

Health Letter

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November 2008 ♦ VOL. 24, No. 11

The Uninsured in the United States: What the Drop to 45.7 Million Means

Last August the U.S. Census Bureau released its most recent data on the uninsured. The number of uninsured went down from 47 million to 45.7 million, reducing the percentage without coverage from 15.8 in 2006 to 15.3 in 2007.

This election year the numbers have particular resonance and must be seen in context. Economic volatility, rising housing foreclosures, fluctuations in the cost of oil, and dwindling jobs have all affected health care spending. Eroding insurance coverage and mounting health costs have created new pressures on household budgets. But the data do not fully capture this: they reflect 2007 numbers, before the economy took a marked downturn. The data reported in August is therefore a rear-view mirror image of the recent past, after which the situation has become increasingly precarious. Moreover, the numbers do not address the fact that coverage has become skimpier for those that are insured.

By the end of this year and, even worse, next year, the uninsured numbers will unfortunately soar.

This temporary drop in the uninsured reflects the fact that government stepped in to cover some of the emerging gaps. While the number of people covered by private health insurance remained stable, their percentage dropped slightly from 67.9 percent in 2006 to 67.5 percent in 2007. And the percentage of those covered by employment-based

insurance went down from 59.7 in 2006 to 59.3 in 2007. These declines were more than offset by an increase in the number of those relying on government health insurance, which rose from 80.3 million to 83.0 million between 2006 and 2007. As a result, the proportion of those relying on government-funded coverage rose from 27.0 percent to 27.8 percent.

Medicaid and Medicare were instrumental in checking the prior decreases in the number of people insured, at least over the short-run. And some state-based programs made a dent in the number of uninsured. Massachusetts' health reform, whatever its limitations, provided coverage for some of the uninsured: by May 2008, about 350,000 residents (5.5 percent of the state's population)

were newly insured. As a result, this one state accounted for over 20 percent of the decrease in the number of uninsured.

Despite a reversal in the previous trend, these data confirm what other economic indicators suggest: a growing proportion of employers are finding it too expensive to offer health coverage to their employees and public financing of care is playing a more prominent role in health coverage. Moreover, even those who have insurance are struggling to meet medical expenses because of higher premiums, less coverage, and heftier deductibles or co-payments.

As in previous years, those who perceive themselves as being at

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We cannot continue to rely on a 'safety net' that catches only some of the population for some conditions some of the time.

lower risk of illness may opt to go without coverage. As a result, young adults between the ages of 18 and 34 represent the largest proportion of the uninsured, accounting for 40.1 percent of those without coverage.

State-based efforts to increase coverage for children through the State Children's Health Insurance Program (SCHIP) had an effect. In 2007, 11.0 percent of children under the age of 18 were uninsured, down from 11.7 percent the previous year. Nevertheless, the U.S. still has more than 8.1 million children without health coverage.

The breakdown by race and ethnicity shows that the decrease in the uninsured was experienced by all groups other than Asians. Among whites, the uninsurance rate went down from 10.8 to 10.4 percent. Among Blacks, the corresponding rate declined from 20.5 to 19.5 percent. For Hispanics, who have the lowest coverage, the rate of uninsured went from 34.1 to 32.1 percent. For Asians, however, the rate rose from 15.5 to 16.8 percent, reflecting the yearly ups

and downs that have affected this population.

The proportion of the uninsured has a marked income gradient: fully 24.5 percent of those with a household income of less than \$25,000 were uninsured, and this proportion declined as income rose. Among those with a household income of \$75,000 or more, 7.8 percent were uninsured. Interestingly, when the data are broken down by income group, only those with the highest income experienced a statistically significant drop in their uninsurance rate, largely as a result of increases in military-related coverage. This made the gradient steeper.

Because each state has its own characteristics, resources, and ways of addressing health coverage, the percentage of uninsured varies greatly across the country. Two-year averages of the state-specific rates indicate that Massachusetts has the lowest proportion of uninsured (7.9 percent) while Texas has the highest (24.8 percent).

The United States is often described as a "mosaic" because of its cultural and ethnic diversity and the many differences that distinguish one state from the other. When it comes to health care, the metaphor is apt. But the current health mosaic consists of ill-fitting shards and crumbling grout. The most recent data reflect a numerical improvement that is ephemeral and inadequate. As unemployment rises, we can expect a decrease in the rate of employer-sponsored insurance. We cannot continue to rely on a 'safety net' that catches only some of the population for some conditions some of the time. We therefore continue to advocate for a single-payer system that would pool all our current health care payments and use them to leverage a fairer and more efficient system that is comprehensive in coverage, that husbands resources, and better allocates health care expenditures. Until we have health care that covers all and is equitable in access and cost, we will not have a society that honors life, secures liberty, and promotes the pursuit of happiness. ♦



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Pharma Should Not Foot the Bill for Your Doctor's Continuing Medical Education

Since the 1970s, in order to be allowed to continue to practice in most states, doctors have been required to take a certain number of continuing medical education (CME) courses per year. It is a system designed to ensure that the patient always receives up-to-date care. But the CME sessions inevitably cost money. When the courses became a requirement for state licensure, commercial interests (primarily drug companies) were happy to pick up the tab; in 2007, 47% of CME funding (over \$1.2 billion) was provided by drug companies, device makers, and other commercial interests.

By paying for the classes, commercial interests get a say in the course agenda. Because of that, the topics addressed are typically those for which a product (usually a drug) exists – and this means that topics about public health or lifestyle and behavioral

interventions may not get the attention they deserve. Evidence that the sponsor's share of prescriptions in a given class of drugs rises after the classes lends weight to the idea that commercial funding is self-serving for the sponsors. This biased "education" of physicians thus compromises the integrity of a system designed to protect patients.

The following letter to the Accreditation Council for Continuing Medical Education (ACCME), sent by Public Citizen on Sep. 12, 2008, urges the ACCME to reject commercial support of mandatory CME for doctors.



We would like to thank the Accreditation Council for Continuing

Medical Education (ACCME) for the opportunity to comment on its Proposed Policy to Support Independence in Accredited Continuing Medical Education (CME). In particular, we would like to comment on the proposal that "the commercial support of continuing medical education end." We strongly support such a proposal because the consequences of the corrupting influence of commercial support on CME are so significant. An outright ban, rather than a compromise that will allow deviations from the objectivity of CME, is therefore justified. Inevitably, in the absence of a ban, there will be conflicts between the educational mission of CME and the financial objectives of commercial

companies; no set of voluntary half-measures can assure that the educational objectives will take precedence.

In considering this proposal, it is important

to recall that CME was born out of the desire to ensure that physicians remained abreast of advances in medical science. This was and remains the primary purpose of CME. However, in the 1970's, shortly after states began adopting CME requirements as a condition for medical licensure, commercial interests (primarily pharmaceutical companies) seized upon physicians' desire to keep the cost of CME as low as possible and inserted themselves into the CME process. By assuming the role of financier, commercial interests were able to influence the substance of CME and, presumably, increase the sales of their products. With 48% of all funding for CME (excluding advertising and exhibit income) now provided by commercial



interests, it has become difficult for many to even imagine CME without commercial support.

Yet CME's reliance on commercial support was neither inevitable, nor is it irreversible. Indeed, to a limited extent, it is currently being reversed. With increasing scrutiny from both the public and the medical profession, a trend toward developing CME that is free from commercial support is gaining momentum. Six academic medical centers (Stanford University, University of California at Davis, University of Colorado, University of Kansas at Kansas City, University of Pittsburgh, University of Massachusetts) have banned direct commercial support of CME, but allow companies to contribute to a central pool that supports CME. Memorial Sloan Kettering Cancer Center bans any commercial support for CME. On the sponsor end, citing growing concern over conflict of interest, Pfizer, the world's largest pharmaceutical company, announced this year that it would no longer directly support CME offered by medical education and communication companies (MECCs); Zimmer, a major manufacturer of orthopedic medical devices, announced it would use only independent, third parties to support CME. With support from the settlement of a lawsuit for off-label

promotion of Neurontin, the Attorney General Consumer and Prescriber Education Grant Program funded the development of an online CME curriculum specifically addressing pharmaceutical company marketing practices.

By some measures, CME's dependence on commercial support is actually decreasing. Despite a quadrupling of commercial support for CME over the past ten years, in 2007 the percentage of CME income provided by commercial interests actually decreased to close to 2002 levels (47%).

Moreover, there is significant evidence that commercial support affects the integrity of CME. Perhaps the most profound effect of sponsorship is that it influences the choice of topics to be

addressed – typically those for which a commercially available product (usually a drug) exists. This skews CME away from topics of great public health significance, but which lack a patent-protected therapy. Compared to conferences with no direct commercial support, commercially supported CME symposia present a narrower range of topics and tend to focus on medical conditions for which there are new therapeutic products. It also ensures that dietary and behavioral interventions receive short shrift.

In our own research, we were able to demonstrate that commercial booths at an annual professional association meeting, a major source of CME for the attendees, frequently violated the professional association's own codes of conduct. In brief, unprompted discussions with research assistants, drug company representatives at 4 of 24 booths (17%) engaged in illegal off-label promotion of drugs.

Finally, commercial support has been associated with the primary objective pursued by sponsors:

increases in prescribing. Following three different commercially supported CME lectures about antihypertensive drugs, the rate of new prescriptions increased after two lectures and decreased after one. In each case, the sponsor's share of prescriptions in that class of drugs rose.

One relatively new development in CME merits particular mention. MECCs are for-profit firms that organize CME conferences and lectures, often on behalf of commercial sponsors. These companies have grown enormously

in the last ten years and over seventy percent of their 2007 income originated from commercial sources. MECCs are thus not objective providers of educational information, but rather marketing firms with an

obvious interest in promoting sales of their sponsors' products.

In principle, several approaches to controlling conflicts of interest in CME could be envisioned: legal restrictions, disclosure, and policy restrictions. The most far-reaching (and the one we favor), legal restrictions would ban commercial support of CME. The advantage of legal restrictions is that they are straightforward and very effective, eliminating the conflict of interest entirely. However, the trend in the CME field has instead been toward not rocking the income boat, relying primarily on enhanced disclosure policies with voluntary policy restrictions for the most egregious forms of conflict. But, in effect, disclosure transfers to the consumer of the CME activity the responsibility for interpreting the often complex conflict of interest. Policy restrictions attempt to establish specific (typically unenforceable) firewalls while still maintaining a role for commercial support. However, just as only partially blocking a river flowing downhill will cause the

water to carve a new path, policy restrictions simply lead to more creative methods of influencing physicians, as demonstrated by the explosive growth of MECCs.

Eliminating commercial support of CME could have the downside of losing the single largest funding source of CME. However, since CME would continue to be a requirement for physicians to maintain their state licensure (and thus board certification), the demand for CME would be essentially unabated. Commercial support has shielded physicians from the true cost of CME. Shifting the burden of funding toward physicians (not exactly a group occupying the lower rungs of the earning ladder) would attenuate the effect of lost revenue.

It is also worth noting that CME is hardly operating at the margins of profitability. Whereas in 1998 CME in the U.S. was operating at a 5% profit margin, only 10 years later (2007) the profit margin had skyrocketed to 23%. This leaves plenty of profit that could be recycled to offset the loss of commercial support. Indeed, an ACCME policy eliminating commercial support of CME is well within reach.

Eliminating commercial support and with it the conflicts of interest that are currently rife would improve the quality of CME and reaffirm the primary mission of CME – promoting life-long learning and enhancing physician competence. It might also serve as an impetus to move away from expensive, lecture-dominated destination meetings and toward cheaper, more content-intensive forms of CME, such as mail-in and online courses. For these reasons, we support ending commercial support of CME. ♦

Moreover, there is significant evidence that commercial support affects the integrity of continuing medical education.

Weighing Conscience Protection Against a Patient's Right to Information

The Department of Health and Human Services has proposed regulations designed to allow workers and institutions that accept federal funding to refuse to perform or to refer patients for abortions. The most recent draft omits a previous draft's definition of abortion as any interference with a fertilized egg, but "still contains provisions that prevent institutions receiving federal funding from firing or refusing to hire employees who have a religious objection to any health procedure, regardless of whether such a procedure is central to the job or the health of the patient." (Health Agencies Update)

The proposed regulations could deprive patients of knowledge of the full extent of their medical options and could lead to sub-optimal care.

The following are Public Citizen's comments to the Office of Public Health and Science at the Department of Health and Human Services on Sept. 25, 2008.

The Health Research Group at Public Citizen fights to protect consumers against unsafe and ineffective drugs and medical devices, advocates for higher safety standards in the workplace, and is an advocate for high standards in health-care delivery. We would therefore like to comment on the proposed changes to 45 CFR Part 88 [Federal Register 73 (166), August 26, 2008] which seek to restrict the use of federal funds for providers, clinics, hospitals and other health care facilities that do not comply with "conscience protections." These protections shield employees from assisting with medical services to which they have moral objections.

The fundamental problem with the regulation is that, by depriving patients of their right to be apprised of all the available medical options and thus to exercise their autonomy,

it would allow unsuspecting patients to receive less-than-optimal medical care. This is in contravention of the most basic precepts in medicine.

The regulation fails to even define the problem it seeks to address.

One might expect an administration with a professed antipathy to regulation that is nearing the end of its term to focus on clearly definable problems. Yet, the regulation fails to

provide evidence that there is a problem justifying a regulation, particularly given the existence of three sometimes decades-old statutes expressly addressing the issues raised in the regulation.

Indeed, to the extent that it is defined, the problem is characterized essentially as one of perception ("There appears to be an attitude..."). No data are provided on the scope and nature of this attitude. Elsewhere, the Proposed Rule states that the Department "is concerned" that health-care workers may be unaware of their rights under the statutes, but, again, no surveys or even anecdotes are provided to support this view. The Department also claims that the absence of the new requirements may be hampering the recruitment of a diversity of people into the health professions, but, again, there are no data to support this claim.

The regulation privileges health care workers' religious rights over patients' health care needs and the needs of employers who seek to meet those needs.

As currently drafted, the regulation does nothing to protect the needs of patients for access to a full array of information and services. Indeed,

the undeniable fact that workers' religious principles may at times conflict with optimal medical care for patients is not acknowledged in the least. Principles of informed consent require providers to tell patients about all treatment options,

The proposed regulations could deprive patients of knowledge of the full extent of their medical options and could lead to sub-optimal care.

including those to which the doctor may not subscribe, so long as they are supported by respectable medical opinion. How will patients know that the person they are relying on is restricting their advice by excluding certain options? In some circumstances, the lack of a referral (or even a requirement that the patient be made aware of the full array of therapeutic options) can jeopardize the patient's safety, particularly in emergency settings or where no other provider is available.

Let us consider this proposal by analogy. Imagine a physician who is a Jehovah's Witness and who is caring for a non-Jehovah's Witness patient who is hemorrhaging. If the patient could die without a blood transfusion, would it be acceptable for the physician to offer only saline or wound compression without as much as mentioning the option of a blood transfusion to the patient? We think few patients (or doctors) would find such medical care acceptable.

The fundamental problem with the Proposed Rule, therefore, is that the regulation fails to balance health-care workers' rights against patient autonomy and the demands of optimal patient care.

While we respect the right of health workers to act in accordance with their moral and religious beliefs, we also feel that this right should not be allowed to trump patients' basic health care needs or violate their autonomy.

The regulation broadens the definition of those who may refuse to provide care based on moral or religious grounds.

While claiming to merely be clarifying the applicability of prior conscience clauses enshrined in statutory language, the proposed regulation goes beyond the statutes to expand those protected to cover those who participate "in any activity with a reasonable connection to the objectionable procedure, including referrals, training, or other arrangements for offending procedures" [Section 88.2]. The Proposed Rule even states that an employee whose task it is to clean the instruments used in a particular procedure would be covered. The Department is certainly correct in characterizing this definition as "broad." Moreover, the proposal includes all members of the workforce, including volunteers and trainees. Indeed the Proposed Rule leaves us wondering if there are any employees of a health-care facility with a connection so tenuous to the offending activity that they would not fall under the Rule.

At the same time, **the Rule does not make clear that the providers' religious objection has to be to the**

activity or procedure, not to the patient. In a recent decision (North Coast Women's Care Medical Group vs. Benítez), the California Supreme Court ruled that doctors are barred from refusing medical care to gays and lesbians based on the doctors' religious beliefs about homosexuals.

The regulation expands the types of activities and procedures covered.

We are concerned that, whereas previous statutes focused largely on abortion and sterilization, the regulation under discussion could encompass a broader set of services. Indeed, the term "health service program" is defined as including "an activity related in any way to providing medicine, health care or any other service related to health and wellness," including programs where the Department of Health and Human Services provides care directly, pays for the provision of services, reimburses an entity for such care, or provides health insurance for such coverage. We are aware that earlier proposals included definitions of abortion so broad that the provision of many well-accepted forms of contraception could have been considered a protected activity.

If this Proposed Rule is ever adopted (and we firmly hope it is not), we recommend that it be tailored narrowly so that certain kinds of contraception, other activities and procedures (e.g., therapeutic cloning, use of embryos from assisted reproduction) would not be covered.

Monitoring compliance with the regulations imposes a significant cost on US taxpayers.

At a time of severe fiscal constraints and multiple competing health needs, it seems unreasonable to adopt a regulation with a price tag of more than \$44 million affecting 584,294 health care entities, particularly to address an undefined problem already governed by three statutes. There are opportunity costs to the proposal, and those must be weighed against the expected benefits.

While we respect the right of health workers to act in accordance with their moral and religious beliefs, we also feel that this right should not be allowed to trump patients' basic health care needs or violate their autonomy. Even if health workers are not required to provide the offending service, they should not be relieved of the responsibility of providing patients a balanced description of the array of therapeutic possibilities and even referral to facilities willing to provide particular services. At present, however, the concern with the protection of workers' conscience seems to outweigh any concern with the patient's right to information, and to their right to be referred to appropriate care. We therefore urge you to withdraw the regulation. ♦

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Health Letter

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Published Monthly by
Public Citizen Health Research Group
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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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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is www.citizen.org/hrg.

Product Recalls

September 17, 2008 - October 20, 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 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

Strovite Tablets, 100 Tablet bottles, Rx only, 11,820 bottles x 100 tablets; Good Manufacturing Practices Deviation; Lack of stability indicating methods by manufacturer. Lot #: 60456A2, exp. date 05/2008; 60904A2, exp. date 10/2008; 70184A1, exp. date 02/2009; 70923A2, exp. 10/2009; Everett Laboratories, 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; Recall Information

Alnico Bar Magnets. Surface paints on the Alnico Bar Magnets contain excessive levels of lead, which violates the federal lead paint standard. Home Science Tools, (800) 860-6272 or www.hometrainingtools.com.

BC-50 Battery Chargers. The plastic portion of the BC-50 Battery Charger's power plug can crack or detach, posing an electrical shock hazard to consumers. Fujifilm U.S.A. Inc., (800) 800-3854 or www.fujifilmusa.com.

Automatic Gas Vent Dampers. The Automatic Gas Vent Dampers could fail, and if the blocked vent switch does not activate, the vent could leak carbon monoxide (CO). This poses a risk of CO poisoning to consumers. Effikal LLC, (866) 790-3739 or www.effikal.com.

Children's Ball and Heart Necklaces, Portable CD and MP3 Players. Surface coatings on Children's Ball and Heart Necklaces, Portable CD and MP3 Players could contain excessive levels of lead, violating the federal lead paint standard. Tween Brands Inc., (800) 934-4497 or www.limitedtoo.com and www.shopjustice.com.

Baby Walkers. The Baby Walkers violate the baby walker voluntary standard and can fit through a standard doorway and are not designed to stop at the edge of a step. Babies using these walkers can be seriously injured or killed. My Way Corp., (787) 758-5848.

"Colonial" Folding Game Chairs. The retaining washers on the legs of "Colonial" Folding Game Chairs can loosen, causing the chair to become unstable. This poses a fall hazard to consumers. Brunswick Bowling & Billiards Corp., (800) 336-8771 ext.2.

Battery Operated Toy "Speed Boats". The two battery terminals can come into contact with each other in the Battery Operated Toy "Speed Boats", causing the battery to overheat, posing a burn hazard to consumers. Dollar General Merchandising Inc., (800) 678-9258 or www.dollargeneral.com.

Cooks Essentials Deep Fryers. The Cooks Essentials Deep Fryers can overheat, posing a burn hazard. QVC Inc., (800) 367-9444 or www.qvc.com.

CONSUMER PRODUCTS

General Electric Toasters. An electrical short circuit can occur between the heating element and the bread cage of General Electric Toasters, posing a fire and electrical shock hazard to consumers. Wal-Mart Stores Inc., (800) 925-6278 or www.walmartstores.com.

Girls' Sandals. The ornamental flowers on the Girls' Sandals can detach, posing a choking hazard to young children. Rack Room Shoes Inc., (866) 344-1213 or www.rackroomshoes.com.

GN9120 Wireless Headsets. An internal short circuit in the GN9120 Wireless Headsets can cause the lithium-ion polymer batteries to overheat, posing a fire hazard. GN Netcom Inc., (877) 803-6467 or www.jabra.com.

Gotham Compact Fluorescent Downlights (Recessed Ceiling Lights). The relay on the backup battery of the Gotham Compact Fluorescent Downlights (Recessed Ceiling Lights) could be programmed incorrectly and prevent the lights from functioning in an emergency. Gotham Lighting, (800) 315-4982 or www.gothamlighting.com.

Harry Potter Bookends. The paint on the Harry Potter Bookends contains excessive levels of lead, violating the federal lead paint standard. Giftco Inc., (888) 448-6728 or <http://mail.giftcoinc.com>.

Heartland/ Yardline/ Backyard Play Systems Outdoor Playset Gliders. Some of the Heartland/ Yardline/ Backyard Play Systems Outdoor Playset Gliders were shipped with assembly instructions that did not inform consumers to tighten all lock nuts during assembly, including those attached by the manufacturer. As a result, some lock nuts were not fully fastened during assembly which could cause the glider to detach, posing a fall hazard to children. Backyard Play Systems LLC, (866) 890-2211 or email customerservice@backyard-play.com.

Igloo Marine Elite Coolers. Sharp edges on the stainless steel latch attached to the Igloo Marine Elite Coolers can pose a laceration hazard to consumers. Igloo Products Corp., (888) 257-0934 or www.igloocoolers.com/safetyalert.

Jack Lift Tools and Kits. The jack lifts in the Jack Lift Tools and Kits can have threads stripping or the nuts breaking, resulting in the shaft slipping and the mower falling from its stand-up position. This could cause serious personal injury to the consumer

or property damage. Country Clipper, (800) 344-8237 or www.countryclipper.com.

"KVIBY" Chests. The glass drawer knobs on the chest can break either during assembly or in use, posing a laceration hazard to consumers. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Lawn Dart Games. The darts in the Lawn Dart Games pose a puncture hazard to young children. Lawn darts were banned in December 1988 to protect children from skull, face and eye puncture wounds. John Jaques & Son Ltd., (877) 374-8881 or www.jaqueslondon.com.

Model Year 2008-2009 Can-Am® Youth ATVs. If the rider is ejected and the cord strap is pulled, the shutoff switch can fail to disable the engine. The Model Year 2008-2009 Can-Am® Youth ATVs can operate uncontrolled, until the engine returns to idle, and cause a collision with bystanders, vehicles or other objects. This poses a serious risk of injury. BRP U.S. Inc., (888) 638-5397 or www.can-am.brp.com.

"MYO" and "MYO Belt" Headlamps. If the "MYO" and "MYO Belt" Headlamps is used with rechargeable batteries, the cable connecting the battery pack to the lamp can spark, melt, or catch fire. This poses a burn hazard to consumers. Petzl America, (877) 740-3826 or <http://www.petzl.com>.

Nerf™ N-Strike Recon Blasters. The Nerf™ N-Strike Recon Blaster's plunger can pull the user's skin during firing of the toy blaster resulting in injury to the face, neck, and/or chest. Hasbro Inc., (800) 245-0910 or www.hasbro.com/nerf.

Portable Generators. The Portable Generators's fuel valve can be damaged by the cover plate during shipment and cause a fuel leak and fuel spillage during use, posing a fire hazard to consumers. General Power Products LLC, (877) 428-3769 or www.generalpowerproducts.com.

Razor® Dirt Quad Electric Powered Ride-On Vehicles. The control module for the throttle can fail and cause the Razor® Dirt Quad Electric Powered Ride-On Vehicles to unexpectedly surge forward, posing a risk of injury to the user or a bystander. Razor USA LLC, (800) 813-3155 or www.razor.com/recall.

Razor® PowerWing™ Three-Wheeled Scooters. The undersides of the foot platforms of Razor® PowerWing™ Three-Wheeled Scooters can have sharp edges, posing a laceration hazard to children. Razor USA LLC, (800) 314-9870 or www.razor.com/recall.

Rechargeable Batteries sold with portable DVD/CD/MP3 players. The Rechargeable Batteries sold with portable DVD/CD/MP3 players can overheat, posing a fire hazard to consumers. Coby Electronics Corp., (866) 945-2629 or www.cobyusa.com.

Ski-Doo® Snowmobiles. Cracks can develop in the welded joints of the drive axle assembly of the Ski-Doo® Snowmobiles and can result in complete breakage. If this happens the track of the vehicle can unexpectedly lock, causing riders to be ejected off the vehicle or lose control and collide with bystanders, a fixed object or other vehicles. This poses a risk of serious injury or death. BRP US Inc., (888) 638-5397 or www.ski-doo.com.

SmartSpace™ Papasan Chairs. The SmartSpace™ Papasan Chairs were sold without a warning label instructing consumers to lock the chair's legs before sitting. This poses a fall hazard to consumers. Jo-Ann Stores Inc., (888) 739-4120 or email guest.services@joann.com.

Toy Boats. The paint on the Toy Boats contains an excess level of lead, violating the federal lead paint standard. Buzz's Boatyard, (877) 207-1923 or www.buzzboats.com/poppop.htm.

Toy Police Cars. The red paint on the Toy Police Cars contains excess levels of lead, violating the federal lead paint standard. TCB Imports, (888) 674-5497 or www.tcbimports.com.

TV Stands. The stability of the TV Stands does not meet industry standards to prevent TV tip-over, posing a risk of injury or death to consumers. Studio RTA, (888) 309-0299 or www.studiorta.com.

Vitodens 200 Boilers. The Vitodens 200 Boilers can leak gas, posing a fire hazard to consumers. Viessmann Manufacturing Co. Inc., (888) 414-9157 or www.viessmann-us.com.

Wood Abacus. The wooden rods on the Wood Abacus can detach, posing a choking hazard to young children. LTD Commodities LLC and ABC Distributing, (866) 736-3654, or www.ltdcommodities.com or www.abcdistributing.com.

Wooden Hammock Stands. When used outdoors, the wood in the hammock stand can deteriorate over time and break, posing a risk of falls and lacerations to consumers. Pottery Barn, (888) 922-9245 or www.potterybarn.com.

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interventions. These often focus on the physical pathology of the conditions and not on the psychosocial aspects that affect how patients cope with their symptoms. The following article addresses the latter issue, and how it is affecting the diagnosis and treatment of fibromyalgia.

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The Annals of Internal Medicine is an august journal published by the American College of Physicians.

The cover of the July 1, 2008 issue had a 2-page "advertisement" paid for by Pfizer showing the profile of a young woman, face glowing but skull revealing a magenta image of her brain. No drug is mentioned; the stated intent is to inform as to the "evolving view of a controversial condition." In bold print, the header announces "Fibromyalgia: 'Neurotic' or Neurologic?" The text goes on to infer that the problem is the latter, that "pain is amplified" by "pain-processing areas of the brain." This header begs close attention. It offers

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as much insight into the way we think of health as it does into why Pfizer is attempting to influence that thinking. Why should any person, patient, physician or pharmaceutical marketing agency think we would consider "neurologic" better than, or even different from, "neurotic"?

"Neurosis" is an antiquated term, expunged from the psychiatric lexicon but not from parlance. Sigmund Freud and Carl Jung used the term to denote psychiatric illnesses in which anxiety-provoking emotional distress leads to physical and mental symptoms.

These range from normal human experiences all the way to phobias, hysteria and depression (but not to disordered thought processes). The notion and term subsequently became an accusation of weakness rather than an assertion that one's coping style needs correction. The current psychiatric terminology would label those with a "neurosis" manifested as physical symptomatology as having a "somatoform" disorder, a rubric that I find as confusing as "neurosis" and that most sufferers find equally insulting.

This is not to say there are no such sufferers. These are subsets of people who tend to combine depression with psychosocial and socioeconomic challenges, and are more likely to seek care, but otherwise they are just people doing the best they can to cope with physical symptoms. The physical symptoms are myriad and often coincident, notably persistent widespread pain, bowel concerns and a lack of energy, let alone *joie d'être*. For most, these symptoms wax and wane over years. Those who go to a specialist are less likely to perceive their symptoms as improving over time. They will acquire the labels that medicalize their chief complaint: fibromyalgia,

irritable bowel syndrome and chronic fatigue syndrome in the examples above. However, they are no more likely than others their age to develop any important damaging systemic disease such as Crohn's, rheumatoid arthritis or lupus. They just never again view themselves as well, let alone feel well.

In my view, they should feel relief in knowing that they are not facing some lurking catastrophe. To my way of thinking, they are suffering from a very bad idea and they need to be taught a better idea (i.e. cognitive behavior therapy, in today's jargon).

More importantly, anyone with a tendency toward such a bad idea needs to be forewarned, and deserves to be offered alternatives long before the bad idea becomes an obsession.

My views stand unshaken in the light of contemporary science. Studies on the biochemistry and physiology of those with this obsession have discerned the most subtle of differences at best. These differences are more likely a consequence of life under a pall than they are the reason for such a life. Most differences are irreproducible or non-specific, and have therefore been abandoned by researchers committed to finding the required though elusive underlying "disease." Many have also dismissed the fibromyalgia label as meaningless, rejected the criteria for the disease established by the American College of Rheumatology as circular reasoning, and considered the "diagnostic tender points" as simply a measure of distress in life.

The evidence for using the label of "neurologic disorder in pain amplification" is another exercise in circular reasoning, to my way of thinking. It is based on functional magnetic resonance imaging. MRI is a cutting edge technique, but the edge is awfully blunt. Our brains

react differently depending on the task at hand: pain, happiness and moral dilemmas light up these images differently. The brain of a Shakespearean scholar will react differently whether she reads a comedy or a tragedy. Patients who have adopted a specific disease label seem to mobilize an image that is distinctive, particularly when faced with a painful stimulus. The differences are subtle, not particularly reproducible or specific, and are readily perturbed by stimuli such as having an empathic family member present. The fibromyalgists, the patients, and the support groups are leaping to this new "disease." Their enthusiasm has substantial underwriting from pharmaceutical firms: Pfizer, Lilly and the upstart Cypress Bioscience.

This is not the first time the pharmaceutical industry has tried to establish a foothold for the benefit of all the people faced with persistent physical symptoms of unknown cause. Merck tried to co-opt this market for cyclobenzaprine (Flexeril), its first generation tricyclic anti-depressant, over 20 years ago. At the time, the drug was not touted as an anti-depressant since the implication would be offensive to these patients. Rather it was marketed as a muscle relaxant which might be useful in fibromyalgia. In trying to educate all involved, Merck underwrote the American Rheumatism Association Committee that crafted the now discredited American College of Rheumatology Criteria for Fibromyalgia. Cyclobenzaprine never captured this market; few patients persisted in taking an agent that made them groggier than they already perceived themselves to be. But the market potential is enormous, and the quest to serve it has never died. It is now coming to harvest.

In June 2007 pregabalin (Lyrica) became the first drug ever to be licensed by the Food and Drug Administration (FDA) specifically for the treatment of "fibromyalgia." Pregabalin is one of many compounds in search of clinical



utility resulting from the molecular biology revolution. This one alters calcium channels in nerve cells and seemed to have tranquilizing and anticonvulsant activity in animal models. Pfizer convinced the FDA that the drug had a role to play in the treatment of seizures and diabetic neuropathy, and then convinced physicians to write about 600,000 prescriptions for these indications, with the average patient footing a monthly bill approaching \$150.

This approval is a testimony to the mindset of the FDA when faced with the perseverance of Pfizer in sponsoring multiple trials with marginal if not disappointing results. In the first trial, published in 2005 by the 1008-105 study group, there was less than a point improvement on a 10-point scale for pain, and this change was statistically significant only at the highest dose studied. However, "dizziness" and "somnolence" was the price paid by over half exposed to this dose. Interestingly, only 10 percent of those on placebo experienced "dizziness" and 5 percent experienced "somnolence." This makes me wonder how the effects were monitored, since "non-restorative sleep" is nearly ubiquitous in this patient population and neurological symptoms such as lightheadedness are nearly as prevalent. How were half the subjects on pregabalin able to distinguish the adverse event of "somnolence" given their prevalence of "non-restorative sleep"? It is therefore not surprising that licensing was withheld pending firmer evidence. This resulted in the "Freedom Trial." In this randomized clinical trial, twice as many "unblinded" patients (who knew what they were taking) found the benefit of pregabalin to be worthwhile compared to their blinded counterparts, who were unaware of the drug. The Freedom Trial also showed that more of those who were randomized to take a placebo relapsed in the withdrawal phase. I can't imagine that blinding was possible in this design given the high likelihood of drug related adverse events. By the end of five months, fully a third of

the pregabalin patients had reverted to their baseline symptoms. But the FDA was convinced of the drug's efficacy and licensed it. Pfizer has been rewarded handsomely. I have no doubt that pregabalin will rapidly fall out of favor but not before it has further cemented the obsession of these patients, and lined the coffers of the stakeholders.

A year later, duloxetine (Cymbalta) followed pregabalin as the second drug to be approved by the FDA specifically for fibromyalgia. Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) that was already licensed for the treatment of depression and diabetic neuropathy. The theory underlying the use of duloxetine in fibromyalgia is contrived; in the trial published in 2005 the rationale was that "central monoaminergic neurotransmission may play a role in its etiology." This leap was enough for Eli Lilly and Company to sponsor the several trials that lead to licensure, after which the company embarked on an aggressive marketing campaign to sell the expensive drug. The trials have much in common with the pregabalin trials. Many patients, as many as half, drop out of the trial early on. Of those who persist, the difference in efficacy between drug and placebo over six months is underwhelming. There is about a 10 percent absolute difference in the many outcome measures purporting to assess pain and other components of the illness experience. Furthermore, this small difference results in considerable nuisance. In the duloxetine trials nearly half the subjects on the agent (vs. less than 15 percent of those on placebo) tolerate nausea caused by the treatment. Duloxetine also has considerable potential for liver toxicity. My prediction is that duloxetine is not likely to survive as a therapy for fibromyalgia any longer than pregabalin.

And there are other drugs in the pipeline. Milnacipran is a variation on the SNRI theme, a norepinephrine serotonin reuptake inhibitor (NSRI) which has been marketed for

depression in Europe as Ixel for the past decade. Cypress Bioscience bought the exclusive rights for approval and marketing of this drug in the U.S. and Canada in 2003 and partnered with Forest Pharmaceuticals in January 2006 to undertake a Phase III trial (following preliminary tests in which the drug has been proved to be efficacious in at least some patients). This multicenter trial involves 1200 patients labeled with "fibromyalgia." In a press release dated May 22, 2007, these companies announced "positive results...statistically significant therapeutic effects" and predicted the submission of a new drug application before long. The results of the trial have not been published. I was invited as one of a "group of expert physicians from across the United States" to a confidential meeting to be hosted by Forest Pharmaceuticals, Inc and Cypress Bioscience, Inc. in October at which they would "present clinical trial data and the clinical features of milnacipran." I do not attend such industry-sponsored meetings; I prefer to review the data myself once published. I would need to see clear evidence that milnacipran is any more than a duloxetine wannabe, and I'm not impressed with duloxetine. But much money is being expended in the lead-up to approval and I anticipate more will be spent should marketing follow.

I am impressed with the industry agenda – impressed by its tenacity in undertaking and underwriting so many trials, its use of composite objectives and other examples of data massaging, and its recruitment of fellow-traveling rheumatologists. The same handful of names appears on the masthead of the papers reporting the trials regardless of the drug or sponsor; the list is always accompanied by revelatory statements concerning paid consultancies and board memberships. This is one happy, conspiratorial family trying to convince these sad patients that "it's in your mind" is a new-age disease requiring pharmaceutical intervention. ♦

Mongering Diseases to Hawk Pills:

The Case of Fibromyalgia

Over three centuries ago, English physician Thomas Sydenham established a system of disease classification based on observing the progress of specific illnesses and their symptoms. This scheme, premised on the idea that disease was a real entity separate from the patient, marked a turning point in the history of medicine. It counteracted the prevailing theological view that disease was the result of karma or punishment for sin, associated with an ethical or spiritual reason. Sydenham's views helped launch the bacteriological revolution and the doctrine of specific etiology, which assume that there is a particular pathogenic agent or causal entity associated with each disease. But this

view also undermined other concepts such as multiple causality, and the role of the host-agent-environment triad in defining disease. It also led to the medicalization of health conditions, with doctors becoming the arbiters of who is ill and in what way they should be treated.

More recent thinkers and holistic theorists have questioned whether diseases are discrete entities apart of the patient. Many agree with William Osler that "it is much more important to know what sort of a patient has a disease than to know what sort of a disease a patient has." Still, the urge to label symptoms has led to new disease entities, which in turn fuel the quest for specific pharmaceutical



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