

Health Letter

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Crime and Punishment, Medical Style

All crime is a kind of disease and should be treated as such.

— Mahatma Gandhi

Over the past decades, Public Citizen's Health Research Group (HRG) has monitored many aspects of health care. While most of its activities focus on the safety and efficacy of prescription medicines and devices, HRG also follows the disciplinary activities of state and federal medical boards because regulation of medical practice occurs at the state, not the federal, level.

In 1989, HRG began requesting information on all disciplinary actions that state medical boards and federal agencies had taken against doctors of medicine and osteopathy. These data were the basis for its publication *Questionable Doctors*, which provided the names of physicians, by state, together with their offenses and the disciplinary actions to which they were subjected. These listings were updated and published periodically, allowing consumers to know which doctors in their state had violated existing laws or regulations governing medical practice. In part because the states are now doing a better job of placing disciplinary information up on their websites, HRG no longer publishes *Questionable Doctors*. However, we will release a survey of the state websites in the Fall.

More recently, doctors Paul Jung of the University of Maryland and Peter Lurie and Sidney Wolfe of Public Citizen's Health Research Group

carried out a descriptive study of all physicians convicted of crimes and disciplined by state medical boards or the federal government between 1990 and 1999. This study is published in the current *Health Matrix*, a publication of Case Western Reserve University School of Law.

Scope of the Problem

All the available data were entered into a database including demographic information on the physician, the disciplining agency, the offense committed, and the orders issued by the disciplinary body. The database included 31,110 disciplinary entries against 20,125 physicians taken over the course of the decade.

These entries were subsequently

categorized by type of offense, one of which was criminal conviction. The original database was therefore reduced to those physicians who were convicted of criminal offenses: 2,903 criminal conviction-related entries for 2,247 physicians.

The number of physicians who committed criminal acts and were disciplined remained stable in the United States over the decade studied. But because of an increase in the total number of physicians, the percentage of convicted physicians dropped from 0.04 percent to 0.03 percent, a statistically insignificant decrease.

The entries related to criminal activity were further examined to determine whether the offense was

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The US FDA at a Crossroads

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The philosophy of one century is the common sense of the next.

Henry Ward Beecher
(1813-1887),

American clergyman and reformer

Vioxx linked to heart attacks. Faulty pacemakers knowingly sold. Glucosamine ineffective. Plan B sacrificed to politics. Antidepressants cause suicidal thoughts. Crestor in trouble. These recent head-

lines paint a vivid picture of an agency in major disarray.

As longtime critics of the FDA, we at Public Citizen have often highlighted the agency's failures, including some of those listed above. But in casting a retrospective eye upon the FDA, it is critical not to lose sight of the agency's many accomplishments in its first 100 years and to make some suggestions for corrective actions in the future.

Referring to the period prior to the establishment of the then Bureau of Chemistry in 1906 as the snake oil era may seem unkind, but it is not far from the mark. Few nostrums were effective, and fewer still had actual evidence of efficacy. Unrestricted claims of magical cures burst from the

pages of newspapers and magazines, to the point that some of the most bellicose voices opposing advertising restrictions on drugs emanated from the publishing industry.

It took Upton Sinclair's *The Jungle*, with its revelations of the appalling conditions in the meat-packing industry, and other less-heralded exposes in *Collier's* and *Ladies Home Journal*, to usher in the [Pure Food and Drug Act](#) of 1906. The Act established the Bureau of Chemistry as the first US regulatory agency.

Even at the time, the Act's requirements seemed transparently weak. Although drugs containing morphine, chloroform, marijuana or the like had to be labelled, there was no require-

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related to the medical system. The researchers found that 44 percent of all entries for disciplinary actions related to criminal activity involved patients, and an additional 33 percent involved the health care system but not patients; the remaining 23 percent of entries involved neither patients nor the health care system.

The most common behaviors resulting in disciplinary actions were insurance fraud and prescribing violations; each represented 29 percent of all entries related to criminal conduct. Overall, 59 percent of entries involving criminal conduct received a severe disciplinary action (revocation, surrender, suspension, emergency suspension, probation and restriction of licensure). Infractions involving patients tended to result in more severe sanctions. But 67 percent of insurance fraud convictions and 36 percent of convictions related to controlled substances received only non-severe disciplinary actions.

Culprits and Convictions

Physicians who are disciplined for criminal offenses are not a representative sample of all U.S. physicians: they tend to be older, are more likely to lack

board certification, and are over-represented in certain specialties: general practice, psychiatry, family practice, and child and adolescent psychiatry. Unlike previous studies which have found an association between discipline for sexual abuse and access to patients, these data do not indicate any relation between specific offenses (e.g., access to narcotics or prescriptions, ability to commit fraud) and the specialty practiced.

In general, more severe actions were taken against those who committed the most serious crimes: murder and sex offenses. These are the offenses most likely to lead to license revocations. The study was able to track eight of the 25 physicians disciplined for murder-related convictions; none of them currently has an active license to practice.

Nevertheless, not all physicians convicted of serious offenses have had to surrender their medical licenses. For example, 80 percent of physicians who committed sex-related offenses had their licenses revoked, surrendered, or suspended. And only 54 percent of entries for those convicted of criminally prescribing, using, or possessing controlled substances and 40 percent of entries

related to the practice of medicine (a category that includes falsifying records, and other types of fraud) have lost their license to practice, either temporarily or permanently.

Rx for Greater Oversight

Patient protections may be significantly enhanced through increased scrutiny of physicians at various points in the licensure and certification process. In addition, open public hearings and public disclosure of information related to medical board deliberations may lead to stronger disciplinary actions. States should also apply stiffer penalties for physicians who are found to have broken the law, and include greater non-medical representation on medical boards. A uniform licensing and disciplinary system would prevent the movement of convicted physicians between jurisdictions and thwart their ability to practice medicine "under the radar."

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The complete reference for the article is: Jung P, Lurie P, Wolfe SM. US Physicians Disciplined for Criminal Activity. *Health Matrix* Vol. 16: 335. Summer 2006.

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ment to list other active ingredients. A section of the Act precluded false effectiveness claims; it fell victim to the poor science of the times when courts ruled that such claims could not be adjudicated because available scientific evidence was so lackluster. Foods could not be adulterated according to the Act, but Congress appropriated literally nothing for enforcement. Nonetheless, the Act established the agency, and its jurisdiction was defined.

It is a truism of US food and drug law history — indeed, of US laws in general — that little changes without a disaster of significant proportions. And the disasters most likely to awaken a slumbering Congress are those that affect children. The next major drug-related legislative development, the 1938 *Food, Drug, and Cosmetic Act*, was the direct result of at least 107 deaths, many in children, due to ingestion of a liquid preparation of the antibiotic sulfanilamide that contained the coolant diethylene glycol.

The 1938 Act was groundbreaking in at least two respects. First, it was the first law anywhere in the world to require regulatory approval before a drug could be marketed. Second, it required that a drug be proved safe before it could be sold. Countries around the globe rushed to adopt similar statutes.

Another drug disaster involving children — phocomelia (short arms or legs) in newborns due to maternal

ingestion of thalidomide — generated the political will to pass the next meaningful drug regulatory reform. Unlike in many European countries, thalidomide was not approved in the US. Nevertheless, the 1962 *Kefauver-Harris Amendments* to the *Food, Drug, and Cosmetic Act* required, again for the first time anywhere in the world, that drugs be proved both safe and effective before they could be marketed. Companies that introduced drugs into the market between 1938 and 1962 would have to provide evidence (usually in the form of new clinical trials) to demonstrate their product's safety and effectiveness; those marketed prior to 1938 were grandfathered in. As a result, hundreds of drugs from the 1938-1962 period were banned and untold numbers of drugs have never entered the US marketplace at all.

In this history, one can readily discern a pattern of gradually escalating levels of regulation. Drug approval stood increasingly on scientific grounds, evidence was substituted for anecdote and groundless claims of safety and efficacy were thrown out. As Beecher probably would have concurred, that philosophy has come to seem like common sense.

There have been relatively few important drug or device statutes passed since that time. The *Medical Device Amendments* of 1976 brought some semblance of regulation to this still under-regulated area; the *Hatch-Waxman Act* of 1984 eased the

passage of generic drugs to market; and the *Food and Drug Administration Modernization Act (FDAMA)* of 1997 included a series of relatively minor changes to existing law on conflict-of-interest disclosure and off-label promotion.

However, an apparently modest statute passed in 1992 — the *Prescription Drug User Fee Act (PDUFA)* — has had major reverberations throughout the agency. The Act permitted the FDA to charge pharmaceutical companies for the review of their drugs — a seemingly innocuous pay-as-you-go attempt to adequately fund a chronically cash-starved agency. In our view, this arrangement presents an irresolvable conflict of interest in which FDA regulators are expected to police their funders. Today the agency collects about a quarter of a billion dollars annually in user fees, about one-half of all expenditures on drug review. The user fee concept has now been extended to the device, biologics and veterinary drugs centres within the FDA. The result has been a fundamental change in the ambience within the agency in which pharmaceutical companies are increasingly seen as stakeholders, customers or even clients. Former FDA Commissioner Mark McClellan's speeches often echoed the familiar drug industry line about the need to maintain prices, and hence profits, at high levels in order to spur research. If you pay them, it seems, they will

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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listen.

The agency's current ills are manifold: an 85% decline in drug advertising enforcement between 1998 and 2004; staff disillusionment and turnover far in excess of that in most other federal agencies; internet-based drug sales that are essentially beyond the agency's control; direct-to-consumer advertising that consigns physicians to the sidelines while converting patients into the companies' marketing agents; counterfeit medicines flooding the market, in part because the agency took 18 years to enact regulations to track drugs through the distribution chain; requirements to conduct postmarketing studies openly flouted by the pharmaceutical industry; and declining public confidence that the agency is ensuring the safety and efficacy of new prescription drugs.

From a philosophical perspective, the most fundamental change may be the assault on rationality, the basis upon which the agency was founded, that justified the various expansions of its mandate and that made it a global pioneer. Disagreements within the agency, the very essence of scientific discourse, are met with stern opposition and bureaucratic isolation. In a study we conducted in 1998, medical officers identified at least 27 drugs approved in the previous three years for which they had recommended non-approval. About a dozen drugs have been removed from the market since 1997, an unprecedented number for such a short period of time. Many had shown the toxicities for which they were later banned in pre-approval clinical trials. The near-total absence of Congressional oversight means that more drug safety disasters loom.

FDAMA also provided for expedited drug review and approval on the basis of a clinical or surrogate endpoint that is "reasonably likely . . . to predict clinical benefit" if the drug is for a serious or life-threatening condition. The law also required companies to conduct a postmarketing study to establish the efficacy of such drugs with respect to a hard endpoint (such as morbidity or

mortality) and empowered the FDA to withdraw approval "if a postmarketing clinical study fails to verify clinical benefit". Yet, after four randomised trials demonstrated that the lung cancer drug Iressa had no impact upon mortality or quality of life, the drug remained on the market, potentially diverting patients from an approved drug with known effectiveness with respect to hard endpoints. Meanwhile, the editorial page of the *Wall Street Journal*, carries articles mounting an assault on randomised, controlled trials and the efficacy standard itself.

Irrationality is not confined to the drug arena. The vagus nerve stimulator (VNS) is surgically implanted at the

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base of the neck, where it generates periodic electrical pulses stimulating the vagus nerve. A randomised, placebo-controlled trial for patients with so-called treatment-resistant depression showed no statistical evidence of benefit after three months of therapy. Yet, the device was approved based on long-term data using a separately recruited, non-randomised, unblinded comparison group. A Senate Finance Committee investigation later found that every one of the more than 20 medical officers, scientists and management staff in the FDA's drug and device divisions who were consulted opposed VNS approval. The FDA's device centre director, Daniel Schultz, overrode them all.

In other areas, FDA regulation has reverted to pre-1938 levels. Thanks to the *Dietary Supplement Health and Education Act* of 1994, dietary supplements are now clearly regulated as foods, rather than drugs. The consequences? No requirement to prove safety or efficacy, no need to register your product with the FDA, no banning of dangerous supplements unless they exceed a very high threshold and no mandatory reporting of adverse events. Even claims that are considered "structure/function" (eg, "promotes prostate health") are permitted as long as they don't cross the line, inscribed in invisible ink apparent only to industry and FDA lawyers, into health claims (eg, "treats the symptoms of an enlarged prostate").

The practice of pharmacy compounding has been similarly rescued from obscurity by FDAMA provisions exempting compounded drugs from having to demonstrate safety or efficacy. As is inevitably the case, entrepreneurs rapidly fill the void with unsustainable claims and hazardous products. Three patients were killed and ten hospitalised when compounded betamethasone, contaminated with the bacteria *serratia*, was injected into their spinal columns.

As the FDA flirts increasingly with departures from the scientific method that underpinned all the agency's successes in the past century, a host of reforms are necessary. We will mention but four. First, PDUFA should be repealed to end the conflict of interest inherent in accepting industry funding. Second, the FDA should be granted authority to levy civil monetary penalties in the drug safety/efficacy arena. This prerogative makes sense for an agency with authority over literally one-quarter of the US economy. Its current inability to levy fines allows companies to brazenly defy the agency's insistence that companies conduct post-marketing studies because they know the agency would never take the draconian step of removing the drug in question from the market. Third, a drug safety unit

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No 'Alternative'

The following article originally appeared in the August 7, 2006, edition of the Wall Street Journal. It is reprinted with the permission of the author, Dr. Jerome Groopman, the Recanati Professor at Harvard Medical School. Dr. Groopman is the author of Second Opinions (2000), Anatomy of Hope (2003) and a staff writer for The New Yorker.

Some 60 million Americans use supplements, megavitamins, herbs and other so-called "alternative" treatments. Their out-of-pocket costs approach \$40 billion a year. Their therapies are promoted by a vast number of self-help books, Web sites and talk shows that feature thrilling testimonials of benefits for maladies that mainstream medicine cannot remedy. But we are now learning what happens when the testimonials are subjected to objective testing. In February, the results of a large clinical trial of the supplements glucosamine and chondroitin sulfate for osteoarthritis were released. These data came on the heels of a rigorous assessment of the herb saw palmetto for symptoms of an enlarged prostate gland. Both studies failed to show clinical efficacy. All this should mark a sea change in how the public views such treatments.

In the first case, some 1,583 patients with symptomatic osteoarthritis of the knee were randomly assigned to receive glucosamine, chondroitin

sulfate, both supplements, the anti-inflammatory Celebrex, or placebo. The trial was sponsored by the National Center for Complementary and Alternative Medicine, NCCAM, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The study found there was no overall statistical benefit except for Celebrex. Of note, 60 percent of the patients receiving placebo reported significant improvement.

This result was greeted without surprise by a colleague of mine who is a primary care physician. Many of her patients swear by the benefits of the supplement for their arthritis; and one of them, a woman in her 70s, never failed to press the physician to take it for her own aches and pains. When the doctor demurred, the patient eyed her with some disdain. "You doctors are so close-minded," she said. "You won't accept a treatment that comes from outside of your own world." One day, a package arrived at her office. It was a large container of glucosamine, which still sits in a cabinet, unopened. "Despite all my patients' testimonials, it didn't make sense," she told me. "Glucosamine is absorbed from the digestive tract and rapidly broken down in the body. How could this supplement survive digestion, travel through the circulation, deposit in worn-down joints, and rebuild cartilage?"

My colleague is a caring and competent clinician, and I was struck

by the barb from her patient about being "close-minded." Most physicians I know feel triangulated in caring for people who pursue alternative therapies. Pointed questioning of the probity of the treatments casts the doctor in the role of adversary rather than ally. Glibly endorsing such therapies may be politically correct but, in essence, patronizes the patient, since the doctor has no objective basis to assess the value of the herb or supplement being promoted for the problem. An honest clinician questions all treatments — ranging from an antibiotic from a pharmacy to an elixir from a health food store — and asks if they pose real risks, offer real benefits, or both. When I was a patient with a serious problem of uncertain outcome, I felt the powerful temptation to seek a magical solution. Most doctors are sympathetic to this sensibility. But a good doctor distinguishes magic from medicine.

The widespread misconception among the public is that what is "natural" is necessarily salubrious and safe, while in fact, the natural world is filled with poisons and toxins. Some of those natural poisons, of course, can be used therapeutically: Two of the most important chemotherapy drugs, vincristine and taxol, are derived, respectively, from the periwinkle plant and the Pacific yew tree.

The patients I care for with cancer or AIDS take multiple prescription

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with direct access to the FDA commissioner must be established. FDA's current plan to house this group within the Center for Drug Evaluation and Research maintains the current conflict of interest in which those who may have erred in approving a drug have to decide whether to withdraw it.

Finally, new drugs in crowded therapeutic classes should be required to demonstrate some advantage in safety

and/or efficacy over existing drugs before approval can be secured. This is the logical extension of the historical widening of FDA requirements — from labelling to pre-approval demonstrations of safety to proof of safety and efficacy. The great majority of the recent drug disasters have occurred among "me-too" drugs — drugs that are only minor chemical modifications of already approved drugs. For clinicians to base their decisions upon simply knowing that these drugs work

better than nothing at all, rather than on how they stack up to their competitors, defies common sense. ■

Lurie, P. Regulatory Affairs Journal Pharma
July 2006 (c) Informa UK Ltd 2006.

Product Recalls

August 22, 2006 — September 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.

Recalls and Field Corrections: Drugs — CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Azathioprine Tablets, USP, 50 mg: Label Mixup; product labeled to contain Azathioprine, 50 mg Tablets may actually contain Methotrexate, 2.5 mg Tablets. Lot # 558470A, exp. date 03/2009. Boehringer Ingelheim Roxane Inc., Columbus, OH.

5H018B, 5M024, 5M030A, 6A014, 6B022B, 5B016, 5F004, 5F010, 5F010C, 5H003, 5H018A, 5L009B, 5M008A, 5M030. IVAX Pharmaceuticals, Miami, FL.

Extra Strength GENAPAP Tablets, acetaminophen (APAP), 500 mg: Misbranded; the labeling on the product incorrectly states, "do not take more than 12 caplets in 24 hours". The correct statement should state, "do not take more than 8 caplets in 24 hours." Lot # 5L020B, 5H018D, 5J006A, 5F001, 5H007, 5H007B, 5L014, 5L018, 5L019, 5B003, 5F002, 5F004A, 5H003A, 5H005, 5H015, 5H016,

Triaminic Vapor Patch Cough, Menthol Cough Suppressant, (menthol), 2.6%, Mentholated Cherry Scent; Triaminic Vapor Patch Cough, Menthol Cough Suppressant, (menthol) 2.6%, Menthol Scent: Misbranded; Use of the product on young children can pose health risks due to potential accidental ingestion. Novartis Consumer Health Inc, Lincoln, NB.

Recalls and Field Corrections: Drugs — CLASS II

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

Name of Drug or Supplement; Problem; Recall Information

Adult Low Strength Aspirin 81 mg, OTC: Dissolution failure: Coating defects may result in the product not being delayed release as labeled. Lot #s 4DE0756, 4DE0703 and 4EE0854; exp. date 01/2007. Perrigo Company, Allegan, MI.

Carbidopa and Levodopa tablets, 25 mg/100 mg, Rx Only: Label on the end panel of the outer carton incorrectly identifies the strength of Levodopa as 250 mg; product contains only 100 mg Levodopa. Strength printed on unit dose strip is correct. Lot #C42986A30, exp. date 05/31/2007. Actavis Elizabeth LLC, Elizabeth, NJ.

Baclofen 10mg Tablets, Rx only: Impurities/Degradation Products: Unidentified extraneous peaks was noted at chromatographic analysis. Chromatographic analysis of extraneous peak was determined to be insufficient. Lot # 140373A exp. date 08/2007. IVAX Pharmaceuticals, Miami, FL.

Cilostazol 100mg Tablets, Rx only: Impurities/Degradation Products: For products and/or lots, unidentified extraneous peaks were noted at chromatographic analysis. Chromatography analysis of extraneous peaks was determined to be insufficient. Lot # 133086VG exp. date 12/2006, Lot # 133086VUF exp. date 12/2006. IVAX Pharmaceuticals, Miami, FL.

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

Name of Drug or Supplement; Problem; Recall Information

Cocaine Hydrochloride Topical Solution 4% packed in 4mL glass bottles: Mislabeling: The folding carton for the Cocaine Hydrochloride 4% topical solution lists the incorrect milligram strength for the product. Lot # 656429A, exp. date: 04/2007, and Lot # 656795B, exp. date: 05/2007. Boehringer Ingelheim Corp., Columbus, OH.

Gabapentin Capsules, 300 mg, Rx Only: The Active Pharmaceutical Ingredient (API) does not meet specifications. Lot # 139631C, exp. date 04/2007. IVAX Pharmaceuticals, Miami, FL.

Hydroxyzine Pamoate 25mg Capsules, Rx only: Impurities/Degradation Products: For products and/or lots, unidentified extraneous peaks were noted at chromatographic analysis. Chromatographic analysis of extraneous peaks was determined to be insufficient. Lot # 132379B exp. date: 10/2006. Ivax Pharmaceuticals, Miami, FL.

Indomethacin 50mg Capsules: Impurities/Degradation Products: For products and/or lots, unidentified extraneous peaks were noted at chromatographic analysis. Chromatographic analysis of extraneous peaks was determined to be insufficient. Lot # 139580A exp. date 07/2008. Ivax Pharmaceuticals, Miami, FL.

Levoxyl® (levoxyroxine sodium tablets), 75 mcg, 112mcg, Rx Only: Potential sub-potency at expiry. Lot #s 9240, SAP batch 21272, 9227 and 9248, SAPs 21274 and 21324, 9222, 9228 and 9212. SAPs 21268, 21271 and 21267. King Pharmaceuticals, Inc., Bristol, TN.

Nadolol 80mg, Rx only: Impurities/Degradation Products: For products and/or lots, unidentified extraneous peaks were noted at chromatographic analysis. Chromatographic analysis of extraneous peaks was determined to be insufficient. Lot # 141316A exp. date 09/2007. IVAX Pharmaceuticals, Inc., Miami, FL.

Zomig (Zolmitriptan), 2.5 mg Tablets, Rx only: Some blister cells may not contain product. Lot # 103158 exp. date: 09/2008. IPR Pharmaceutical, 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

Apple Laptop Computer Batteries. Rechargeable, lithium-ion batteries with cells manufactured by Sony for certain previous iBook G4 and PowerBook G4 notebook computers only can overheat, posing a fire hazard to consumers. Sony Energy Devices Corp., (800) 275-2273 or <http://support.apple.com/batteryprogram>.

Children's Bathrobes. "Que Cute" Children's Bathrobes fail to meet the children's sleepwear flammability standard, and pose a burn hazard. Roden Industries Inc., (877) 455-7677 or www.rossstores.com.

Children's Science Kits. The battery case in the "Ideal" and "Brighter Child" Brand Science Kits can overheat, posing a thermal burn hazard. School Specialty Publishing, (800) 253-5469 or www.schoolspecialtypublishing.com.

Children's Sweatshirts. A drawstring is threaded through the hood, posing a strangulation hazard to children. True Religion, (800) 685-6695 or www.neimanmarcus.com.

Counterfeit Extension Cords. The counterfeit extension cords have undersized wiring and no fuse in the cord to provide over-current protection, which can cause overheating and pose a fire hazard. Pride Products Corp., (800) 898-5550 or www.prideproducts.com.

Decorative Lawn Sprinklers. The plastic body of the Frog, Fish or Duck Lawn Sprinkler can crack when placed under intense water pressure and pieces of it can break off and be projected 5 to 10 feet in the air. This could pose a risk of injury to consumers and bystanders. Syratech Corporation, (800) 471-3986 or consumerservices@syratech.com.

Desktop Copiers. An improperly fitting electrical connection inside Canon Desktop Copiers can cause overheating, smoking and fire. Canon Inc., (800) 828-4040 or www.usa.canon.com.

Drinking Glasses. The inner walls of the double-walled Thermo Drinking Glasses can break during use, posing a laceration hazard to consumers. OVC, Inc., (800) 367-9444 or www.qvc.com.

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Name of Product; Problem; Manufacturer and Contact Information

Fire Suppression System Pumps. A mechanical part on Goulds Pumps(r), Bell & Gossett® and Red Jacket Water Products Brand Pumps for Fire Suppression Systems was not fully tightened, which can lead to the pump failing during use. If pumps sold with fire suppression systems fail, the risk of fire damage increases. The pump itself does not pose a fire hazard. Water Technology Inc., (800) 984-9199 or www.bellgossett.com.

John Deer Gas Barbeque Grills. Operating the grill in windy conditions can blow the flame under the control panel, causing the grill to overheat or cause flashbacks. Flames could damage the hose that supplies gas to the burner, causing an uncontrolled flame. Also, the grill's control knobs could overheat, resulting in burns to hands. Onward Manufacturing, (877) 535-5336 or www.mitm.com.

John Deere Lawn Tractor. A problem in the manufacturing process of the John Deere X300 Select Series Lawn Tractors could cause damage to the circuit in the interlock module. If the interlock module fails, the mower blades will be able to run with no operator on the tractor seat. Consumers could suffer injuries from contact with operating blades. Deere & Company, (800) 537-8233 or www.deere.com.

Lawnmower Replacement Blades. When the lawnmower is operated, Oregon® and Silver Streak® Replacement Snapper Lawnmower Blades can crack and pieces can break away, posing a serious laceration hazard to consumers and bystanders. Blount International Inc., (866) 685-5449, www.blount.com or www.Oregonchain.com.

Olympus Cameras. A defect with the flash circuit in various Olympus-Brand 35mm Film Cameras can cause it to smoke and overheat when the camera is turned on. This poses a possible burn hazard to consumers. Olympus Imaging America Inc., (800) 480-1247 or www.olympusamerica.com.

Outdoor Fireplaces. Touch-up paint used on the "Garden Treasures" Steel Dome Fireplaces' exterior can ignite during use, posing a fire hazard. Agio International Company, Ltd., (866) 284-9161 or www.lowes.com.

Patio Umbrellas. The 9-Foot Patio Umbrella poles contain paint with excessive levels of lead, which can cause adverse health effects if ingested by young children. Zhejiang Nengfu Tourist Products Co., Ltd, (877) 546-4835 or www.aticousa.com.

Pool Toys. When partially filled with water, Jet Streamers(tm) Water Blasters Pool Toys can stand upright on the pool floor with the rigid narrow end pointed upward, posing an impalement risk. Wild Planet Toys Inc., (800) 247-6570 or www.wildplanet.com/jetstreamers.

Segways. The Segway personal transporter can unexpectedly apply reverse torque to the wheels, which can cause a rider to fall. This can occur when the device is tilted back by the Speed Limiter and the rider comes off and then back onto the device within a short period of time. Segway Inc., (800) 750-6557 or www.segway.com.

Snowmobiles. The steering shaft used on certain 2002, 2003, 2004, 2005 and 2006 Arctic Cat snowmobiles can fail at the steering shaft/steering arm attachment. This could cause a loss of steering control of the vehicle, and result in injury or death. Arctic Cat Inc., (800) 279-6851 or www.arctic-cat.com.

Stools. Milano Counter and Bar Stools can be unstable due to missing screws, loose screws or wrongly sized screws, posing a fall hazard to consumers. FDL Inc., (866) 284-9160 or www.lowes.com.

Toy Airplanes. The rechargeable battery pack inside the Air Hogs RC Skywinder Radio-Controlled Airplane can overheat posing a burn hazard. Spin Master Toys, (800) 622-8339 or www.spinmaster.com.

Travel Cots. The plastic cap on the corner connectors of "phil & teds" T2 Travel Cots can come loose, posing a small parts choking hazard to young children. Regal Lager Inc., (800) 593-5522 or info@regallager.com.

Water Heaters. The burner plate and flue hood seal on Delta Performance or Delta Performance Plus Series Combination Water Heaters can fail due to an improper seal causing a leak of flue gases and carbon monoxide (CO). This poses the risk of CO poisoning to consumers inside of the house. Triangle Tube/Phase III, (800) 856-6271 or www.triangletube.com.

Weightlifting Bars. Due to a defect in the sleeve mechanism, Olympic Weightlifting Bars can break under the pressure of significant weight, which could injure consumers and by-standers. York Barbell Company Inc., (800) 358-9675 or www.yorkbarbell.com.

medications, and how these drugs interact with each other can be no simple matter; throw into the mix an herb of unclear composition and unknown metabolism, as well as unknown side effects, and there is a recipe for trouble. I witnessed this as the first group of pharmaceuticals against HIV were being tested during the late 1980s. There was a groundswell of demand among understandably desperate patients for alternatives to medicines like AZT that can have serious side effects and, as single agents, only modest benefit. One "natural" alternative was an extract from a Chinese cucumber termed compound Q. It was imported from Asia and taken by a number of desperate AIDS patients based on testimonials that it could eradicate HIV. The fact that the cucumber extract was used as an abortifacient in China seemed not to register, until several patients developed severe toxic reactions, including coma. Physicians and researchers who challenged compound Q were vilified as being ignorant, wed to the pharmaceutical-medical complex, or envious that a cure had arrived from outside of "mainstream" medicine.

Then there was St. John's wort. This popular herb was touted as a treatment for depression and alleged to have antiviral activity in people with HIV. It was shown to be no better than placebo for depression and, most worrisome, to interfere with the activity of the lifesaving anti-HIV protease drugs.

That alternative therapies are coming under the sharp lamp of science is of some irony. In 1991, Congress passed a bill to create an Office of Alternative Medicine within the National Institutes of Health. Seven years later, this became NCCAM. Sen. Tom Harkin of Iowa was one of the main drivers behind the legislation. Mr. Harkin was said to believe that nontraditional potions and procedures were important therapies, his faith stemming in part from friends and family who testified to their importance. A collective groan was heard in the halls of university

*An honest clinician
questions all treatments
— ranging from an
antibiotic from a phar-
macy to an elixir from
a health food store —
and asks if they pose
real risks, offer real
benefits, or both.*

hospitals and research centers. Precious federal dollars were being diverted from "real science" to shamanism. Some alternative medicine gurus also objected, worried that their therapies would be tested "the NIH way."

The academic opponents were proven wrong — because the fears of the gurus came true. The reason for this can largely be attributed to Stephen Straus, who directs the NCCAM. Dr. Straus is neither a naysayer nor a believer, but rather a scientist, meaning that he is agnostic about any particular therapy. Dr. Straus explained that the same rigorous metrics used to evaluate normal medicine are applied to the numerous unproven alternative treatments — "the NIH way." The justification for spending federal funds is still hotly debated, as evidenced by an impassioned article in a recent issue of the journal *Science*, with a call for the Congress to re-examine the issue. But rigorous testing of popular alternative therapies is a matter of public health and informs proper medical practice. On the wall of Dr. Straus's office is a framed quote: "The plural of anecdotes is not evidence." A billion Chinese cannot be wrong, goes the old saw, but in fact they can and often

are.

But it is not a matter of geography or culture. Until the 19th century, Western practitioners were badly wrong, attributing diseases to an imbalance in humors, bleeding patients and prescribing poultices and purgatives. Modern Western medicine has also embraced therapies that were later disproven. In the 1960s, surgeons tied off an artery under the breastbone in patients with angina, believing this increased circulation to the diseased heart. Many patients swore by the surgery, but when the procedure was subjected to a clinical trial, it turned out that the sham operation was equally beneficial.

Placebos are very powerful. Beyond yoga for lower back pain and acupuncture for analgesia, there has not been a study showing an unequivocal benefit of an alternative therapy when subjected to the rigor of an NIH trial. This negative outcome should not be greeted smugly, because most experimental drugs developed by pharmaceutical or biotechnology companies fail to fulfill their promise. The difference is that these companies rely on biological mechanisms to select candidate drugs for testing, rather than unsubstantiated testimonials and anecdotes.

Dr. Straus believes the public should acquire an historical perspective on the urban legends of alternative therapy. Beyond compound Q and St. John's wort, he recalled the euphoria around laetrile, the extract from apricot pits promoted as a cancer cure, that brought Steve McQueen to Mexico and to his death, and also the story that shark cartilage caused tumors to melt away because sharks never develop cancer (not true). On the other hand, one of the most important new therapies for leukemia is an arsenic derivative identified in western China as part of traditional practice that resulted in well-documented remissions; its effects on key molecules in the malignant cells have been elegantly mapped by scientists. And qualified researchers are testing components of tumeric and other spices than can inhibit

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NO ALTERNATIVE, *from page 9*

melanoma and breast cancer cell growth. Science is enthusiastic when it meets reality.

Still, the failure to prove that so many popular alternative treatments have any benefit has generated resistance among the believers. The promoters of saw palmetto objected to the study, saying that the dose and preparation used in the trial were not optimal. But, in fact, the most frequently used preparation was the

one studied. The clinical trial of glucosamine and chondroitin sulfate will be extended, but lacking a scientific rationale for the treatment should lower expectations about a different outcome.

How long does it take for a false messiah to be abandoned when redemption does not arrive? "Things that are wrong are ultimately set aside," Dr. Straus said, "and things that are right gain traction. There are the conflicting tides of belief and fact, and

each has its own chronology. Things don't change quickly, but over time a cumulative body of evidence becomes compelling." I reflected on this when I read that one major vendor of saw palmetto asserted he would continue to promote the herb despite the new data. As science spreads in his world, doubt will chip away at blind faith, and he will find a shrinking group of believers. ■

OUTRAGE, *from page 12*

Fully 25 percent of 25-to-34-year olds are uninsured, as are 19 percent of those between the ages of 35 and 44. And when these prime childbearing cohorts lack health insurance, their children are also likely to be uninsured.

While all states have State Child Health Insurance Plans (SCHIP) that could presumably cover some of these children, eligibility requirements and cost-sharing vary from state to state and are therefore uneven. Moreover, enrollment in these programs has flattened as states have increased SCHIP premiums, curtailed outreach, and erected administrative hurdles to enrollment.

The rise in uninsured Hispanics highlights the relative disadvantage of this segment of the population. While the uninsured rate remained statistically unchanged from 2004 to 2005 for non-Hispanic whites and blacks — 11.3 percent and 19.6 percent, respectively — it rose for Hispanics. In fact, although Hispanics account for 14 percent of the U.S. population, they represent nearly half the increase in the number of uninsured. This reflects not only the precarious status of many Hispanics but also their recent arrival: out of a total of 7.2 million unauthorized workers in the United States (most of whom are Hispanic), 35 percent arrived between 2000 and 2005. It is therefore not surprising that 32.7 percent of Hispanics in the United States currently lack health insurance. For a propor-

tion of this population, Medicaid, which is largely limited to citizens, is not an option.

Because neither children nor unauthorized Hispanics can vote, the lack of health coverage among these two groups has been distinctly muted as a national political issue. But the situation varies greatly from one state to another, and the lack of health coverage is definitely salient at the local level. For example, 24.6 percent of Texans lack health insurance, while only 8.7 percent of Minnesotans are uninsured. In the absence of a national commitment to provide universal health insurance to all residents of the United States, the burden of coverage has fallen, by default, on the states.

At present, two major states — California and New York — are discussing major health reforms to expand coverage and alter the way in which health care is paid for and delivered. In California, 30 counties have either instituted or are planning Children's Health Initiatives to ensure that all children in low and middle-income families have health coverage. These counties have embarked on outreach campaigns to enroll eligible children in Medi-Cal and Health Families (the state's Medicaid and SCHIP Programs, respectively) or a new "Healthy Kids" Program for those who are not otherwise covered. Even more significant, the legislature in California passed a bill that would provide universal coverage while instituting a single payer, thereby eliminating the multiple premiums

and payers now operating in the state. Although the bill had widespread legislative support, it was vetoed by Governor Arnold Schwarzenegger, giving new meaning to his "Terminator" role. This setback, however, has not entirely derailed the plan. California's OneCare Campaign continues, and will continue to keep health reform on the state's political agenda.

On the opposite coast, New York's political campaign has also provided a new platform for the debate on health care coverage in that state. Eliot Spitzer, currently a candidate in the gubernatorial race, has stated that, if elected, he will advocate for universal health insurance in New York State.

With these two bellwether states discussing a way to reduce the number of uninsured, the question is: will the rest of the country follow? Often called the "third rail" of American politics because of its potential to zap those who touch it, universal health care is nevertheless an issue whose time has come, and come again and again. It may re-emerge as important as more people realize that it is unconscionable for so many to be uncovered in a country that spends one out of every six dollars on health. Perhaps the figure of 46.6 million uninsured will be the "tipping point" leading policymakers to once again focus on providing affordable, accessible quality care to their constituents. ■

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The Number of Uninsured in the United States Reaches 46.6 million

At the end of August, as children are getting ready to go back to school and adults are looking forward to the Labor Day weekend, the U.S. Census Bureau releases its most recent data on the uninsured. This election year, the numbers are not encouraging: a record-setting 46.6 million Americans lacked health insurance in 2005. These data confirm what other economic indicators portend: many employers are finding it too costly and risky to offer health coverage to their employees. And faced with a choice between losing employer-based health insurance and losing jobs, unions are opting to protect jobs. As a result, the percent of Americans with employer-sponsored insurance decreased from 59.8

percent to 59.5 percent, the lowest percentage since 1995. And, because many workers losing their insurance are unable to obtain adequate health coverage on the market, the number of people with privately purchased plans has also dropped. With incomes that are too high for Medicaid and too low to allow them to buy a policy that will cover them and their families, uncovered workers are "self-insured." In other words, they are gambling with their health, hoping to stay healthy and avoid major medical costs.

The number of uninsured has fluctuated over time, but has risen steadily since 2000. Because this trend has occurred during a time of relative economic stability or growth, it cannot be attributed to a recession or

economic slowdown. Indeed, 74 percent of the increase in the number of people who are uninsured were full-time workers. The decrease in the insured population cannot be therefore dismissed as a temporary setback; rather, it signals a potentially ominous trend that needs to be addressed.

The rise in the uninsured has not affected all segments of the population equally. In the most recent data, children and Hispanics emerge as particularly vulnerable. Of the nation's 74 million children, about 8.3 million or 11.2 percent lacked insurance in 2005. This represents a significant rise over the previous year, a situation that most likely reflects their parents' uninsured status as well.

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