PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Single Payer Health Care in Taiwan: Borrowing Ideas, Improving on Medicare

Few countries have an opportunity to create a health system anew. Even those that embark on drastic reforms have to take into account the existing resources: providers, infrastructure, financing mechanisms and the culture of care, all of which have to be combined and balanced against patient needs. The difficulties of bringing all these into alignment lead most nations to make limited adaptations at the margin rather than tackling major changes. Occasionally, however, a nation will launch a really new system, and that is what Taiwan did in the early 1990's. As the U.S. once more contemplates the prospect of health reform, it needs to look at how others have achieved universal health care. The Taiwanese system and its evolution are therefore of interest.

Taiwan, which has a strong capitalistic economy, opted for a system that is programmatically decentralized but fiscally centralized. One of the cornerstones of the reform is a single payer that collects and pools revenues and purchases health services for the entire population. But the delivery of care is largely in private hands, and the locus of service depends on a combination of patient choice, geography and the linkages between the different levels of care.

A bit of history

Prior to 1995, some 59 percent of Taiwan's population was covered by one of 13 different health insurance schemes, most of which followed occupational lines, e.g., labor insurance, government employee insurance, military personnel insurance and farmers insurance. The 41 percent who were uninsured had very restricted access to medical care, resulting in wide socio-economic disparities among the population. It was these inequities that prompted policy makers to rethink how health care was delivered and paid for. The new system had two major goals: to equalize access for all citizens and to control total health spending.

Taiwan's process of health reform was characterized by leisurely planning but hasty enactment. The country devoted seven years to redesigning its health system and followed the dictum of thinking globally while acting locally. Taiwanese policy-makers and health care experts examined the health care systems of more than 10 countries, including Medicare in the United States, choosing those structures and practices that best furthered their objectives. As a result, Taiwan's National Health Insurance (NHI) is commonly described by its managers as a vehicle "made from imported parts but assembled in Taiwan." At the end, the NHI timetable was determined by political considerations. The need for the party in power to pre-empt the opposition, which had long advocated for universal health insurance, resulted in a compressed implementation schedule. After 18 months of parliamentary debate, the NHI bill was passed in July 1994. The Bureau of National Health Insurance began operating in January 1995, and the plan was launched a mere two months later.

Given the complexities of health care and the short time span between approval and delivery, it is not

continued on page 2

CONTENTS

from page 1

surprising that the plan got off to a rocky start. Providers had difficulty adjusting to some of the changes, but the public welcomed the change. Over time, the NHI has introduced the latest information technology, made adjustments in how services are paid, equalized access to care, and strategically modified some of its incentives in order to curtail some practices and promote others.

Basic Principles

Whether or not it started with these specific guidelines at the outset, the Taiwanese NHI is now characterized by the following:

Universal coverage

The NHI is described as a "mandatory social insurance system whose main purpose is to ensure that everyone is insured." Starting from slightly more than half of the population insured before the new system began, the NHI had covered 96 percent of the population in less than two years; it is now estimated to enroll 99 percent of the total. Because the previous insurance schemes were employment-based, the increase in coverage that accompanied NHI benefited mainly the elderly, children, students, and housewives.

Comprehensive benefits

The state sets uniform benefits so that everyone has the same coverage. This includes ambulatory care, in-patient care, emergency care, prescription drugs, lab tests, rehabilitation, mental health services, dental care, prevention and home care. Moreover, the system covers both Western allopathic services and Chinese medicine. There is cost-sharing, but this is designed to reflect the types of consumer behaviors the system seeks to promote. Most preventive services are free, and regular office visits have a modest copayment (approximately $5 per visit), from which certain groups are exempt. Hospitals stays have a 10 percent co-insurance, but the total is capped at 6 percent of the average national income per person for each admission and at 10 percent for each calendar year. Co-payments have been waived for the very poor, veterans, and aboriginal populations.

Freedom of choice

Patients have a free choice of a primary care physician, through which they are expected to go through for referrals to ensure continuity of care. Patients can also opt to go directly to specialists, but they are subjected to a higher charge. Pre-authorization is required for some high-tech and experimental procedures. In addition, the charges to patients who are not exempt from cost-sharing increase with level of health care complexity. Thus a visit for a given service will cost more at the secondary or tertiary level than it will at the primary level.

Public/private delivery of care

Taiwanese health services are delivered by either public employees in government-owned facilities or by private providers who contract with the state. In 2006, the NHI had contracted with over 18,000 medical care facilities, more than 91 percent of Taiwan's total. In addition, the NHI contracts with pharmacies, home care institutions, laboratories, and rehabilitation and other specialized providers. The goal is for all facilities to be under contract with the NHI.

The central government exerts its power as the single payer by setting the scope of the benefits package, deciding the extent of cost-sharing, contracting with providers and other vendors (including the pharmaceutical companies), setting fees and budgets and monitoring service utilization and costs.

Cost control through global budgets

Before the NHI went into effect, and in the early stages of the system, providers in Taiwan were paid on a fee-for-service basis. And because physicians were allowed to prescribe and dispense pharmaceuticals freely, they tended to overprescribe and kept their visits short. Fee-for-service promoted demand, and led to a rise in utilization of services and the proliferation of new medical technology. This in turn resulted in a rapid escalation in spending, which the NHI addressed by modifying the modality of paying providers. In order to control induced demand and reduce the number of visits per person, Taiwan introduced a sliding fee schedule which paid doctors less for visits above a given volume. In addition, the insurance system reduced the high profit margin by lowering the reimbursement rates for drugs and promoting the use of generics. Another change was the gradual introduction of paying physicians per case rather than per procedure. The "case payment" method currently covers 53 diagnosis related groups. Finally, the NHI has phased in global budgets for different types of services (dental, inpatient, hospital care), which are centrally allocated to the different regions. This has artificially capped payments, with some grumbling on the part of providers. The system is also introducing pay-for-performance measures designed to reward certain provider behaviors indicative of quality care. The latter is still being done on pilot basis, with results being carefully monitored.

Administrative and operational efficiency

As a single payer, the central authority has the ability to monitor care and keep close tabs on health spending. The fact that there is a set benefit package for everyone simplifies administrative transactions. Moreover, provider and patient profiles enable to system to identify outliers and reduce fraudulent claims, overcharges, and duplicate services and tests. In addition, there is only one system to report procedures and file claims, thereby greatly reducing administrative costs. Because hospitals and clinics are required to submit completed claims within 24 hours

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after delivery of service, the Bureau of National Health Insurance is able track in almost real time what is happening in the Taiwan's health system.

Probably the most visible symbol of the system is the 'smartcard' carried by all who are enrolled in the system. Its introduction in 2004 was hailed as a "major breakthrough in the digitalization of NHI-related medical care information." In addition to establishing the identity of the holder, the card allows for the flow of information through Taiwan's medical network while employing a number of safety features to protect against counterfeiting and security breaches. By inserting the card into a reader, the physician can obtain the patient's history and list of medications. The information system allows all medical providers to file expenditure claims electronically, thereby shortening the time between the delivery of care and its payment.

As a result of these governance and data-gathering systems, the direct operating cost of Taiwan's NHI program is approximately 2 percent of total expenditures. This is in marked contrast to the transaction costs of commercial insurance in the U.S., which are estimated to account for 10-12 percent of premium revenues.

Social solidarity

The way in which health services are financed can not only achieve administrative and programmatic objectives, but also foster social solidarity and redistribute wealth. The financing of Taiwan's NHI comes primarily from payroll taxes. This tax was originally set at 4.25 percent of income, and has since been raised to 4.55 percent. This premium is paid by households, employers, and government. The share of each of these groups varies by demographic subgroup and has a highly redistributive effect, with those whose incomes are higher contributing a larger percentage. For example, a public employee will pay 30 percent of the premium, while his employer will pay 60 percent and the government, the remaining 10 percent. Self-employed persons, be they in business or in the professions, pay the entire premium themselves, while government subsidizes the entire premium for veterans, military personnel and those in the lowest income groups. This redistributive effect is somewhat attenuated by cost-sharing, which is uniform across income levels except for the very poor. Nevertheless, the overall impact has been beneficial, with the equity in financing health care in Taiwan having improved since the NHI went into effect.

Growing pains

Taiwan takes pride in its system, which is in many ways innovative and successful. It is therefore engaging in "medical diplomacy," introducing its NHI at different international forums and publishing its reports in English and other languages to reach a global audience. Some of this is designed to bolster its political case for inclusion as a member in the World Health Organization, a much-coveted entry into participation in the United Nations that has been barred by China because of its antagonism to Taiwan. But at least a portion of the "cheerleading" reflects a need for well-deserved recognition on the part of other countries that have struggled with the same issues with less-favorable outcomes.

Despite its successes, Taiwan has been facing increasing budgetary deficits. Although the system's financing is based on principles of self-sufficiency and pay-as-you-go, in recent years the collection of revenues has been outstripped by rising medical costs, causing serious shortfalls. These have been met with rising premiums and more stringent cost controls, including closer oversight of utilization data. The NHI has also adopted an agenda of "micro-adjustments" to better align expenses with revenues. The system is sufficiently nuanced and complex to allow changes in multiple aspects. Moreover, it has been able to secure strong political support, with 80 percent of the Taiwanese population expressing satisfaction with their national health care. ✦

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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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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Health Letter Volume Index, 2008

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Indulgence and Innovation in Medical Care

A convergence of dissatisfied patients and entrepreneurial doctors has led to novel modalities of care. Medical services are being delivered through new channels, both because technology has made it feasible and because some physicians and their associates have found that health entrepreneurship can be lucrative for them and convenient for consumers. How do these modalities operate, and what are their limitations and policy implications?

It is our view that many of these new ways of delivering medical care are fringe phenomena that are, hopefully, unlikely to catch on or affect a large fraction of the population. Nevertheless, they are emblematic of our fragmented services and the willingness of both patients and practitioners to seek new ways to obtain and provide health care. Are they — to use that tired metaphor — attempts at "putting lipstick on a pig"? We think so. At their best, they represent innocuous attempts at innovation. But at their worst, they nurture frivolous needs and further stratify a system in which services are rationed by ability to pay. For those who believe in health without tiers, these attempts at care are yet another diversion from fundamental reform and a way to indulge the healthy and wealthy at the expense of the ill and poor.

Boutique or concierge medicine sounds like an oxymoron. After all, as one writer has indicated, isn't "boutique" most often "a chi-chi word for a small shop that sells you things you don't really need, for occasions you should really have ignored, at prices you couldn't afford?" Well, much of that applies to health care as well, and certain savvy doctors have capitalized on patient complaints concerning impersonal and hurried care and long waits. The result is the practice of boutique medicine, which now has a 10-year history. The term refers to a medical practice in which patients pay a set annual fee for "special service." Patients who pay their "dues" are therefore admitted into a "club" with certain privileges. The latter usually include the following:

- guaranteed same-day or next-day appointments;
- e-mail and telephone access to the doctor;
- extended time with the physician;
- routine checkups or preventive care that may not be covered by insurance.

Other perquisites may be nicer and less crowded reception areas, spa-like amenities and décor, the possibility of house calls, and wellness counseling for particular risk factors.

Patients are therefore guaranteed 24/7 accessibility without having to rely on an emergency room. But because this care is strictly ambulatory and excludes the vast majority of tests and procedures, this care most often supplements and does not supplant health insurance. It is therefore strictly for those who are willing to pay extra to "jump the queue," get unfettered access to their doctors and receive special treatment. They will still need coverage for the rest of their health care, and have to be aware of the fact that added amenities are no substitute for quality.

For physicians, boutique medicine is partly a way of limiting their clientele to those who are healthier and wealthier. At the same time, this option can help doctors exert more control over their time and income, avoid some third-party payment, and develop longer-term relationships with their patients. Boutique medicine may therefore attract primary care physicians or internists who have ongoing relationships with their patients. Nevertheless, doctors who choose this type of practice must abide by the laws that apply in their state. And because collecting fees in advance for medical care may be considered "insurance," some practitioners of boutique medicine have run afoul of the insurance regulations in their jurisdictions.

When it comes to inpatient care, some hospitals offer concierge

continued on page 6

from page 5

floors and their attendant services at a significant premium. In-hospital concierge care may include larger rooms, greater privacy, gourmet meals, movies, lounges, Internet access and a coffee bar. These "perks" are paid out-of-pocket and are not covered by insurance.

Medical spas are at the margin of medical care, the bulk of their services being outside the purview of physicians' practices. Most of what they do is cosmetic (e.g., manicures, massages), the very name "spa" conjuring up images of fluffy towels and the sounds of soothing music. But many medical spas also provide services that are perilously close, if not identical, to medical treatment and that involve shots, lasers and prescription-strength medicines. For example, they may give "fat-burning energy shots," perform dermabrasion and inject Botox or ReStylane and other dermal fillers.

Patients may be unable to distinguish pampering from prescription, and therefore place themselves in the hands of ill- or inappropriately-trained practitioners.

While the term "medical spa" is most often reserved for those facilities that operate under the full-time supervision of a licensed health professional, there may be a lot of latitude in what is considered "supervision" and "licensed health professional." Staff and services may be supervised by someone off the premises, and the health professional may be a nutritionist or a therapist who is not trained to perform or oversee these procedures. Because there is no uniformity in practices within the medical spa industry or across states, services may be unregulated and unmonitored. And patients may be unable to distinguish pampering from prescription, and therefore place themselves in the hands of ill- or inappropriately-trained practitioners. Not surprisingly, those in the business are moving towards developing guidelines and adopting standards of care. Their goals: raising the bar on criteria and ensuring some consistency in practice.

Retail medicine comprises services offered in a drugstore or other type of retail establishment. They have names such as TakeCare, RediClinic, QuickCare and MinuteClinic, and offer primary care services for a finite number of easy-to-diagnose conditions. Their goal is to provide "routine, non-emergency services to walk-in patients at affordable prices." These clinics have been growing fast — there are approximately 900 of them now — and major players such as the Mayo Clinic have joined the trend, opening Mayo Express Care in a shopping center in Minnesota. Most clinics are operated by nurse practitioners and are open seven days/week, for longer hours than most physicians' offices. Moreover, because these clinics limit the type of services they provide, patients are usually in and out in 15 minutes. Offering convenience and accessibility at relatively low costs, these "McDocs" are meeting some of the needs of some of the population. A study of retail health clinics carried out by the RAND Corporation found about 90 percent of the visits were for preventive care or for treatment of simple acute conditions; these conditions represent 18 percent of primary care visits and 12 percent of emergency department visits.

This modality has understandably also incurred the wrath of some doctors. The American Academy of Pediatrics is on record opposing retail-based clinics as an appropriate source of care for infants, children and adolescents. The Academy feels that the clinics foster the fragmentation of care, have possible negative effects on quality, replace on-going care with episodic care, lack adequate mechanisms for follow-up and create gaps in the patient's medical record. And, because many of the clinics are in drugstores such as CVS, Rite Aide, and Walgreens, last year the American Association called for an investigation into the burgeoning phenomenon, based partly on the potential conflict of interest regarding drug sales. More recently, however, the entry into the business of doctor-staffed clinics with "brand-names" such as Mayo and MedStar may have assuaged some of the critics.

Therapy on wheels is the brainchild of two New York psychologists who came up with the idea of chauffeured sessions for patients who are too busy or stressed to go to a therapy but who are able to fit in sessions when they are en route somewhere else. For those who have more money than time, these psychologists will pick them up in a customized van (outfitted with a couch and chairs) with a driver, hold a therapeutic session, and deposit them at their destination. The service costs $175 per session. Given New Yorkers' hectic lifestyles, the service has found a niche, expanding to six therapists, three drivers and four vans within the first seven months. Although perhaps specific to the Big Apple, this type of service reflects the willingness of consumers to pay for convenience and of health providers to pamper them.

If we had a much better health care system, with everyone having access to a permanent primary care physician or other health professional such as a nurse practitioner, the need for these profitable "innovations" would be greatly reduced if not eliminated.✦

Product Recalls

November 16, 2008 – December 10, 2008

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

DRUGS AND DIETARY SUPPLEMENTS

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

Recalls and Field Corrections: Drugs – CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplemenmt; Problem; Recall Information

Viril-Ity-Power (VIP), Maximum All-Natural Fast Acting Male Sexual Stimulant Dietary Supplement, Proprietary Blend of 560 mgs Per Serving, packaged in 2 tablets per blister pack and 8 count bottles, Polygonum Multiflorum, Epimedium Extract (leaves) 20% Extract, Dogwood Fruit-Cornus Officinalis, Foxglove Root (rehmannia Glutinosa), Gingko Biloba, Rhodiola Rosea (whole plant), Korean Ginseng Tribulus Terrestris Extract (70% Saponins), L-Arginine; 930,864 tablets; Unapproved New Drug; undeclared ingredient, hydroxyhomosildenafil, an analog of sildenafil. Sildenafil is the active chemical ingredient of an FDA-approved drug used for Erectile Dysfunction (ED). All Lot #s (to include): 6J001, 6J009, 6K027, 6K028, 6K029; International Pharmaceuticals Ltd.

Recalls and Field Corrections: Drugs – CLASS II

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

Name of Drug or Supplemenmt; Problem; Recall Information

Alka-Seltzer Plus® Cold Formula, Sparkling Original, each tablet contains Aspirin 325 mg, Chlorpheniramine maleate 2mg, and Phenylephrine bitartrate 7.8mg packaged in convenience packs which contain 4 effervescent tablets (2/2-tablet pouches per convenience pack); 73,116/2-pouch retail packages; Mis-packed; outer carton labeled to contain product with aspirin, chlorpheniramine maleate and phenylephring bitartrate actually contains product with acetaminophen, chlorpheniramine maleate and phenylephrine bitartrate. Lot #s: BTA6PP4, BTA6PP8, BTA6KU6, BTA6KU7, and BTA6KU4. All lot numbers have an exp. date of 10/2010; Lil' Drug Store Products Inc.

Chlor-Trimeton Allergy, Chlorpheniramine maleate, 12mg, 10 tablets or 24 tablet Blister Packs; 40 lots; cGMP (Good Manufacturing Practices) Deviations (by mfr Actavis). Lot #s and exp. dates: 6-CTM-5 11/30/2008; 6-CTM-5 11/30/2008; 6-CTM-6 11/30/2008; 7-CTM-1 01/31/2009; 7-CTM-2 01/31/2009; 7-CTM-3 03/31/2009; 7-CTM-4 03/31/2009; 7-CTM-4 06/30/2009; 7-CTM-6 06/30/2009; Schering-Plough HealthCare Products, Inc.

Drixoral Cold & Allergy, Dexbrompheniramine 6mg and Pseudoephedrine 120mg, Sustained Relief, maximum strength, 20 and 30 extended release tablets, blister packs; 40 lots; cGMP (Good Manufacturing Practices) Deviations (by mfr Actavis). Lot #s and exp. dates: 6-DRT-26 07/31/2008; 6-DRT-27 07/31/2008; 6-DRT-28 07/31/2008; 6-DRT-29 07/31/2008; 6-DRT-31 10/31/2008; 6-DRT-32 10/31/2008; 6-DRT-33 10/31/2008; 6-DRT-34 11/30/2008; 6-DRT-35 12/31/2008; 6-DRT-36 12/31/2008; 6-DRT-37 12/31/2008; 7-DRT-1 01/31/2009; 7-DRT-2 01/31/2009; 7-DRT-3 01/31/2009; 7-DRT-4 01/31/2009; 7-DRT-5 04/30/2009; 7-DRT-6 04/30/2009; 7-DRT-7 04/30/2009; 7-DRT-8 04/30/2009; 7-DRT-9 05/31/2009; 7-DRT-10 05/31/2009; 7-DRT-11 05/31/2009; 7-DRT-12 05/31/2009; 7-DRT-13 07/31/2009; 7-DRT-15 08/31/2009; 7-DRT-16 08/31/2009; 7-DRT-17 09/30/2009; 7-DRT-18 09/30/2009; 7-DRT-20 09/30/2009; 7-DRT-21 10/31/2009; 7-DRT-22 10/31/2009; 7-DRT-23 11/30/2009; 7-DRT-24 11/30/2009; 8-DRT-1 12/31/2009; Schering-Plough HealthCare Products, Inc.

Formulation R(TM) Hemorrhoidal Ointment, 1 and 2 oz tubes, Also packaged as: Publix Hemorrhoidal Ointment, 1 oz. tubes; ShopRite Hemorrhoidal Ointment, 1 oz tubes; Exchange Select Hemorrhoidal Ointment, 2 oz tube; Laura Lynn Hemorrhoidal Ointment, 2 oz. tube; Food Lion Hemorrhoidal Ointment, 2 oz tube; 7,128 x 1 oz tubes; 17,880 x 2 oz tubes; Phenylephrine hydrochloride level may exceed specification due to inadequate validation of blend uniformity. Lot # 029807011, exp. date 03/2009; G&W Laboratories, Inc.

Kerlone Tablets, (betaxolol hydrochloride), 10 mg and 20 mg, Rx only, 100 tablet bottles, Sanofi-aventis/sanofi-synthelabo; 3 lots, 19526 bottles of Kerlone 10 mg; 2 lots, 7916 bottles of Kerlone 20 mg; cGMP (Good Manufacturing Practices) Deviations (by mfr Actavis). All lots within expiry; Sanofi-aventis.

Metoprolol Succinate Extended Release Tablets USP, 25mg, 50mg, 100mg and 200mg, 100 count (NDC 0185-0281-01) and 1000 count (NDC 0185-0281-10) bottles, Rx only; 6,369,592 bottles; Inadequate documentation and in-process controls such that product may not meet specifications through shelf life. All lots with expiry through 08/2010; Recalling Firm: Sandoz, Inc.

Primidone Tablets, USP, 50mg, Rx only, 500 count; 3,449 units; Subpotent; 12 month stability. Lot #: T081C07A; Vintage Pharmaceuticals, LLC.

Quinapril Tablets, USP, 5 mg and 10 mg, 90 Tablets, Rx only; 2 lots 5 mg, 15 lots 10 mg; 21,153 bottles of 90 count 5 mg and 171,894 bottles (90 count) of 10 mg; McGMP (Good Manufacturing Practices) Deviations (by mfr Actavis). All lots within expiry; Par Pharmaceutical, Inc.

Talacen Tablets CIV, (pentazocine hydrochloride and acetaminophen), 25mg base/650mg base, Rx only, 100 tablets, Sanofi-Aventis; 1 lot, 7351 bottles of Pentazocine HCL and APAP; cGMP (Good Manufacturing Practices) Deviations (by mfr Actavis). Batch # 70520A1, exp. date 10/2010; Sanofi-aventis.

Talwin NX Tablets, pentazocine and naloxone hydrochloride, USP, 50mg base/0.5mg base, Rx only, 100 tablet bottles; 8 lots of Talwin NX; cGMP (Good Manufacturing Practices) Deviations (by mfr Actavis). All lots within expiry; Sanofi-aventis.

48-Part Drug Recall due to Good Good Manufacturing Practices Deviations in Actavis Totawa, LLC, are the reason for a 48-part drug recall (names of products to follow). The manufacturer reports that the volume of products is too numerous to count, and all lots within expiry are affected. Check with your pharmacist to see if your lot is affected.

Oxycodone and Acetaminophen Capsules, 5 mg/500 mg, Rx only, 100 count bottles; Chlorzoxazone Tablets, 250 mg, Rx only, 100 count bottles; Ursodiol Capsules, 300 mg, Rx only, 100 and 250 count bottles; Naltrexone Hydrochloride Tablets, 50 mg, Rx only, 30 and 100 count NDC bottles; Carisoprodol Tablets, 350 mg, Rx only, 100 and 1,000 count bottles; Meperidine Hydrochloride Tablets, 50 mg, Rx only, 100 count bottles, Meperidine Hydrochloride Tablets, 100 mg, Rx only, 100 count bottles; Betaxolol Tablets USP, 10 mg, Rx only, 100 count bottles; Also labeled as Kerlone (Betaxolol Hydrochloride); Betaxolol Tablets 20 mg, Rx only, 100 count bottles; Also labeled as Kerlone (Betaxolol Hydrochloride); Trimethobenzamide Hydrochloride Capsules, 300 mg, 100 count bottles, Rx only; Loxapine Capsules, 5 mg, Rx only, 100 and 1,000 count bottles; Loxapine Capsules, 10 mg, Rx only, 100 and 1,000 count bottles; Loxapine Capsules, 25 mg, Rx only, 100 and 1,000 count bottles; Loxapine Capsules, 50 mg, Rx only, 100 and 1,000 count bottles; Pentazocine HCL and Acetaminophen Tablets 25 mg (base) and 650 mg, Rx only, 100 count bottles, Also labeled as Talacen CIV pentazocine hydrochloride and acetaminophen; Oxycodone Hydrochloride Tablets, 15 mg, 100 count bottles, 10 x 10 blister packs; Oxycodone Hydrochloride Tablets, 30 mg, Rx only, 100 count bottles, 10 x 10 blister pack; Rifampin Capsules, 300 mg, Rx only, 30 count bottles; Buspirone Hydrochloride Tablets, 5 mg, Rx only, 100 and 500 count bottles; Buspirone Hydrochloride Tablets, 10 mg, Rx only, 100 and 500 count bottles; Buspirone Hydrochloride Tablets, USP, 15 mg, Rx only, 100, 180 and 250 count bottles, Also labeled for Major Pharmaceuticals, 100 and 180 count bottles; Buspirone Hydrochloride Tablets, 30 mg, Rx only, 60 and 180 Tablets bottles; Tizanidine Hydrochloride Tablets, 2 mg, Rx only, 150 and 500 count bottles; Tizanidine Hydrochloride Tablets, 4 mg, Rx only, 150 and 500 count bottles; Mirtazapine Tablets, 15 mg, Rx only, 30 and 500 count bottles; Mirtazapine Tablets, 30 mg, Rx only, 30 and 500 count bottles; Mirtazapine Tablets, 45 mg, Rx only, 30 and 500 count bottles; Quinaretic (Quinapril Hydrochloride and Hydrochlorothiazide) Tablets, 10 mg/12.5 mg, Rx only, 30 and 90 count bottles; Quinaretic (Quinapril Hydrochloride and Hydrochlorothiazide Tablets) 20mg/12.5mg, Rx only, 30 and 90 count bottles; Quinaretic (Quinapril Hydrochloride and Hydrochlorothiazide Tablets) 20mg/25 mg, Rx only, 30 and 90 count bottles; Quinapril Tablets, USP, 5 mg, Rx only, 90 count bottles; Quinapril Tablets, 10 mg, Rx only, 90 count bottles; Cilostazol Tablets, 100 mg, 60 tablets, Rx only; Hydromorphone HCL CII Tablets, 8 mg, Rx only, 100 Tablets; Isradipine Capsules, 2.5 mg, Rx only, 60 Capsules; Isradipine Capsules, 5 mg, Rx only; Dipyridamole Tablets, USP, 25 mg, Rx only, Film coated tablets, 100 and 1000 count bottles; Dipyridamole Tablets 50 mg, Rx only, Film coated tablets, 100 and 1000 count bottles; Dipyridamole Tablets, 75 mg, Rx only, Film coated tablets, 100 and 1000 count bottles; Meloxicam Tablets, 7.5 mg, Rx only, 100 and 500 count bottles; Meloxicam Tablets, 15 mg, Rx only, 100 and 500 count bottles; Trimipramine Maleate Capsules, 25 mg, Rx only, 30 and 90 count bottles; Trimipramine Maleate Capsules, 50 mg, Rx only, 30 and 90 count bottles; Trimipramine Maleate Capsules, 100 mg, Rx only, 30 count bottles; Cyclobenzaprine HCL Tablets, 5 mg, Rx only, Film coated tablets, 100 count bottles; Cyclobenzaprine HCL Tablets, 10 mg, Rx only, Film coated tablets, 100 and 1000 count bottles; Hydroxyzine HCL Tablets, 10 mg, Rx only; 100 and 1000 count bottles; Hydroxyzine HCl Tablets, 25 mg, Rx only, 100 and 1000 count bottles; Hydroxyzine HCL Tablets, 50 mg, Rx only, 100 and 1000 count bottles; Phendimetrazine Tartrate Tablets, 35 mg, CIII, 1000 tablets.

CONSUMER PRODUCTS

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

Name of Product; Problem; Recall Information

Air Compressors. The air compressor's components can fail, which could cause a stoppage of air flow. This poses a risk of drowning to users. Brownie's Third Lung, (800) 327-0412 or www.browniedive.com.

Anthropologie Tin Candles. The candle flames could flare up out of the tin container during the burning of the last half inch of wax, posing a fire and burn hazard. Candela Group, (866) 961-9050 or www.candelagroup.org.

Arizona® Newborn and Infant Denim Pants. The metal snap at the waist can detach posing a choking hazard to infants. JCPenney Co., (888) 333-6063 or www.jcp.com.

Army Figures. Surface paint on the face of the Army figures contains excessive levels of lead, violating the federal lead paint standard. OKK Trading, (877) 655-8697 or www.okktoys.com.

Bead Maze Toys. The trees on the toys can detach, exposing a metal screw. This poses a laceration hazard to young children. ImagiPLAY, (800) 882-0217 or www.ImagiPLAY.com.

Century Cookware Stainless Steel Stockpots. The stainless steel pots have metal handles that can detach during use, posing a serious burn hazard to consumers. Ocean State Jobbers Inc., (800) 603-9601 or www.oceanstatejoblot.com.

DiNotte Lighting Lithium-Ion Batteries. A loose wiring connection and improper venting of the DiNotte Lighting Lithium-Ion battery used with bicycle lights can cause the battery to overheat, posing a burn hazard to consumers. AA Portable Power Corp., (866) 822-7694 or www.dinottelighting.com.

Dive Sticks. The recalled dive sticks could remain in an upright position, posing an impalement hazard to young children. CPSC banned pre-weighted dive sticks in 2001. Target, (800) 440-0680 or www.target.com.

EDP 3112 Rotor and Shaft Assemblies. If the assembly was installed in a fire suppression system and remained in a closed position, sufficient water might not have been available in the event of a fire. This posed a fire hazard to consumers. Watts Water Technologies Inc., (800) 615-9394.

GE®, GE Profile™, Monogram® and Kenmore® Wall Ovens. The extreme heat used in the self-clean cycle can escape, if the wall oven door is removed and incorrectly re-attached by the installer or the consumer. This can pose a fire and burn hazard to consumers. GE Consumer & Industrial, (888) 569-1588 or www.GEAppliances.com.

Groovy Fashions™ Sassy Jammies™ Doll Clothing Sets. Surface paints on the pajama pants contain excessive levels of lead, which violates the federal lead paint standard. Manhattan Group, (800) 541-1345 or www.manhattantoy.com.

Heavy Duty Acidic Cleaner Bottles. Pressure can build up in a full or nearly full bottle of the acidic cleaner when it is stored in elevated temperatures over an extended period of time, which can result in the cleaner leaking from underneath the cap. If the product comes into contact with skin, it can cause severe skin irritation. DuPont, (888) 241-2780 or www.stonecare.dupont.com.

Hockey Helmets. The helmet's chinstrap can unexpectedly disengage while in use. If this happens, the helmet can fall off, posing a head and neck injury risk to consumers. Reebok-CCM Hockey U.S. Inc., (800) 451-4600 or www.reebokhockey.com and http://en.ccmsports.com.

Insulated Black-Out Roller Shades and Insulated Roman Shades. The black-out roller shades and insulated roman shades have a continuous looped bead chain that when not attached to the wall or floor, hangs loosely by the blind, posing a fatal strangulation hazard to children. Green Mountain Vista Inc., (800) 639- 1728 or www.gmvista.com.

IRIS and ALVINE Roman Blinds. Strangulations can occur when a child places his/her neck in an exposed inner cord on the backside of the roman blinds. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Toddler Girl's Hat and Mitten Sets. The magnets in the hat can detach and fall out, posing a choking and aspiration hazard to young children. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Meijer Inc., (800) 927-8699 or www.aquariusltd.com.

Young Colors Children's Hooded Jackets. The jackets have drawstrings through the hood and at the waist. Children can get entangled in the drawstrings that can catch on playground equipment, fences or tree branches. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstring in upper garments, such as jackets and sweatshirts. From 1985 through June 2008, CPSC received reports of 27 deaths and 70 non-fatal incidents involving the entanglement of children's clothing drawstrings. R&D International Inc., (719) 539-3812 or www.youngcolors.com.

from page 12

hype therefore touts prevention and early detection, and promises "peace of mind" and the possibility of a "clean bill of health."

Although the procedure is fast and easy, and the result has been described as "dazzlingly sharp 3D pictures of the organs and the plumbing connecting them," full-body scans are not to be taken lightly. Indeed, the Food and Drug Administration (FDA), the U.S. Task Force on Preventive Services, the American Medical Association, the American Association of Physicists in Medicine, the Radiological Society of North America, the American College of Radiology, the American College of Cardiology, the American Cancer Society and the American Heart Association are all on record NOT recommending these scans for screening of asymptomatic individuals. Their reasons include the following:

1. Full-body scans can produce false positives. They most often uncover harmless abnormalities that may require, at the very least, watchful waiting, but may also result in painful and expensive biopsies, or further scanning. Even when the patient is ultimately found not to have anything wrong, this process can produce anxiety and generate unnecessary services and health expenditures. Some of this additional care may be harmful, thereby subjecting the patient to further risks.

2. Full body CT scans can produce false negatives. However dazzling the images, the pictures in full-body scans are usually not as high in quality or resolution as the images ordered for a specific reason. As a result, some abnormalities may not be picked up, lulling the patient into a false sense of security.

3. Any potential gain must be offset by the risks of radiation. Because the effective dose from a CT procedure is so much higher than the effective dose from a conventional x-ray, the former is justified only when the benefits are commensurate with the outcomes. **The American College of Radiology has said that there is no evidence that total body CT scans are either cost-effective or effective in prolonging life.** Indeed, there is a danger that repeated scans may result in radiation-induced cancer. The risk for 45-year old persons undergoing a full-body is that one in 1,200 will die from such a cancer. This may seem small, but it is an unnecessary risk to take in the absence of a clear pay-off.

Given the reasons listed above, the FDA Center for Devices and Radiological Health has stated that they "know of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death."

More broadly, Dr. Nortin M. Hadler, professor of medicine at the University of North Carolina at Chapel Hill, counsels against any such indiscriminate screening: "No one should be screened for any disease, ever, unless :

1. The test is accurate.
2. The result has meaningful predictive value.
3. There is something meaningful to be done if the test is positive."

The partying couple should do well to heed this advice and get themselves a gift that is a true treat rather than a test that is dubious and possibly harmful. ✦

Smokeless Tobacco: Rebranding Nicotine, Repackaging Death

If the first thing you think of when you hear the word "Sweden" is smorgasbord, Strindberg or streamlined glassware, think again. In addition to exporting the best products of its culture, Sweden has also given us snus, or snuff. This product has been embraced by the big tobacco companies in the U.S. hoping to boost their profits with a product to counteract the dwindling market for cigarettes.

There are two main types of smokeless tobacco in the U.S.: chewing tobacco and snuff. The former requires sucking the chopped tobacco and spitting out the juices. It is most often associated with baseball players, including the late, great Babe Ruth. Snuff is more finely ground and can be dry, moist, or put into teabag-like pouches. Some types of snuff can be used by sniffing or inhaling into the nose, but it is most often placed between the upper gum and the lip.

R. J. Reynolds's *Camel Snus* is the latest product in the arsenal of tools designed to entice new smokers and divert those who are already hooked but cannot quit. Following the lead of Altria (formerly Philip Morris), which also trades on the pristine beauty of Scandinavia by marketing its smokeless tobacco as *Copenhagen* and *Skoal*, R. J. Reynolds is branding its product as one that is socially desirable: it does not require spitting and does not produce second-hand smoke, thereby circumventing indoor-smoking bans. In addition, the snuff has been packaged in discreet sachets, and sold in sleek, well-designed tins. As result, the product looks more like an innocuous cosmetic than a deliverer of nicotine. Having secured male smokers, the company is targeting a younger, more female market. Moreover, the snuff comes in different flavors, further segmenting the market to tap into an array of tastes.

The slick packaging nevertheless conceals a deadly product. The disguised version of Joe Camel and the Marlboro Man packs enough nicotine to addict users after the use of one tin. Although the tobacco companies claim that the new products are preferable to cigarettes and may be seen as a tool of harm-reduction and even as an aid to smoking cessation, smokeless tobacco products often serve as an "appetizer" to other products. One study showed that adolescent boys who use smokeless tobacco products have a higher risk of becoming cigarette smokers within four years. The Surgeon General has therefore warned that smokeless tobacco is "a significant health risk and is not a safe substitute for smoking cigarettes." The law bans all advertising for smokeless tobacco on radio and television and requires a warning on packages.

However it is wrapped or sold, snuff contains 28 carcinogens, and increases the risk of developing cancer of the oral cavity. Smokeless tobacco can cause lesions of the soft tissue in the mouth, and can cause gums to recede. It also can discolor or stain teeth and cause bad breath. It has therefore not surprising that smokeless tobacco has long been banned in several countries, including Ireland, New Zealand, Hong Kong and Israel. More recently, snus is being banned in most parts of the European Union. In the U.S., however, money often trumps health. It is particularly ironic that even a public health measure such as the ban on smoking in public places has been exploited as a growth opportunity for the selling of smokeless tobacco products.

The price of addiction to nicotine in the U.S. is high and deadly:

- Smoking is the number one cause of preventable death in the United States. Smoking-related diseases claim an estimated 438,000 American lives each year.
- Approximately 8.6 million people in the U.S. have a serious illness caused by smoking.
- In 2004, smoking cost the U.S. $96 billion in health care expenditures.
- Exposure to tobacco smoke resulted in $96.8 billion in productivity losses in 2007.
- The noxious effects of smoking begin *in utero*: smoking in pregnancy accounts for 30 percent of low birth-weight babies.

For more than two decades, Public Citizen has repeatedly pointed out the dangers of smoking, whatever the product. Among other things, Public Citizen fought in Congress for the passage of the Comprehensive Smokeless Tobacco Health Education Act. And the Public Citizen Litigation Group successfully sued the Federal Trade Commission for its failure to require that the industry's promotional give-aways include warning labels. In addition, in order to protect minors, our lawyers have testified before Congress in support of the constitutionality of legislation that would several restrict or deny a tax deduction for the advertising of tobacco products. Our organization also supported the FDA in its struggle to define nicotine as a drug and regulate tobacco products as drug-delivery systems.

This relentless effort has had a salutary impact. The percentage of Americans who smoke cigarettes has fallen below 20 percent, the lowest in over 80 years. It would be a pyrrhic victory if this significant gain were offset by a rise in the use of smokeless tobacco. So, if you have a craving for something Swedish, have some gravlax or pancakes with lingonberries. Just say no to *snus*. ✦

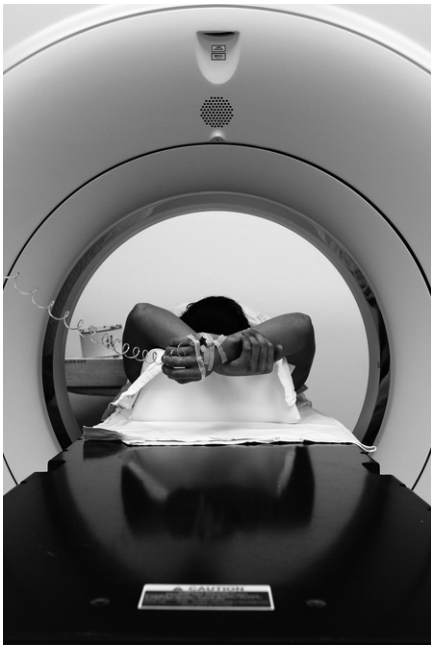
Full Body Scams: Not Your Source for Peace of Mind

At one holiday party, a woman announced that she and her husband had decided to give each other "the gift of health" as a present. What could this be? Membership to a gym, a heart-healthy cookbook, the services of a personal trainer? No, what they bought – to the tune of several thousand dollars, even with a "couple's discount" — was a full-body scan for each. And they had to pay for the whole "gift" out-of-pocket because the procedure is justifiably not covered by insurance.

This technology uses computerized tomography (CT) to screen for early-stage cancers and calcium in the coronary arteries. The 'full body' part refers to the fact that the scan delivers radiation from the chin to just below the hips. The machine fires x-ray beams from different directions, providing 3D images of the organs. Because the patient is receiving multiple x-rays, the dose of radiation can be hundreds of times greater than the dose from a conventional x-ray.

These scans have gained popularity as a result of the technological imperative (the belief that if something can be done, it should be done) and a full panoply of marketing tools: an endorsement by Oprah Winfrey, numerous companies touting their services in widely disseminated brochures, direct-to-consumer ads in health magazines, special offers. The ads make use of a vocabulary designed to entice the "worried well," a not-insignificant fraction of the population, into believing they need this kind of screening. The media

continued on page 10



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