PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Patients without Borders: The Emergence of Medical Tourism

Most Health Letter *readers are familiar with the extraordinary international organization of doctors, Doctors Without Borders (Médécins Sans Frontières), that transcends and travels beyond national boundaries to bring better health conditions and better health care to those in need. But a rapidly emerging phenomenon is medical tourism, a sort of "patients without borders", reflecting different kinds of need. This article is the first in a two-part series.*

Bathing suit, sun block, x-rays, medical records... these may all be priorities in packing for travel to a far-flung location. In recent months, the media have picked up on a growing trend: medical tourism, or travel with the express purpose of obtaining health services abroad. For this country, the trend is not new, although the direction of patient flow certainly is. The United States, with its large pharmaceutical and medical device industries and high-tech hospitals, has traditionally been a destination for patients, primarily those affluent enough to pay out-of-pocket or those who have generous insurance coverage that extends beyond their countries of origin. But recent years have seen a flow in the opposite direction, with large numbers of American patients traveling abroad in search of less expensive and often more luxurious health care.

For a patient in, say, New York or Washington, who may be under the care of an Indian physician and a Jamaican or Filipino nurse, going abroad for medical services may not seem dissimilar to getting care at home. And the promise of comparable services at lower cost, with some exotic travel thrown in, is often tempting. As a result, patients are increasingly looking for newer horizons in medical care, including elective surgery and long-term care. Some countries such as India, Brazil, the Philippines, and Thailand are actively capitalizing on the trend, offering health care/resort packages that promise the best of medicine with the attractions of tourism.... all for a fraction of what equivalent health services would be in the US. In a two-part series, *Health Letter* will examine some of the implications of this trend. Here, we will look into what this means for the countries involved on either side of the exchange. In the second part of the series, we will focus on what the individual consumer should know when contemplating going abroad for the main purpose of getting health care.

A segmented market

There has always been a market for celebrities or the wealthy seeking care outside the US, usually for reasons of privacy. It is not only Angelina Jolie, who gave birth in Namibia, who travels

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for health care. Other medical tourists undergo cosmetic surgery or other 'delicate' procedures where they do not have to explain their temporary absences. Plastic surgeons in Europe and Israel often attract international clients, and some hospitals have built reputations based on both their discretion and their results.

Beyond these special cases, there are others who go abroad for routine services. As has been well documented, many Americans travel to Canada to buy prescription drugs, and border drugstores cater to this growing clientele. Along the southern border, poor Mexicans can buy less expensive insurance from US insurers, benefiting from services on both sides of the border. They often go to Mexico for routine care, while relying on US services for serious problems. Retired Americans who have second homes in Mexico, or who live in South Texas and Arizona, similarly avail themselves of services in Mexico. The growing market for these services has attracted both providers and more patients, with some border towns specializing in certain types of services and drawing from a broad catchment area. Indeed, a recent *Time* article describes the towns of Nuevo Progreso and Los Algodones in Northern Mexico as "dental oases" attracting chartered flights full of patients from Minnesota and California in search of more affordable dental care.

In the past decade, a growing number of US patients have turned to other countries for surgical and other care. Trade in health care services therefore now includes a number of countries promising "first-class services at third-world prices." These, which include countries as diverse as South Africa and Poland, Singapore and Argentina, among others, cater to a population demanding less expensive care (from countries in which care is market-driven) or who want to "jump the queue" (from countries where publicly funded services are universally available, but where there may be unacceptably long waiting lines). Whatever the motivation, medical tourists are on the move and on the rise, and their mere presence has implications for both their home country and their hosts. The examples of India and Thailand shed some light on what is at stake nationally and internationally.

Think locally, market globally

Countries that actively promote medical tourism do so for self-serving reasons. Investing in the medical industry is a way to increase GDP, upgrade services, generate foreign exchange and create a more favorable balance-of-trade situation, and boost tourism. Other more subtle benefits include stemming a brain drain of health professionals and buying international goodwill.

The full impact of these gleaming "islands of medical excellence in a sea of medical neglect," however, is the subject of intense debate. What does the trend mean for the public's health? Do benefits accrue to the local population, or are private hospitals benefiting at their expense? Those who advocate for this potential growth industry stress two main points: (1) that the increased revenues provided by medical tourism can be plowed back into health care to benefit the population at large; and (2) that the upgraded facilities catering to foreigners can have a leavening or demonstration effect on health services throughout the system, serving as an example of what is possible in the developing world given existing know-how and additional resources. Both of these arguments assume a favorable 'trickle down' effect of improved services. The opposing view is that luxury health care designed for foreigners (or, in the case of India, expatriates) widens the gap between have and have-nots, and that poor countries are being lulled into thinking that they are improving their health services by having impressive high-tech hospitals that serve only the needs of affluent outsiders. The full impact of the trend will most likely vary from one country to another, and its effects are being watched by other countries and global organizations.

The case of Thailand

If there is an apex in the hierarchy of hospital services in Asia, it is Bumrungrad Hospital in Bangkok. Aiming at what John D. Rockefeller Jr. called "catalytic bigness," this 554-bed facility with a staff of 2,600 has spent the last decade striving to be the biggest and best in its class. It attracts international patients from over 150 different countries and has become a pioneering force in global medical entrepreneurship. In order to establish itself as a brand apart in the health tourism industry, it hired not only experienced doctors but also foreign management expertise. It was also the first hospital in Asia to receive accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an organization that offers its stamp of approval to healthcare organizations that meet certain standards for patient safety and other predetermined criteria. This paved the way for others. At present, it boasts an international medical center catering primarily to foreign patients, who account for 50 percent of their clientele. The hospital staff includes interpreters for 26 languages and a department specifically for Japanese visitors. In 2003, Bumrungrad treated one million patients. In 2005, it treated 55,000 American patients, three-quarters of whom flew directly from the US. A recent financial report for the hospital reveals that the company is increasing its outpatient capacity, exporting its managerial expertise to hospitals in Myanmar and Bangladesh, and aggressively pursuing other opportunities to strengthen its position in Asia. It has also acquired stock in hospitals in the Philippines and Bangladesh, and is providing consulting services throughout the region. In addition, the CEO is quoted as saying that the hospital is looking into opportunities in Malaysia, Vietnam, China, and the Middle East, "where the number of health-conscious middle-class people is growing."

While Bumrungrad may be unique in its scale and relative endowment, it is emblematic of what may be happening in other private hospitals also vying to attract patients from abroad.

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Study Finds Many Favor A Single Payer System

Health services in the United States aren't good enough, cost too much, and leave too many people out: that is the consensus emerging from a two-year long process that has not yet concluded. The interim results are in a federally-funded document, *The Health Report to the American People*, worth reading not only for what is included but also for what was left unsaid.

Best known for Part D, which provided drug coverage, Public Law 108-173 — the Medicare Prescription Drug Improvement and Modernization Act of 2003 — also included a provision to allow the American public to "engage in an informed national public debate to make choices about the services they want covered, what health

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Because few patients travel for routine care, medical tourism means emphasizing treatment over prevention, and promoting technology-intensive tertiary services at the expense of primary care. The fact that the private health sector in Bangkok has more gamma knife, CAT scan, and mammogram capacity than all of England is evidence of the distortions that occur in the allocation of resources when these are spent for status symbols rather than to meet local needs.

The implications of this for the country are being discussed by WHO and its regional offices as well as by the World Bank and other development and international trade organizations. Because technology is more mobile than labor resources, a country such as Thailand can import the former, upgrade the latter, and bolster its comparative advantage vis-à-vis the developed world. But to do so successfully, it has to invest a disproportionate share of finite resources in services for the affluent, thus distorting any redistributive effect of better care. And the presence of well-endowed hospitals tends to prompt an internal brain drain from the public to the private sector, thereby decreasing equity in access to health care for the local population. This siphoning off of health personnel from the public to the private sector is already occurring in Thailand. The effect of these trends thus reinforces a two-tiered health system, with different standards for different economic classes.

Medical tourism in India

Building on its experience in selling its labor and expertise in information technology on the international market, India is following Thailand in promoting "hi-tech healing" in order to become a global health destination. The country has already established a reputation in cardiac care, cosmetic surgery, joint replacement, and dentistry, and is actively working to expand into other areas that may attract well-heeled foreigners and the 12 million Indian expatriates who can combine regular visits to India with non-emergency medical procedures. India also hopes to capitalize on its traditions of Ayurvedic and other non-allopathic treatments, which might constitute a special niche and attract another clientele.

But positioning itself in the global medical market means a lot of changes, and most of those require government subsidies. The ingredients for success include inducing the government to support the enterprise through incentives or tax breaks, adopting international accreditation standards, negotiating with insurers to facilitate coverage for overseas patients, and aggressively selling India as a desirable medical Mecca. The possibility of earning $1 billion from medical tourism by 2012 looms large. India's National Health Policy adopted in 2002 therefore explicitly seeks to "encourage the supply of services to patients of foreign origin on payment;" such payment is treated as 'deemed exports,' which makes them eligible for all fiscal incentives extended to export earnings. As in the case of Thailand, the redistributive effect of these policies favors the private sector at the expense of the public. Government spending on public health infrastructure is shrinking; data released in 2004 show that nearly 82 percent of all health expenditures in India is private.

This has raised the issue of equity in access to care. In the words of the dean of the King Edward Memorial Hospital in Mumbai, "The need to benefit Indian patients is the main goal, and medical tourism cannot be at their cost." And another critic has attacked the current policies as undermining equity in both India and the countries of origin:

> Medical tourism...reinforces the medicalized view of health care. By promoting the notion that medical services can be bought off the shelf from the lowest priced provider anywhere in the globe, it also takes away the pressure from the government to provide comprehensive health care to all its citizens... The services are 'cost effective' for those who can pay and ...come from countries where medical care costs are exorbitant because of the failure of the government to provide affordable medical care.

In short

US consumers who view medical tourism as a relatively harmless international means to share the wealth should rethink their position. There are compelling reasons not to encourage the outsourcing of health services. The international market in health care can have adverse effects on the host country as well as on the exporting one. Whatever the lures of the "scalpel safari" or the "rainforest-and-rhinoplasty" package, the undermining of fair shares in health may be the unkindest cut of all. ■

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coverage they want, and how they are willing to pay for coverage." The vehicle for this was the creation of a Citizens' Health Care Working Group, consisting of 14 individuals appointed by the Comptroller General of the United States.

The Working Group held 31 community meetings across the country, conducted an Internet poll, and received close to 5,000 commentaries on health care issues submitted by residents throughout the nation. These have been compiled and analyzed in a report that is being disseminated in an effort to get the public to "tell America's leaders what works and what doesn't" and what should be done about it.

Once more, with feeling

The politics of health care are traditionally contentious, both because the stakes are high and because every citizen is a stakeholder. Many attempts at reform have therefore fizzled in acrimonious battles that have pitted providers against each other, providers against patients, practitioners against payers, politicians against advocates, and narrow self-interest against public objectives.

The most recent attempt at providing universal health coverage in this country was the Clinton Health Care Plan. Initially, the combination of the propitious moment and the right leadership appeared to augur success. US businesses were feeling the pinch of rising health care costs, the number of uninsured was rising, the country as a whole was losing its comparative advantage in world markets, hospitals were eager to shed the burden of their "bad debt and charity" pools, and even physicians were complaining about the costs and complexities of billing multiple third parties. In 1993, President Clinton announced the promise of "health care that is always there, health care that cannot be taken away" amidst great fanfare. What ensued was a formidable, year-long national debate and the predictable mobilization of an opposition that derailed the discussion and ultimately the plan itself. The insurance industry and its allies exploited the proposal's complexity in a campaign to portray the plan as excessively bureaucratic and restrictive of patient choice. In print and non-print media alike, "Harry and Louise," a middle-class couple discussing their concerns about the plan, became the fictional spokespersons for the insurers' fears. In an attempt to seize the moment, salvage the original plan, or confuse the issue, a number of legislators introduced separate reform plans; before long, 27 different legislative proposals were vying for public attention and support. In the end, the Clinton plan had more opponents than supporters, the public became increasingly confused, and the issue of universal coverage was laid to rest. The matter has been largely dormant since then.

Given this history, it is surprising that the most recent effort at obtaining input from the population at large has yielded a number of areas on which there is significant agreement. The factors that propelled the 1993 health care debate are still present; indeed, the situation has been compounded by the increased recognition that the United States has the highest health care costs in the world while having worse health status and a substantial fraction of its population lacking health coverage.

Those attending the community meetings are not a representative sample of the population as a whole: they tended to be older, whiter, and more educated than the population at large. With this caveat, they revealed an unusual level of agreement on key issues, including: appraisal of the present situation, universal coverage, uniform comprehensive benefits, consumer input, financing, and desire for a system that is easier to maneuver and is more administratively efficient.

Appraisal of the current situation

An overwhelming majority (96.8 percent) of the persons attending the community meetings feel that the health care system is in crisis or constitutes a major problem. This opinion is particularly strong in larger cities including New York and Los Angeles, where 100 percent of participants so indicated. Similarly, over 94 percent feel that affordable health care should be part of national public policy.

Universal coverage

While a small minority (8.9 percent) believes that health care should cover only certain groups (presumably defined by age, income, or health status), the rest agree that there should be a uniform level of benefits for all.

A majority of those expressing an opinion feel that "everyone should be required to enroll in basic health coverage, either private or public." However, some feel that this should be an individual mandate requiring individual enrollment; others favor everyone having automatic coverage and access to care under a new national system. The former are in turn divided on coverage for undocumented persons and non-citizens, an issue that is likely to become more salient given the current sentiments on immigration.

Comprehensive benefits package

The Working Group adopted as a basic principle the need to guarantee "a defined set of benefits..., for all, across their lifespan, in a simple and seamless manner." These benefits are to be portable, unrelated to health or working status, age, income, or other categorical status.

While the specific content of the benefits package was left undefined, the Working Group's point of departure was that it should include wellness and preventive services, as well as treatment and management of health problems. The majority of participants in the process feel that coverage should be wide-ranging, including medical and mental, dental, and vision care. Participants also agree that both consumers and medical professionals should have a "major role" in defining services covered, with other players (government, employers, insurers) playing minor roles in the decision-making process.

Financing the system

The issue of how health coverage is paid tends to elicit more controversy than other aspects of reform. Nevertheless, a majority of those expressing an opinion (between 55

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Product Recalls

May 24, 2006 — June 19, 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 II Recalls

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

Name of Drug or Supplement; Problem; Recall Information

Acetaminophen 500 mg Tablets, OTC; Firm received a complaint of spotted (discolored) tablets due to mold contamination. PDK Labs, Inc.

Pulmicort Respules 0.25 mg/2mL (budesonide inhalation suspension); Lack of assurance of sterility. Lot Number: MA0133 exp. date: 01/2008, AstraZeneca LP.

Retavase Half-Kit (Reteplase recombinant) with 1 single-use vial Retavase powder (10 unit vial; 10.4 U strength); Kit may contain unlabeled vial of drug product. Lot numbers: 767174E (exp. date 12/2006), 767174F (exp. date 12/2006), 767486B (exp. date 03/2007), 767486D (exp. date 03/2007), PdI Biopharma.

Theophylline Extended-Release Tablets, 450 mg; Subpotent: OOS result obtained for the 6 month stability station during the L3 drug release analysis at the 12th hour time point. Lot 5185001SB, exp. date 02/2008, Pliva, Inc.

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and 88 percent of those attending community meetings) felt that "everyone should be required to enroll in basic health care coverage, either private or public."

At the same time, there is support for some persons paying more than others, their contribution usually being pegged to income, and to a lesser extent, to health behavior.

According to the report, in the course of the town meetings, "many individuals advocated a single payer system to eliminate the middleman, possibly one structured like Medicare or similar to the public school system." This would require everyone to pay taxes to support the system, whether or not they use it. This would not only be more equitable; it would also simplify the current multiplicity of payers and result in lower administrative costs.

Because resources are not unlimited, the matter of trade-offs was addressed through several questions. When asked how much more they would be willing to pay per year in order to support a system in which every American would have access to "affordable, high quality health care coverage and services," a majority of participants expressed a willingness to pay more for this goal: about one-third said they are willing to pay $300 or more per year in addition to their current payments, with one in seven willing to pay an additional $1000/year.

When confronted with different priorities competing for public spending, respondents ranked *"Guaranteeing that all Americans have health coverage/insurance"* as the highest. Similarly, when asked to evaluate different proposals for expanding access to care, respondents ranked *"Create a national health insurance program, financed by taxpayers, in which all Americans would get their insurance"* highest.

Open-ended comments submitted to the Working Group also emphasized a desire for a "single health care system." Among the 1,814 respondents who favored this alternative, fully 46 percent recommended a single payer system.

Consumers who are interested in commenting on this report may do so in one of three ways. The deadline for submitting comments is September 1, 2006. Comments may be submitted via e-mail to citizenshealth@ahrq.gov, online at www.CitizensHealthCare.gov, or via regular mail to Citizens' Health Care Working Group; Attn: Interim Recommendations; 7201 Wisconsin Avenue, Room 575; Bethesda, MD 20814. ■

DRUGS AND DIETARY SUPPLEMENTS

CLASS II Recalls *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

Trimethoprim Tablets, USP, 100 mg; Oversized Tablets; may contain a superpotent dose. Lot # 139935A, exp. date 11/2007, Teva Pharmaceuticals.

Verelan® PM extended-release capsules (verapamil hydrochloride), 300 mg; Low fill weight capsules. Lots: 5K066 (exp. date 07/2007), 5K124 (exp. date 08/2007), Elan Holdings, 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

Abrasive Cut-off Wheels. Packages are not properly labeled with precautionary information on proper use and operation. The failure of a user to follow the instructions below could result in injury. Robert Bosch Tool Corp., (800) 742-3869.

All-Terrain Vehicles. The cushion lever mounting bracket on the Suzuki 2006 model year QuadRacer ATV's frame can break. 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.

Bicycles. Bicycles with SW Carbon Stem with Magnesium Faceplate stems have a magnesium faceplate that holds the handlebar in place. The faceplates on the recalled stems can crack allowing the handlebar to break off the bicycle, posing a serious fall hazard. Specialized Bicycle Components Inc., (877) 808-8154 or www.Specialized.com.

Children's Cloth Books. The felt ears and limbs on the pop-up characters in Curious Buddies Children's Books can detach or come apart when pulled, which may pose a choking hazard to young children. Simon & Schuster Inc., (800) 732-9531 or www.simonsays.com.

Children's Windsuits. The Reebok logo appliqué on the clear rubber zipper of the Reebok Children's Windsuit pull on the jacket can detach, posing a choking or aspiration hazard to young children. Adjmi Apparel Group, (800) 873-5570 or www.Reebok.com.

Coffeemakers. The Black & Decker® Brand Thermal Coffeemaker may not turn off as programmed, causing the unit to overheat and melt, and posing a risk of fire and burn injury. Applica Consumer Products Inc., (800) 239-7145 or http://www.acprecall.com.

Crosstrainer Gliders. The resistance pistons on the Gazelle® Freestyle Cross Trainer and Gazelle® Freestyle Cross Trainer Pro Gliders can come off during exercise. If this happens, a person using the glider can fall off the exercise machine. Fitness Quest Inc., (800) 321-9236 or www.fitnessquest.com.

Digital Cameras. The HP Photosmart R707 Digital Cameras can cause certain non-rechargeable batteries, such as the Duracell CP-1, to overheat when the camera is connected to an AC adapter or docking station, posing a fire hazard. Hewlett-Packard Company, (866) 304-7117 or www.hp.com.

Digital Dive Computers. When using the Versa Pro 2A Digital Dive Computer set for "User Selected Digital Gauge Mode," the "Elapsed Dive Time" displayed can exceed the actual elapsed time under water. This can cause divers to ascend before fulfilling a decompression obligation, resulting in decompression sickness. Oceanic, (888) 854-4960 or service@oceanicusa.com.

Diving Regulators. A manufacturing error could cause the main housing of some Scubapro® X650 Second Stage Regulators to change shape over time, which could cause the cover and diaphragm to become dislodged. If this occurs, air flow will be interrupted and the regulators will no longer function, posing a drowning hazard to users. Scubapro®, (800) 808-3948 or www.scubapro.com.

Drill Bits. The Vermont American® 13-inch-Long Masonry Drill Bits packages are not properly labeled with precautionary information on proper use and operation. These and other manufacturers' 13-inch bits can bend when run at a high speed without being in contact with a work surface, resulting in loss of control of the drill and possible lacerations. Robert Bosch Tool Corp., (800) 742-3869.

Electric Pressure Cookers. The lid on these Welbilt Electronic Pressure Cookers can open prematurely while contents are under pressure, and hot contents can be expelled posing a burn hazard. QVC Inc., (800) 367-9444 or www.qvc.com.

Name of Product; Problem; Manufacturer and Contact Information

Electric Smokers. Smoldering wood chips used in the wood chip box of Electric Smokehouse Smokers can ignite into flames when the door of the unit is opened, posing a risk of burn injuries to users and property damage to nearby combustibles. Sporting goods stores sold these smokers nationwide from July 2005 through May 2006 for between $200 and $250, contact Masterbuilt at (800) 489-1581 or www.masterbuilt.com.

Flokati Rugs. These Wool Flokati Rugs fail to meet the federal mandatory standard for flammability under the Flammable Fabrics Act and could ignite, presenting a risk of burn injuries. Phil Vassil Rugs, (800) 844-5345 or www.flokatirug.net.

Full-Body Safety Harnesses. The Safety Harnesses Sold with Hunting Tree Stands could fail during use, resulting in consumers falling from tree stands and suffering serious injuries or death. Summit Treestands LLC, (800) 226-1157 or www.harnessrecall2005.com.

Gas Grills. The Nexgrill Gas Grill has a hose that connects the propane tank to the burner manifold. If this hose runs up too close to the firebox, the heat can cause the hose to detach from the burner manifold, causing a gas leak and a fire hazard. Nexgrill Industries Inc., (888) 361-0888 or http://nexgrill0025.serorder.com.

Gas Ranges. These Sunbeam Gas Ranges lack an adequate heat shield, and can cause scorching of certain flooring materials directly under the appliance. Atlas Industrial S.A., (888) 597-8660 or www.sunbeammajorappliances.com.

Hammocks. The welds attaching the arms to the frame of the Garden Treasures Foldable Steel Hammock Stand can fail, allowing the hammock to fall. Users can be injured from falling to the ground, striking the hammock stand's base, or being struck by the arms of the hammock stand. LG Sourcing Inc., (866) 208-0827 or www.lowes.com.

Lighted Ficus Trees. The lights attached to the Lighted Ficus Tree have undersized and exposed wires, which pose a risk of electric shock and fire hazards. LTD Commodities LLC, (866) 736-3654 or www.ltdcommodities.com.

Mirrors. Exposed wires inside the Simply Basic Lighted Mirror could pose an electrical shock hazard to the user when they touch the mirror. Wal-Mart Stores Inc., (800) 925-6278 or www.walmartstores.com.

Money Bag Candles. The decorations on the "Money Bag" Candles can ignite, posing a fire hazard. Also, excessive pooling of wax from the burning candles poses a burn hazard. The Swiss Colony, (800) 991-4442 or www.swisscolony.com.

Pacifiers. The nipple of "Baby 2 Pack" Pacifiers can easily detach from the guard, posing a serious choking hazard to young children. KI, also known as Kole Imports, (800) 874-7766 or recall@koleimports.com.

Portable Radios. The battery in Etón E1XM-Model AM/FM/SW/XM-Ready Radios can overheat and possibly rupture when using the AC adapter, posing a fire and burn hazard to consumers. Etón Corp., (800) 872-2228 or www.etoncorp.com.

Sandals. The Sam & Libby Girl's Thong Sandals' metal tacks, which help to hold down the sides of the strap to the sole, can detach or be pulled out, posing a laceration hazard. Nine West Footwear Corp., (800) 999-1877 or recall@SamAndLibby.com.

Speakers. On some Yamaha In-Ceiling and In-Wall Speakers, the mounting clamps can break causing the speaker to fall. Falling speakers could possibly hit consumers. Yamaha Electronics Corporation, (800) 609-or yecsupport@yamaha.com.

Swivel Rockers. The Herrington Swivel Rocker can be assembled incorrectly, causing them to break at the base or tip over backward easily. This poses a fall hazard to consumers. LG Sourcing Inc., (866) 259-8170 or www.lowes.com.

Thunderstick Rocket Fireworks. The Thunderstick Rocket Fireworks rockets are overloaded with flash powder, violating the regulatory standard for this product. During use, these fireworks could explode with a greater force than expected and cause burns and bodily harm to nearby consumers. BJ Alan Co., (800) 777-1691or www.fireworks.com.

Torchiere Lamps. An electrical problem in Dragonfly, Petunia, Iris, and Rose Torchiere Lamps can cause the torchiere lamps to spark, smoke or burn posing a fire or burn hazard to consumers. River of Goods, (800) 676-5523 or www.ShopNBC.com.

Treadmills. Due to a programming defect with the console, the 2006 Model Year Premier Console (sold with Vision Fitness treadmill frames) can unexpectedly increase in speed and elevation when the User Programs 4 or 5 are set for longer than 30 minutes. If this happens, the user could fall and suffer injuries. Vision Fitness, (800) 335-4348.

Treadmills. The Endurance Treadmills can unexpectedly accelerate or decelerate, possibly causing the user to lose control and fall. Joong Chen Industries, (800) 496-5632 or treadmillrecall@endurancecardio.com.

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Much-Needed Corrective Lenses for the 'Clinical Eye'

The year 1915 is considered a milestone in the history of medicine: prior to that, it is thought that the average person had little more than a fifty-fifty chance of benefiting from an encounter with the average medical doctor. But it turns out that that was an optimistic appraisal of medical efficacy. In fact, there is relatively little evidence that most tools in the medical armamentarium actually work. Now, as in 1915, a large proportion of what physicians recommend for patients is unfortunately based on history, hunches, and hope.

Some 34 years ago, policy-makers became aware that the costs of medical care were increasing without a commensurate pay-off in health status. As expenditures for medical care approached 9 percent of the gross national product, there were growing concerns with "the lack of a direct and explicit relationship between the sharp increases of health care, the expanded use of medical technologies and improved health." This in turn raised questions about the efficiency and efficacy of health care, and created a demand for information on whether or not these "improvements" were indeed providing value for the money invested. In 1972 Congress created an Office of Technology Assessment (OTA) as an analytical arm of Congress aimed at helping policymakers "anticipate and plan for the consequences of technological changes and to examine the ...ways in which technology affects people's lives."

During the 11 Congressional sessions during which it operated, OTA became an extremely valuable source of information for members of Congress and their staffs in helping to craft policy that affected or had implications for technology. It also raised the value of technology assessment, prompting many health science schools to include courses on safety and efficacy of medical technologies in their curricula. This productive research arm of Congress issued 750 reports before it fell victim to the Gingrich revolution in 1994.

Shortly after the OTA was created, it was estimated that only 10 percent to 20 percent of all procedures in medical practice had been shown to be efficacious by controlled trial. Now, almost 30 years later, OTA no longer exists and the situation is not much better. While many clinical trials of drugs, procedures, and devices have been conducted during the past three decades, developments in medical technology have outpaced the resources available to evaluate them. As a result, the United States has a high-tech health care system that costs more than $2 trillion a year, but there is little or no evidence that much of the existing technology now is actually safer and more effective than older, cheaper alternatives. Indeed, although results of randomized clinical trials are reported in the daily press and consumers confront confusing and conflicting guidelines with disturbing frequency, the portion of medical practice that has been proven effective is still in the range of merely 20 percent to 25 percent.

A recent article in *BusinessWeek Online* comments on this sorry state of events, and reports on the work of Dr. David Eddy, who has spent his career "proving that the practice of medicine is more guesswork than science." Trained in both medicine and mathematics and devoted to evidence-based medicine, Eddy uses simulation models to replace hunches and conventional wisdom with proof of efficacy. The computer-based techniques he has developed with physicist Len Schlessinger thus seek to bring rationality into the medical system. The team developed a software system named "Archimedes" under the sponsorship of Kaiser Permanente. This tool has allowed them to simulate clinical trials, mimicking the human body's responses to alternative treatments to test their costs and efficacy. These simulations are not only faster and less costly than long-term randomized clinical trials, but they also avoid many of the pitfalls of trials, including selection bias, attrition of the study population, non-adherence to protocol, and the encroachment of history and maturation, among others. Furthermore, the models provide responses to 'what if?' questions that could not be answered in human trials because of logistical or ethical constraints. It must be stated, however, that for many purposes, such as adequately testing the safety and effectiveness of drugs and medical devices, there is currently no substitute

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Wall Climbing Cable. The cable eye, or round metal tube that holds the Cable Assemblies (used in wall climbing) cable, could have a fracture, reducing the overall strength of the cable assembly. If the cable assembly were to fail, this would result in a free-fall hazard for the climber. Extreme Engineering, (916) 663-1560 or info@extremeengineering.com.

Water Shoes. Though H&M Girl's Water Shoes are marketed for use around water for traction, they become extremely slippery when wet. This poses a risk of slipping and falling on smooth, hard surfaces such as tile. H&M USA, (877) 439-6261 or www.hm.com.

Yo-Yo Toys. The Light-Up Yo-Yo Toy giveaway at Ruby's Diner, Inc., can separate and expose small parts. This presents a choking hazard to young children. The Ruby Restaurant Group, (800) 439-7829.

Laser Therapy for Smoking: Shining a Laser on Bad Advertising Practices

On June 22nd, Public Citizen petitioned the U.S. Food and Drug Administration (FDA) to stop five companies from illegally promoting low-power laser therapy as a means to quit smoking. The clinics, Freedom Laser Therapy Inc., the Anne Penman Laser Therapy clinics, New Beginnings Laser Therapy, Laser Concept and the Stop Smoking Laser Center, are marketing laser therapy as a safe and effective smoking cessation treatment despite the lack of FDA clearance or any evidence that it is effective.

Laser therapy, also known as laser acupuncture, aims a low-power laser beam rather than needles at various points of the body. It is approved by the FDA for marketing only for the temporary relief of pain. For all other uses, the therapy may be used only for investigational clinical trials or studies. "The laser device does not

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CORRECTIVE LENSES, *from page 8*

for randomized clinical trials in human subjects.

For each of the diseases it has modeled to date, "Archimedes" creates a virtual study population at risk of getting or who already have the condition. Different treatment options and management protocols can then be programmed to order to gauge results in outcomes and costs. Because between 50 and 100 biological variables can be incorporated into the model, the simulation is quite comprehensive and accurate. Using "Archimedes," Eddy has been able to overturn the conventional approaches to treating diabetes, debunked the indiscriminate use of certain types of cancer screening, and proved the lack of efficacy in using bone marrow transplants to treat breast cancer. He has therefore protected patients from exposure to useless or even harmful treatment, while saving payers millions of dollars. The software's accuracy and versatility have been proved over the course of several years, and the system is being expanded to include more diseases and the interactions between them. More important, because of its connection to Kaiser, the results of the virtual trials are already informing decisions about both medical care and resource allocation. Kaiser Permanente has therefore changed its practice guidelines for treating a number of high-prevalence diseases, including cardiac disease and diabetes.

In addition to looking at collective data to ferret out what treatments work, Archimedes has the potential to counsel individual patients. Last year, Kaiser Permanente and the American Diabetes Association launched the use of the system to allow patients to predict their risk of getting diabetes or its complications. The "Diabetes PHD (Personal Health Decisions)" tool includes an online intake form that collects data on the individual — e.g., age, race, weight, medications, blood pressure, family history — to produce a personal health-risk profile. The system's capabilities to answer "what if?" questions can then be used by patients to see how changing their diets or exercise patterns can affect their risks of developing diabetes.

The tool therefore holds the promise of testing new regimens while challenging much of what is considered medical "knowledge." Unlike its namesake, Archimedes of Syracuse, whose discoveries and inventions led to weapons of mass destruction, the new "Archimedes" can be life-enhancing, promoting more targeted disease prevention and more effective management. If it succeeds in replacing medical guesswork with evidence, the health community may join Dr. Eddy and his associates with a well-deserved "Eureka!" ■

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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LASER, *from page 9*
have marketing clearance for smoking cessation, and promotion of such use as well as claims of safety and/or efficacy for this use are illegal," reads the seven-page Public Citizen petition.

Although all five companies are violating FDA laws and regulations, the petition focuses on Freedom Laser Therapy (FLT), which has garnered the most news coverage on multiple local and national television programs. FLT claims an 85 percent success rate for curing smoking addiction in just one 30-minute session. It also touts the support of "international clinical trials" to back up its claims. But inspection of the three "international clinical trials" offered on the company's Web site reveals that none has been published and none is a proper trial that would offer scientific evidence that laser therapy is a valid treatment to stop smoking.

FLT's therapy is $399 for the single 30-minute session, an expensive treatment for typical smokers who are trying to quit. According to the petition, this money would be better spent on treatments that have been proven to show some success: nicotine replacement therapy, physician advice, certain antidepressants and individual behavioral counseling.

Despite the lack of scientific evidence supporting its claims, the company has launched an aggressive marketing campaign to recruit a wide audience of vulnerable clients who are looking to stop smoking. It has created two promotional videos, orchestrated coverage on at least 20 local and national news programs and has run a demonstration booth backstage at the nationally televised American Music Awards to appeal to celebrities as potential spokespeople. In all of its advertising, FLT presents laser treatment as a much more credible option than has been shown in the medical literature.

"FLT claims it is conducting clinical trials authorized by the FDA, however the nature and extent of its advertising and promotional activities portray a company that is clearly marketing a self-proclaimed proven treatment," said Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. "At this time, there is a lack of any scientific support for the use of laser therapy for smoking cessation, and to claim otherwise is illegal."

A thorough review of the medical literature reveals only a single well-designed study that could answer the question about laser effectiveness for smoking cessation and this study revealed "no difference" between laser acupuncture and placebo.

Its violation of the law and misleading advertising to a susceptible audience make this industry a prime target for FDA action. According to FLT's Web site, it plans to open franchises across the country and expand the treatment to include weight loss in addition to smoking cessation.

"Manipulative and aggressive marketing campaigns such as this must be met with equally aggressive FDA action in order to protect the health and interests of the public," states the petition. ■

OUTRAGE, *from page 12*
were more than twice as high among unmarried women (67 per 1000 women, compared to 32 for married women); there was also a marked difference in how women dealt with their unwanted pregnancy: 58 percent of unmarried women (vs. 27 percent of married women) opted for abortion.

Cohabiting women were particularly vulnerable to both unintended pregnancy and abortion and therefore should be a particular target for pregnancy planning services.

There is a sharp income gradient in unintended pregnancy rates that became even steeper during the 7-year study period. In 2001 the rate ranged from 112 per 1000 women for those with incomes under the poverty line to 29 per 1000 women for those whose income was at least twice the poverty level. This 3.8-fold higher rate among poorer women represents a substantial increase over the 2.4-fold ratio registered in 1994. Furthermore, because the disparity in abortion rates by income increased as well, in 2001 poor women had unintended births at 5.3 times the rate of their more affluent counterparts. The corresponding ratio was 3.3 in 1994, again underlining the widening gap in fertility control among women from different economic strata.

A similar gradient is found with respect to educational level: the rate of unintended pregnancy declines with years of schooling, while the likelihood of ending an unintended pregnancy by abortion increases with education. As a result, in 2001 the unintended birth rate was four times higher among those with less than a high school diploma than for those with a college degree. Again, this represents a widening over time: in 1994, the corresponding ratio was 3.1.

Because socio-economic status (income, education) is so clearly linked with race/ethnicity in this country, unintended pregnancy rates vary dramatically by race. But even holding income constant to control for its effects on pregnancy outcomes, race/ethnicity continues to exert an influence. Among poor women, Hispanics have an unintended pregnancy rate that is twice as high as that of their white counterparts. Above the poverty line, however, it is black women who have a rate significantly higher than that for the rest of the population.

These trends are disturbing both because they reflect intrinsic inequities and because they suggest disparities that begin in utero and most likely carry over to another generation. Moreover, women who lack control over their fertility are relatively powerless to effect change in other aspects of their lives. Unintended pregnancy is therefore a marker for lack of social control, which in turn affects the health of women and their children in a self-reinforcing cycle of powerlessness and poor health. ■

The Growing Gap In Reproductive Health

No woman is completely free unless she is wholly capable of controlling her fertility...no baby receives its full birthright unless it is born gleefully wanted by its parents.

— Alan F. Guttmacher, MD

Control over reproduction is of vital importance for the well-being of women and their children. But, even with seeming widespread access to contraception, not every child is a wanted child. A recent article published by the Guttmacher Institute examined measures of pregnancy intent and outcomes, comparing data from 1994 with those for 2001. Not unexpectedly, the study found that women's childbearing options and outcomes are not evenly distributed: whether or not a pregnancy is intended varies markedly by age, marital status, socio-economic status (income, education), and race/ethnicity. But what is surprising and disturbing is that most of these disparities increased significantly between 1994 and 2001.

In 2001, 3.1 million (49 percent) of all pregnancies were not intended; of these, 44 percent ended in births, 42 percent in abortions, and 14 percent in fetal losses. The unintended pregnancy rate was 51 per 1000 women between the ages of 15 and 44. Although these two indicators — the proportion and the rate of unintended pregnancy — were virtually unchanged from 1994, they mask significant differences over time that emerge when the data are broken down by specific subgroups.

The rate of unintended pregnancy was highest among women between the ages of 18 and 24. This cohort had one unintended pregnancy for every 10 women, a rate twice that for all women. The proportion of unintended pregnancies was highest among those under 19 years of age, and generally declined with age. Adolescents experienced the greatest decreases from 1994 to 2001 in the rate of intended pregnancy (a decline of 40 percent); but, because the rate of unintended pregnancy rate fell less steeply, the proportion of unintended pregnancy actually increased overall for the youngest groups.

The proportion of unintended pregnancies ending in abortion declined for all age groups but was particularly high among adolescents. While the abortion rate decreased overall, the trend in pregnancy termination varied by age group: it declined among women under 25, but remained stable among older cohorts.

Rates of unintended pregnancy

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