed Buckle Harnesses could be threaded incorrectly. If threaded incorrectly, the webbing will easily slip when loaded. Incorrectly threaded buckles can loosen, which could cause climbers to slip out of the harness and fall. Black Diamond Equipment Ltd., (801) 278-5533 or www.blackdiamondequipment.com/.

Suunto Dive Computers. Suunto D9 and D6 Model Wristop Dive Computers could incorrectly track dive time, which could cause incorrect calculation of decompression requirements. This could lead to decompression sickness. Suunto Oy, (800) 543-9124 or SuuntoD9-D6@nordictelecenter.fi.

Table Height Chairs and Bar Stools. The down shaft on the seat plate assembly of Framework Table Height Chairs and Bar Stools can fracture, which can cause an occupant of the seat to fall. Brunswick Bowling & Billiards Corp., (800) 937-2695.

Utility Tractors. The seat bracket to which the seat belt of John Deere 3000 Twenty Series and 4000 Twenty Series Open Station Compact Utility Tractors is attached could have been positioned incorrectly during the manufacturing process resulting in a poor weld. In a tractor roll over, the weight of the operator could cause the bracket to break off of the seat's pivot plate. Deere & Co., of Moline, (800) 537-8233 or www.deere.com.

Weed Trimmers. The blade of the Troy-Bilt 4-Cycle Gasoline String Trimmers that trims the excess string of these weed trimmers can detach from the plastic shield covering the trimmer head. The blade can be thrown outward, hitting the user or bystander, resulting in a laceration. MTD Southwest Inc., (888) 848-6038 or www.troybilt.com.

CIGARETTE SMUGGLING, from page 5 explode, affecting China's transitional healthcare system and its economic stability.

Smuggling as a Marketing Tool

TTCs have used cigarette smuggling as a market-opening tool throughout recent history (such as in Latin America and the former Soviet Union). Now, in an important new study published in *PLoS Medicine*, Lee and Collin document evidence that British American Tobacco (BAT) has exploited China's large cigarette

smuggling problem.

Smuggling of cigarettes into China is an especially critical issue in light of China's desire both to open trade through membership in the World Trade Organization and to participate more fully as a global partner in health. With the 2002 SARS epidemic and the potential avian flu pandemic serving as grim reminders of the need for international collaboration in health, China now participates more openly in other health agreements. Specifically, China ratified the World Health Organization's first ever global health treaty, the

Framework Convention on Tobacco Control (FCTC), on October 11, 2005. This treaty will have as one of its major areas of focus the control of global cigarette smuggling. Although the United States has not ratified the FCTC, it may join in a protocol that addresses smuggling. At present, one-quarter of total global cigarette exports are illegally traded. This illegal trade is a big, multinational problem, and multinational efforts are needed to control it; in addition, there is still insufficient scholarly research on this problem.

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CIGARETTE SMUGGLING, from page 9
Getting Inside Information

Lee and Collin used BAT documents from the Guildford Depository in the United Kingdom. These documents were made public as a result of legal actions against the TTCs. The terms of a legal settlement in Minnesota, United States, stipulated that the public should be allowed, for ten years, access to documents produced during litigation against the tobacco industry, via the creation of two depositories, one in Minnesota and one in Guildford.

Document research is of specific value in examining the smuggling issue, since data on smuggling are not easily found in other public sources. The authors found suggestions of large-scale smuggling of foreign cigarettes into China to circumvent barriers to market access. By triangulating official documents on legal imports subject to tariffs, reported imports by all TTCs, and BAT sales figures in China, they found significant discrepancies between what was reported and what was sold. The sales reported in internal company documents made China one of the larger profit centers for BAT Industries, with 25 percent of profits coming from “transit” trade to China, a code word for smuggled cigarettes. Moreover, the Guildford documents

“Thinking about Chinese smoking statistics is like trying to think about the limits of space”.

— Robert Fletcher,
regional public affairs manager
for the tobacco company Rothman

show evidence of BAT’s efforts to build market presence in competition with other popular brands, using whatever it takes to succeed in the new market, including smuggling.

What Must Be Done

The FCTC came into force on February 27, 2005. The signatory member states now have the best-ever opportunity to shut down the pipeline of smuggled tobacco products and the associated illicit profits for BAT and other TTCs through multinational efforts to better track

exports and enforce customs regulations. There are three major reasons why it is crucial to stop tobacco smuggling: (1) the profits from smuggling fuel TTCs’ efforts to buy political influence and maintain economic strength across non-tobacco sectors; (2) smuggling leads to countries losing tariff revenue from the legal trade of cigarettes; and, most importantly, (3) the health of target groups such as young Chinese women will suffer immeasurably unless the FCTC is effective in reducing TTC market success.

Much can be done to combat smuggling as a tool of the TTCs, including implementing more aggressive litigation to assure corporate liability, pursuing anti-money-laundering actions to remove the influence of organized crime, improving cigarette tracking systems, and strictly enforcing recordkeeping of shipments and receipts by TTCs. There must be binding obligations to carry out such anti-smuggling activities, enforced through a multinational protocol of the FCTC, not voluntary compliance as proposed by the TTCs. The world is a global marketplace, and global problems such as cigarette smuggling need global solutions as put forth in the FCTC. ■

OUTRAGE, from page 12

woman’s skin color on her marketability to marriage partners.

The craze for modern fairness creams has emerged in the last 50 years. International cosmetics giants were the initial manufacturers, but these days Indian and South Asian companies are playing an important role in the skin bleaching and cosmetic markets. Fairness creams have been estimated to account for up to 40 percent of the profits of the cosmetics industry. Recently, a fairness cream has been launched exclusively for men.

Advertisements aim to produce a hierarchy of values based on the notion that “fairness” is an object of desire. Being fair has been represented as an active process. Regular use of fairness creams has been claimed

to halt the production of melanin and to bring out “natural” beauty.

Promoting a particular body image or behavior pattern as the preferred one and then selling medicines or products to help people attain the particular ideal may be regarded as disease mongering. Fairness cream manufacturers have exploited the preference for fair skin, portrayed it as a necessary prerequisite for success, and promoted the use of their product to achieve the ideal. Controlled studies on the efficacy and safety of fairness creams are lacking.

Disease mongering companies form alliances with doctors, consumer groups, and the media to promote sales of their drugs. Fairness cream manufacturers sponsor beauty pageants and carry out an advertising blitz in the print

and audiovisual media. They create hype about their product. Many leading manufacturers have expanded their range to include lotions, cold creams, and soaps.

Most fairness creams are non-prescription products, and the medical profession may not be the main target of marketing professionals. However, doctors as responsible and respected members of society have an important role to play in spreading awareness about this racial distortion of body image. Fairness creams may satisfy many of the criteria of disease mongering. The issues of freedom of choice, economic impact (personal and on the society), profits, social issues, and ideal body image should be seriously debated. ■

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Fairness Creams in South Asia — A Case of Disease Mongering?

The following article, written by three researchers, Ravi Shankar, Bishnu Rath Giri, and Subish Palaian, from Manipal College of Medical Sciences in Pokhara, Nepal, continues our discussion of disease mongering. It is reprinted from the Public Library of Science (PLOS), a free, web-accessable journal on science and medicine (www.plos.org).

We read with interest the article by Moynihan and Henry on disease mongering. The authors argued that disease mongering is the opportunistic exploitation of a widespread anxiety about frailty and of faith in scientific advance and “innovation.”


In South Asia there is a widespread preference for “fair skin” and this has

Fairness cream manufacturers have exploited the preference for fair skin, portrayed it as a necessary prerequisite for success, and promoted the use of their product to achieve the ideal.

been exploited by the manufacturers of “fairness creams.” “White” skin has a colonial connotation of power and superiority. The emergence of a “paler” global entertainment industry has served as a fillip to the marketing of an international beauty ideal. Beauty pageant winners in India are all

extraordinarily tall and breathtakingly slim, have light honey-colored skin, and peddle Western ideals of beauty. South Asian culture has carried within itself a capacity for female objectification. Matrimonial columns and Web sites reveal the influence of a young

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