PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Patent Fiction

The following article was contributed by Dean Baker, a nationally-known economist who is the Co-Director of the Center for Economic and Policy Research in Washington, DC.

The pharmaceutical industry has been so successful in dominating the debate over the regulation of prescription drugs that it has managed to get its opponents to adopt its language. It has become standard to refer to a system of selling drugs under patent protection — a government imposed monopoly — as the "free market." Efforts to limit patent monopolies are then viewed as government regulation.

This perversion of the language is unfortunate not only for rhetorical purposes, but more importantly because it prevents the public from assessing the impact of patent monopolies in the same way as it assesses other forms of government intervention in the market. The impact of patent protection for drugs can only be properly understood if it is recognized that this is a form of interference with a competitive market, not the outcome of a free market.

This point is fundamental, because the point of a patent monopoly is to raise the price of drugs above the cost in a competitive market. With few exceptions, drugs are cheap to produce. These means that if they were sold in a competitive market without patent protection, the price would typically be less than one quarter of the patent protected price. In many cases, for example some of the anti-retroviral drugs, the competitive market price is just one to two percent of the original patent protected price.

The fact that patents raise the price of drugs so far above the competitive market price leads to huge inefficiencies — exactly as economic theory predicts — many of them with very serious consequences. First, in order to earn profits from patents, the drug industry has an incentive to keep its research findings secret, and in some cases to even falsify results. There are endless incidents of industry funded studies being suppressed because they imply that their drugs are either ineffective or harmful. There are also numerous cases in which researchers have been paid to put their names to studies that tout the merits of drugs, even when they have not fully scrutinized the research. This sort of corruption flows directly from the pursuit of patent profits.

Similarly, the massive sales efforts by the major pharmaceutical firms would not be as extraordinarily profitable as it now is if they were selling their drugs in a competitive market. These promotions only make economic sense in the pursuit of patent profits that divert a large

continued on page 2

CONTENTS

PATENT FICTION, *from page 1*
portion of research into duplicative drugs. The FDA has consistently found that more than 70 percent of the new drugs it approves do not constitute qualitative breakthroughs. According to research sponsored by PHARMA, the trade association for the major U.S. pharmaceutical companies, researching duplicative drugs costs approximately 90 percent as much as researching breakthrough drugs. This implies that more than 60 percent of the industry's research is spent on duplicative drugs rather than breakthrough drugs. While duplicative drugs occasionally provide medical benefits for some patients (they may also, because of a slight molecular modification, provide risks not seen in the drug they are duplicating), and they provide a limited amount of competition between drugs in a world with patent monopolies, most of this research would not be undertaken without the market distortions created by drug patents.

There are other predictable results from patent monopolies. For example, the massive lobbying and public relations campaigns carried on by the industry to protect its patent profits is a predictable outcome from having drugs sell at prices far above production costs, as is the production of gray market drugs, sometimes of questionable quality. These are all problems from this sort of intervention in the market that are directly predictable from economic theory.

Economists usually become extremely concerned about forms of government interference that lead to much smaller distortions than inevitably occur with drug patents. For example, the Bush administration's steel tariffs had a *maximum* level of 30 percent for a small category of products. By contrast, drug patents lead to the equivalent of tariffs that average 400 to 500 percent, and in some cases run well over 1000 percent. In other words, if the steel tariffs provided grounds for concern to economists (which they did), then economists should be far more concerned about the much greater economic distortions created by patent protection for prescription drugs, especially since the market for prescription drugs is currently more than $200 billion a year, several times larger than the market for steel.

While any honest economist would acknowledge all of these points about the economic inefficiencies caused by drug patents, arguably, according to the industry, these costs can be justified by the benefits derived from patent supported research. However, the numbers suggest that this is not the case. The industry claims that it conducts just over $30 billion a year in research in the United States. If drug prices fell by 70 percent in the absence of patent protection, the annual savings would be more than $140 billion, or more than four dollars in savings for every dollar of research carried through by the industry. Furthermore, since much of the research done by the industry is for duplicative drugs of relatively little, if any medical value, the ratio of patent inflated drug costs to useful research spending might be closer to eight to one.

The drug industry likes to pretend that there is no alternative to patent supported research, but this is absurd on its face. The government already supports close to $30 billion in biomedical research each year, primarily through the National Institutes of Health. No one disputes the quality of the work done by NIH. In fact, PHARMA has been one of the biggest lobbyists in favor of this spending. Most of this research is in basic science, but there have been important cases (e.g. Taxol and AZT), where the NIH has actually supported clinical trials. There is no logical reason that much more government funding could not be explicitly directed towards actually developing drugs, instead of just basic research.

Of course, the current structure of NIH would not be the best way to coordinate a publicly supported drug development program. Such a program should include a strong component of competition. Toward this end, the government could establish eight to ten competing centers, each with annual appropriations in the range of $3 to $4 billion. These centers could carry on both in-house research and contract out, much as the drug industry does at present. However, a key difference would be that all research findings would have to be made publicly available in a timely manner. Furthermore, all findings would be patented and then placed in the public domain, subject to a "copyleft" principle. (Any manufacturer is free to make use of the patents at zero cost, as long as their product is not subject to patent protection.)

In order to ensure that researchers have substantial incentives, a substantial pool of money (e.g. $500 million) can be set aside to provide prizes for outstanding accomplishments. These prizes could be awarded to individuals or teams of researchers who are considered to have made major advances in medicine in the same way that the Nobel prize is awarded, except there would many more recipients and much more money. Finally, to ensure that the centers are all performing efficiently, there can be periodic reviews at eight to ten year intervals, that would result in the two least productive centers being dismantled and replaced by new ones.

Representative Dennis Kucinich has proposed a bill that provides for this sort of alternative funding system for drug development ("The Free Market Drug Act of 2004"). The principle is to promote competition and openness as an alternative to patent monopolies. The savings that the government would incur from the Medicare prescription drug benefit alone would more than cover the cost of the additional research spending.

While there are obviously huge political obstacles towards moving down this path, the economics suggests that there may be no alternative. The Centers for Medicare and Medicaid Services (CMS) project that spending in prescription drugs will continue rising at a more than a 10 percent annual rate over the next decade. Even assuming that the

growth rate slows substantially in the following years, spending on prescription drugs would still rise to 4.5 percent of GDP by 2024, an increase that is equal to 2.7 percentage points of GDP over its current level.

By comparison, the size of the Social Security shortfall over the next seventy years is projected to be just 0.73 percentage points of GDP. In other words, the increase in prescription drug spending over the next two decades will impose a financial burden on the country that is more than three times as large as the burden of filling the Social Security shortfall.

It is understandable that the public would be wary about trusting the government with supporting prescription drug research, but given the incredible abuses of the current system of government granted patent monopolies, and the enormous costs of this system, it is not clear that there is much to lose. There are obvious examples of government enterprises performing quite well — NIH is one. The system of public universities and community colleges is a second. This system competes quite successfully with private schools.

But even a less well performing system — for example the defense department's system of weapons procurement — would almost certainly be vastly preferable to the current system, as the numbers show. While there is obviously much waste in the defense department, the system has managed to give the United States by far the most powerful military in the world. (It is important to note that one of the key factors that leads to waste in weapons procurement is secrecy. This would not be an issue in drug development, since a requirement of funding is that all results are promptly placed in the public domain.) Even if it is assumed that it takes a dollar and half, or even two dollars, of government funded research to match a dollar spent by PHARMA, the enormous savings from having drugs sold in a free market would still make the publicly supported system far more efficient.

Also, if the government neglects a particular area of research for political reasons (e.g. birth control), the private sector would still be free to develop drugs in this area, exactly as is the case at present. Presumably, a public supported system would also devote more resources to developing drugs to combat diseases, such as malaria, that are prevalent in the developing world.

Adopting a qualitatively different system for supporting drug development will undoubtedly be a difficult political task. But the current system is so obviously broken beyond repair that there is no alternative. Taking the case of the Medicare prescription drug benefit as an example, seniors will on average be paying 40 percent more for drugs in 2006, even with the new benefit, than they were in 2000 when drug costs were a major issue in the presidential election. The benefit does not come close to solving the problem of making drugs affordable to seniors, even though it adds a major expenditure to the federal budget.

If drug prices continue to rise at the projected pace, the quest for lower priced drugs in Canada and elsewhere will only intensify. If the government accommodates this process, by certifying the safety of foreign drugs, then the current system of pricing in the U.S. will become irrelevant for most of the population, victimizing only those who lack the information and access to buy lower priced foreign drugs.

Alternatively, if the pharmaceutical industry got its dream and had unfettered monopoly pricing power everywhere, it would just leave open a vast market to underground producers. The effort to maintain monopoly drug prices that are five, ten or even one hundred times the cost of production is comparable to the Soviet Union's efforts to prevent the sale of black market blue jeans or chewing gum. It won't work, the market will win.

In addition to the gains to people's health from having drugs sold at competitive market prices, the potential economic gains are enormous. The savings to consumers from a scenario in which prescription drugs are sold in a competitive market are enormous and growing through time. The CMS projections of drug costs imply that the *annual* savings from a free market in prescription drugs are likely to be more than $600 billion in two decades. Such savings would

continued on page 4

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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National Health Insurance: Falling Expectations and the Safety Net

The following editorial is reprinted from Medical Care, *Volume 42, Number 5, May 2004, pp. 403-405. The authors are Steffie Woolhandler, MD, MPH, and David U. Himmelstein, MD.*

In October 2003, a *Washington Post*/ABC poll found that 62% of Americans favor "a universal health insurance program, in which everyone is covered under a program like Medicare that's run by the government and financed by taxpayers." A similar proportion of doctors agree (at least in Massachusetts), and 12,000 physicians have endorsed a proposal for national health insurance (NHI).

Yet, over the past 3 decades, discourse on health reform in the United States has swung sharply away from NHI. In 1971, Senator Edward Kennedy and Congresswoman Martha Griffiths introduced a single-payer NHI bill that attracted considerable support.

President Nixon countered with a proposal to achieve universal coverage through an employer mandate approach. Today, Kennedy is pushing for Nixon's plan. The leading Democratic presidential contenders in 2004 moved even further to the right; all except Kucinich and Sharpton proposed to cover only a fraction of the uninsured, generally by some combination of an expanded Medicaid program and increased tax subsidies for purchasers of private insurance. The academic health policy community has been blown by these political winds.

Where once NHI was a central issue for academic research (The Rand Health Insurance Experiment was initiated as a test of NHI), today it rarely surfaces in the health services literature. A quick Medline search for English-language articles in which the titles include the words "national health insurance" confirms this shift. Between 1971 and 1980, an average of 40 articles appeared each year, virtually all addressing the U.S. situation. Over the past decade, the number dwindled to 8 per year, most (besides the ones we authored) describing experience in Taiwan or elsewhere.

The gap between what patients (and doctors) want and what the policy community offers mirrors the widening chasm between the possibilities and actual performance of our healthcare system. Despite skyrocketing health spending and a proliferation of dazzling gadgets and miracle drugs, patients' satisfaction has been falling. Life expectancy and other measures of health status in the United States lag further and further behind those in other wealthy nations. In 1980 (when we were medical residents), the United States spent 8.7% of Gross Domestic Product on health care, slightly less than Sweden and Denmark, about the same as Germany, and a bit more than Canada. In 2002, health care consumed 14.9% of GDP in the United States, almost 50% more than in any other nation.

As residents, we were outraged by the blatant injustice of America's healthcare system; urgently ill patients "dumped" from private hospital emergency departments; vast public subsidies handed to private hospitals that did the dumping; and medical resources wasted on useless paperwork.

Last week, we met with residents and young colleagues who told us of the continuing abuse suffered by the uninsured: a patient with a heart attack sent by taxi from a private hospital emergency department to our public facility; fractures that were diagnosed but not treated at private hospitals; people examined at a university hospital emergency department (as required by the Federal antidumping law) who were judged stable and therefore refused treatment, then subsequently sent a $300 bill for their examination; and a diabetic woman refused admission for treatment of osteomyelitis who was found dead at home after she failed to appear for her scheduled outpatient visit.

For us (and many patients), it is cold comfort to be reassured by Marquis et al. in this issue that the safety net for the poor did not fray even further during the mid-1990s. Should we cheer the fact that over 700 community health centers survived? Our city of 100,000, which has upgraded access to primary care through a network of 6 neighborhood health centers, provides a glimpse of what might be an adequate number; an equivalent population-to-clinic ratio nationally implies the need for over 17,000 clinics. Moreover, even Marquis et al.'s conclusion that things did not get worse could be overly optimistic. Their analysis examined trends in the use of "safety net" resources per low-income person, not per uninsured

continued on page 5

PATENT FICTION, *from page 3*

provide a huge boost to the economy — in fact, they provide a similar boost to a tax cut of the same size, without the negative effect of increasing the deficit. In standard economic models, such savings would generate between one and three million jobs — more than twenty times the number of jobs that are estimated to result from oil production in the Arctic National Wildlife Refuge. In other words, replacing patent monopolies for prescription drugs is not only good health care policy, but it is good economic policy. There are few, if any, policies that could provide as much boost to the economy in the years ahead.

NATIONAL HEALTH INSURANCE,
from page 4
person. During the period they studied, the number of poor and near-poor persons fell by 10%, whereas the number of uninsured rose by 13% (Himmelstein DU, Woolhandler S. Unpublished analysis of the March Current Population Survey for 1994 and 1999). Hence, an analysis of safety net resources using the number of uninsured people rather than the number of low income people as the denominator would likely find a downward trend.

Other aspects of Marquis' analysis are also problematic. She classifies academic medical centers as safety net providers. It is quite plausible that academic centers, and even some community health centers and public hospitals, intensified their marketing to the affluent and tightened restrictions on care for the uninsured during the period studied. Hence, sustained levels of care at "safety net" institutions could well reflect the expansion of care for those with coverage rather than the maintenance of care for the uninsured. Finally, the authors curiously dismiss their positive findings that HMO penetration and for-profit ownership are associated with some small, but significant, decrements in the use of services. Their measure of competition appears so flawed that the analysis of the effect of competition is uninterpretable; they apparently treat multiple hospitals owned by a single firm as competitors. Hence, their analysis ignores the dramatic decrease in hospital competition in Boston (and many other cities) as a large number of hospitals congealed into a handful of networks. The news about prenatal care in California presented by Hessol et al. in this issue is somewhat better. In California, like in the rest of the nation, the rate of grossly inadequate prenatal care shrank during the mid-1990s thanks, in part, to expanded Medicaid coverage for poor pregnant women. Moreover, even controlling for insurance coverage, rates of grossly inadequate prenatal care fell. We would speculate that this broad effect — over and above improvements in insurance coverage-resulted from a community-wide spotlight on the importance of prenatal care, with broadening access to this service contributing to a wider cultural change.

Unfortunately, progress on prenatal care since 1998 has, according to national estimates, slowed to a crawl. Moreover, although the rate of grossly inadequate prenatal care, which the authors focus on, fell, they found scarcely any change in the proportion of women receiving fully adequate care. This is not surprising, because the coverage expansion mostly excluded women until a pregnancy was proven. For many women, this gap probably prevented early (and preconceptual) care. Thus, the California story is both encouraging (coverage expansions really do work to increase the use of essential services) and cautionary (narrowly targeted programs that provide coverage under limited circumstances are not equivalent to a straightforward system that guarantees universal access to comprehensive care).

Moreover, the California data reinforces a message from earlier studies: Medicaid coverage is better than nothing, but far inferior to private insurance. In essence, we are learning that in health care, like in education, separate means unequal. Segregating the poor, and many minorities, in a public insurance program that pays lower rates than most private coverage assures a lower standard of care. Segregation is also implicit in the reliance on a narrow group of "safety net" providers to assume primary responsibility for the care of the poor. We are proud to have spent our entire careers working as clinicians in city hospitals. However, we are painfully aware of the limitations of such institutions. So long as different facilities are designated for rich and poor, the health gap in our society cannot be bridged. Shortly before his death, Martin Luther King, Jr., told a meeting of the Medical Committee for Human Rights: "Of all the forms of injustice, injustice in health care is the most shocking and inhumane." However, like many other researchers, we have experienced a kind of tachyphylaxis; we have become desensitized to the inhumanity of the healthcare system. The 44 million uninsured and the more than 18,000 deaths each year that result no longer shock us. The $300 billion wasted annually on needless administration and outrageous profits is written off as a necessary concession to the powerful private insurance and drug industries, even as we accept that funds cannot be found to achieve universal coverage.

Too often the health services research community limits its discourse to narrow incrementalism: reforms that aspire to cover a few more, to slow the increase in the uninsured, to defend the meager resources allotted to the safety net. Although many colleagues privately endorse NHI, recognizing that the rational deployment of the $1.6 trillion now spent annually on health care could secure high quality care for all Americans, too frequently we self-censor. By concluding in advance that rational reform is not politically conceivable, we accept and reinforce a political consensus that blocks change. We are old enough to recall an age when legal segregation was the norm and ending it seemed a pipe dream. We vividly remember academicians' confident predictions that the Berlin wall would endure beyond our lifetimes.

It is time for the health services research community to spend more time exploring bold ideas, not just tinkering with old ones. The *JAMA* has urged clinicians to donate time to care for the uninsured. We ask research colleagues to tithe themselves in like manner, to devote a fraction, perhaps 10% of their professional time, to unfunded research and advocacy efforts on behalf of the poor and uninsured. We hope that some will find latitude in unfunded research that unleashes creativity too often squelched by the need to shape ideas to meet funding priorities, in short, the freedom to dream.

Product Recalls

April 18 — May 17, 2004

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. A Class I recall is a situation in which there is a probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. 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*.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Acyclovir Tablets, USP, 800 mg tablets, 100 count bottles; Class III; Tablets crumbling.	Lot Nos. 116009A; 113874A; Exp. 03/2005; 5,906 bottles distributed nationwide; IVAX Pharmaceuticals; Miami, FL
Altace (Ramipril) Capsules, 1.25 mg, unit dose pack (10s/10 to a box - 100 units), Rx only; Class III; Mislabeling: Product dosage labeling missing on a unit dose package.	Lot No. 1053616; Exp. 08/2004; 2,696 units distributed nationwide; King Pharmaceuticals Inc; Bristol, TN
Doxazosin Mesylate Tablets, 1mg, 100 count bottles; Class II; Dissolution Failure: 18 month timepoint (stability).	Lot No.107678A; Exp. 06/2004; 7,008 bottles distributed nationwide; IVAX Pharmaceuticals; Miami, FL
DURAGESIC 75 mcg/h CII (FENTANYL TRANSDERMAL SYSTEM), 75 mcg/h fentanyl and 0.3 mL alcohol USP, 75 mcg patches; Class II; Defective Container: Due to a seal breach on one edge of the system, product has the potential to release higher or too little medication than intended amount.	Lot Nos. 0327192, 0327193, 0327294, 0327295, and 0330362; 438,888 patches/2,043,364 patches distributed nationwide; Janssen Pharmaceutical Products, L.P.; Titusville, NJ
Lorazepam Tablets, USP, 0.5 mg, 60 count, 100 count and 500 count bottles, Rx only; Class III; Stability Failure: 18 month CRT stability time period.	Lot No. 47500; exp. 06/04; 851,900 tablets distributed nationwide; Mutual Pharmaceutical Co., Inc.; Philadelphia, PA
PREMARIN (conjugated estrogens tablets USP), 0.625 mg, 5,000 count bottles; Class III; Dissolution Failure.	Lot No. A15477, Exp. 09/04; 3,491 bottles distributed nationwide; Richmond Division of Wyeth; Richmond, VA
a)**Senokot Granules (standardized senna concentrate)**, Natural Vegetable Laxative, 2 oz and 12 oz, 15 mg sennosides per teaspoon b) **Senokot Tablets (standardized senna concentrate)**, 8.6 mg sennosides, Natural Vegetable Laxative, 100 count bottles c) Senokot Syrup (extract of senna concentrate), Sennosides 8.8 mg, Natural Vegetable Laxative, 8 Fl oz., Alcohol-Free Formula d) Senokot Children's Syrup, (extract of senna concentrate), 8.8 sennosides, 2.5 Fl. oz. Alcohol Free e) X-Prep Bowel Evacuant Liquid, extract of senna concentrate, 130 mg sennosides, 2.5 Fl oz. f) X-Prep Bowel Evacuant Kit-1, Extract of Senna concentrate, 130 mg sennosides, Bisacodyl 10 mg, Docusate sodium 50 mg, 2.5 Fl oz. ontents: X-Prep Liquid 2 1/2 Fl. oz, Alcohol-Free Formula, 2 Senokot-S Tablets, 1 Rectolax suppository; Class III; Superpotent: Out of specification results obtained during retesting.	Numerous lots; 331,885 units distributed nationwide; The Purdue Frederick Company; Stamford, CT

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
a) **SOTATOL HCl TABLETS (sotalol hydrochloride)**,120 mg, 100 TABLETS, Rx only, Distributed under the Par label b) ACYCLOVIR TABLETS, 400 mg, Rx only, 100 TABLETS; Class II; Mislabeling: some bottles of "ACYCLOVIR TABLETS 400 mg" were affixed with an additional outer label (outsert) over the base label incorrectly identifying the product as "SOTALOL HCL TABLETS, 120 mg".	Numerous lots; .30,523 bottles of 100 tablets distributed nationwide; Par Pharmaceutical; Spring Valley, NY
Wellskin Facial Cream, (octinoxate 5%; avobenzone 2%), SPF 15, 14% Glycolic Complex; Class II; Mislabeling: The jars of labeled sunscreen were mispackaged with nightcream which product has no sunscreen properties.	Lot No. 119304; 233 jars distributed nationwide and in Canada; Genesis Pharmaceutical, Inc.; Hazel Park, MI
Z-Cof DM Liquid, Each 5mL/one teaspoon contains: Dextromethorphan HBr 15mg, Pseudoephedrine HCl 32mg, and Guaifenesin 200mg, 16 fl oz (473)mL bottles , Alcohol free, No antihistamine, Grape Flavor, Rx Only; Class II; Misprint in package insert; insert indicates dosage administration as adults and children 2 years of age and older rather than adults and children 12 years of age and older.	Lot No. 40318; 6,139 pints distributed nationwide; Elge, Inc, Rosenberg, TX

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*.

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Baby Strollers. The fold joint can collapse unexpectedly, causing the baby to fall.	Baby Trend "Passport" Strollers. 11,300 sold nationwide from July 2003 through February 2004; Baby Trend, Inc.; Ontario, CA; (800) 328-7363; www.babytrend.com
Bunk Beds. A gap between the step of the built-in ladder and the top bunk allows enough room for a child's body to slip through but will not allow for a child's head to pass through. This poses a serious strangulation risk.	Metal Twin/Twin and Twin/Full Bunk Beds, modeld 2008, 2056, 2256 and 2258; 22,000 sold nationwide from June 2000 through February 2004; Coaster Co. of America; Santa Fe Springs, CA; (800) 282-9362; www.coastercompany.com
Children's Board Books. The sound maker mounted inside a plastic covering on the last page of the books poses a choking hazard to young children if removed.	Children's Board Books with Sound Maker; DK logo in lower left corner; About 214,000 sold nationwide from March 2001 through April 2004; DK Publishing Inc.; New York, NY; (800) 505-4726
Cordless Sweepers. The sweeper can overheat, posing a fire hazard.	ProSweep Rechargeable Cordless Sweepers; 59,300 sold nationwide from December 28, 2003 through February 16, 2004; L&N Sales and Marketing Inc.; Hatboro, PA; (800) 367-9444
Electric Outlet Adaptor Plugs. Multiple metal plugs can be extended from the product at one time. Consumers touching an exposed plug while the adaptor is inserted into an electric outlet can receive an electric shock.	Universal Electric Outlet Adaptor Plugs; sold under four brand names: Samsonite Royal Traveller, American Tourister and El Portal; about 187,000 sold nationwide from January 2001 through March 2004; E & B Giftware LLC; Yonkers, NY; (800) 624-5671

continued on page 8

Do Not Use!
Dangerous Drug for Irritable Bowel Syndrome: Constipation-Predominant Tegaserod (ZELNORM)

Tegaserod has been approved by the FDA for the treatment of women with IBS in whom constipation is the predominant symptom. The drug is not approved for men. The drug stimulates the 5-HT4 receptor, one of a family of serotonin receptors. Public Citizen opposed the approval of the drug based on its marginal efficacy and concerns about the induction of cysts in the ovaries.

IBS itself is not a life-threatening condition, although it can be debilitating. If the major symptom is diarrhea, the condition is known as diarrhea-predominant IBS; if it is characterized by constipation, it is called constipation-predominant IBS. The diagnosis of IBS should be based on a set of internationally recognized symptoms known as the Rome II Criteria which include, for constipation-predominant irritable bowel syndrome, having fewer than three bowel movements a week and requiring exclusion of treatable causes of the patient's symptoms, such as ulcerative colitis. This is especially important if the following signs of ulcerative colitis are present: onset after age 50, rectal bleeding, fever, weight loss or anemia. There are no abnormal laboratory tests or changes in the cells of the GI tract on biopsy that can objectively establish the diagnosis of IBS. In fact, the diagnosis of IBS can only be made if all tests for other diseases that might explain the patient's symptoms are negative and the patient continues to have recurrent abdominal discomfort or pain associated with diarrhea, constipation, or both.

There were eight cases of ovarian cysts in women taking tegaserod during the clinical trials, compared to

continued on page 9

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Espresso/Cappucino Makers. The steam tube inside the espresso/cappuccino maker can burst under pressure, presenting a risk of injury to consumers.	Hamilton Beach Cappuccino Plus Espresso and Cappuccino Makers; 20,160 sold nationwide from March 2003 through March 2004; Hamilton Beach/Proctor-Silex, Inc.; Glen Allen, VA; (800) 672-5872; www.hamiltonbeach.com
Fireplace Remote Receivers. The circuit board can overheat and catch fire, posing a burn and fire hazard.	Majestic Vermont Castings fireplace remote receivers; 4,300 sold nationwide from November 2001 through February 2004; CFM Corporation, of Mississauga, Ontario, Canada; (866) 757-6649; www.cfmcorp.com
Hair Dryers. These hair dryers do not have an immersion protection device or ground fault circuit interrupter (GFCI) on the power cord, which poses a serious electrocution hazard if dropped in water.	Electric hand held hair dryers; Turbo 2000, Turbo Laser 1500, Super Turbo 3000, Turbo Plus 2800 and Turbo Plus 1800; 900 sold nationwide between March 2003 and December 2003; Virgo Enterprises; Irvington, NJ; (800) 552-0961
Piano Benches. The screws and bracket assemblies attaching the legs to the bench can weaken and detach, causing the bench seat to collapse during normal use.	Models Bench DK and Bench LT; 18,000 sold nationwide from September 2003 through March 2004; Casio Inc.; Dover, NJ; (800) 454-4678; www.casio.com
Wall to Wall Carpets. Due to a manufacturing error that over-treated the carpet with a "soil-resist" application, the carpet could readily ignite, presenting a serious risk of burn injuries.	Tuftex Wall-to-Wall Carpets, "Moon Shadow" and "Chic to Chic"; 2,300 square yards of carpet (approximately 125 pieces of carpet as sold) sold nationwide from January 15, 2004 through February 15, 2004; Shaw Industries Inc.;Dalton, Georgia; (800) 441-7429; www.shawfloors.com
Water Disinfectant Systems. Some of the lamp pins used in these disinfection systems are improperly soldered, and can cause the units to overheat, posing a fire hazard.	TrojanUVMax(r) Water Disinfection System; About 3,900 sold in the U.S. from August 2000 through April 2004; Trojan Technologies Inc., of London, Ontario, Canada; (800) 241-7923

IRRITABLE BOWEL SYNDROME, *from page 8*

one in the placebo groups. Although the company ultimately convinced the FDA that these were not related to the drug, we remain concerned because tegaserod induced ovarian cysts in rats and because there are 5-HT4 receptors in human ovaries. In addition, there was an increase in abdominal surgeries in patients taking tegaserod during clinical trials compared to placebo-treated patients. The increase was attributed primarily to an increase in gall bladder removals.

After marketing, new safety concerns with tegaserod arose. In April 2004, the FDA announced that the drug would be relabeled because of 21 cases of serious diarrhea and 23 cases of ischemic colitis or closely related diseases.

In addition to the ovarian cysts, the diarrhea, the ischemic colitis and the non-life threatening nature of IBS, tegaserod also has questionable efficacy: none of the three pivotal clinical trials demonstrated effectiveness, as judged by the original, predetermined primary clinical outcome measures. When it was seen, after the fact, that there was no significant improvement for either of the two original outcome measures in the first completed trial, Novartis cunningly altered the endpoints for the other two ongoing (but still blinded) trials, eliminating one measure and redefining the other in a manner that created a lower threshold for declaring improvement. However, even this manipulation produced only one pivotal trial with a statistically significant result, and that result was only half of what Novartis had expected.

In sum, tegaserod is a potentially dangerous drug of minimal efficacy used in the treatment of a non-life threatening condition.

In sum, tegaserod is a potentially dangerous drug of minimal efficacy used in the treatment of a non-life threatening condition. We recommend that you not use it and try the measures suggested below instead. If you are using the drug, the following precautions were issued with the above warning:

If you get new or worse abdominal pain with or without blood in your stools, stop taking Zelnorm right away and tell your doctor. Your doctor may need to do tests to find out if you have a serious problem. Sometimes Zelnorm causes diarrhea. Stop taking Zelnorm and call your doctor right away if you get so much diarrhea that you get light-headed, dizzy, or faint.

What You Can Do:

Alternative treatments for Irritable Bowel Syndrome

General measures include reducing intake of caffeine, alcohol and fried foods. Because intolerance to lactose (milk sugar) can mimic some symptoms of irritable bowel syndrome , a test to determine if you are lactose intolerant should be done. Sorbitol, the sugar in sugarless gum or candy, should be avoided. Minimization of stress and the use of relaxation techniques have helped many people. For constipation-predominant IBS, increased dietary fiber and/or the use of psyllium (METAMUCIL) and increased fluid intake may be helpful.

Improper Antibiotic Treatment for Bladder Infections

In a recent study of more than 13,000 women going to a doctor because of a bladder infection, more than 95% of whom had an acute bladder infection (not a recurrent one), only 37% were prescribed the preferred treatment for this condition: the combination antibiotic trimethoprim/sulfamethoxazole (sometimes prescribed by the brand names of Bactrim, Septra, or Cotrim). Almost as many (32%) were prescribed one of the heavily-promoted fluoroquinolone antibiotics such as ciprofloxacin (CIPRO) which are not the first-choice drug for acute bladder infections. When such drugs are used even though there is a better alternative, this contributes to the rapidly increasing and health-threatening problem of resistance to antibiotics, whereby when the fluoroquinolones are actually needed, people are resistant to them (see article below). The recommended duration of treatment for an acute bladder infection is three days of the antibiotic, and yet, less than 10% of the prescriptions were for three days. The most common duration of treatment was 10 days, followed by seven and five days. Thus, in addition to using the wrong antibiotic most of the time, the duration of therapy was too long most of the time, further contributing to the problem of antibiotic resistance.

When the authors examine the medical specialties of the doctors who prescribed these drugs, they found that obstetricians/gynecologists and urologists were only half as likely to prescribe the preferred treatment, trimethoprim/sulfamethoxazole, as were specialists in internal medicine or family practice.

OUTRAGE, *from page 12*
wanton misprescribing of antibiotics to people who do not have bacterial infections or the wrong antibiotic to those who do have infections (see article above), there has been a more than 13-fold increase in resistance. For another common cause of bacterial illness and death, enteroccoccus, the resistance of these bacteria to vancomycin (VRE) has increased from about 1% in 1988 to about 27% in 2000, a 27-fold increase.

The consequences of increased resistance by bacteria to antibiotics are very serious: infections with staph aureus resistant to methicillin (MRSA), can cause ventilator-assisted pneumonia and blood infections associated with catheters in people in intensive care units (ICU). In ICU patients, infections with VRE are taking the form of abdominal or blood infections. The authors of this review on the impact of antibiotic resistance summarized the possible outcomes caused by antibiotic-resistant organisms:

- Increased mortality
- Prolonged length of hospital stay
- Need for more costly therapy and management
- Medical complications

These examples illustrate that newer, improved antibiotics are not the final answer to bacterial resistance. If new antibiotics are developed but then overused, bacteria will find new ways to develop resistance, rendering those drugs ineffective.

Many bacteria in the hospital setting have now become resistant to multiple antibiotics, and, as a result, infections with these bacteria have become a very dangerous occurrence. The only way to help stop the development of bacterial resistance is by discouraging the gross misuse and overuse of antibiotics. It makes sense to use these "magic bullets," especially the newer ones, only when necessary so that their power will still be effective when it is truly needed.

Thus, there are both dangers and benefits to antibiotics. When you have an infection that can be cured with the proper antibiotic, the benefit of taking the drug is much, much greater than its dangers. But since there are dangers, there are compelling reasons to avoid unnecessary use of antibiotics and to select the safest and most effective ones.

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What You Can Do:

Avoiding Unnecessary Use of Antibiotics or the Wrong Antibiotic

There are several basic principles that should be followed in determining the correct antibiotic:

1. Establish that an antibiotic is necessary. This means that your infection has to be the type that can be effectively treated by an antibiotic. Antibiotics are used specifically to treat bacterial infections. Antibiotics do not treat viral infections, such as the common cold. (Although there has been some heartening progress in the development of specific antiviral agents such as amantadine and acyclovir, ribavirin, AZT and other drugs for HIV infections, viral infections, for the most part, cannot be treated with drugs.)

2. Choose the correct antibiotic. It must be effective against the most likely organisms that can cause your infection.

3. Take a culture before using an antibiotic. A culture should be taken from where you have an infection, such as your throat, urine, or blood, and then grown to determine the specific organism that is causing your infection and whether it is susceptible to the preferred antibiotic. For example, if you have a urinary tract infection, the doctor should take a urine specimen and send it for culture before treating your infection. This does not mean that your infection cannot be treated right away, only that a culture is sent before you start antibiotics. In this way, if your infection persists, your doctor can determine which alternative antibiotic can be used against the bacteria. Your doctor may find out that you do not have an infection and do not require antibiotics.

4. Consider the cost of the antibiotic. This should be done when everything else is equal. If several antibiotics are equally effective, their cost should be taken into consideration when selecting a drug to use. Newer drugs on patent are much more expensive than older antibiotics that have been on the market for some time. For example, the oral cephalosporin cefuroxime (CEFTIN) is often used to treat urinary tract infections. There is no advantage between using this drug and using a generic drug such as trimethoprim and sulfamethoxazole. Cefuroxime, however, costs 12 times as much for two weeks of treatment. Clearly, in the case of a simple infection, the less expensive drug is preferred as an initial choice.

The Importance of Completing a Full Course of Therapy

It is important with any antibiotic to take the entire amount of the drug that your doctor prescribes. Often, after the first few days of taking antibiotics, you will begin to feel better. Perhaps you think that you do not have to finish your course of treatment, since you are, after all, feeling healthy. This is not the case, however. The length of the regimen that your doctor prescribes for you is

continued on page 11

OUTRAGE, *from page 10*
designed to eliminate all of the bacteria that are causing your illness. As mentioned above, this may be as short as three days for an acute bladder infection. If you do not take all of your medication, the bacteria will not be completely eliminated and can quickly multiply, causing another infection. This infection may then be resistant to the original antibiotic.

In general, antibiotics taken by mouth are preferred if you do not require hospitalization and can take the pills without any problem. There is no advantage to having an injection of an antibiotic.

Newer Versus Older Antibiotics

Remember, newer antibiotics are more expensive than the older ones. They should be used only when an advantage can be shown over older antibiotics-for example, if the new antibiotic is more active against resistant bacteria and this has clinical significance.

In summary, antibiotics can make a world of difference when the right antibiotic is chosen for the right situation. Unfortunately, in the United States today, this is only being done a minority of the time. Questioning your doctor about why he or she is prescribing an antibiotic is a step in the right direction toward safer and better antibiotic use.

Serious and Growing Problem of Antibiotic Resistance

In a current campaign to educate doctors and the public about the seriousness of the problem of antibacterial resistance, the Federal Centers for Disease Control, part of the Department of Health and Human Services, has published these worrisome statistics:

Drug-resistant pathogens are a growing threat to all people, especially in healthcare settings.

- Each year nearly 2 million patients in the United States get an infection in a hospital.

- Of those patients, about 90,000 die as a result of their infection.

- More than 70% of the bacteria that cause hospital-acquired infections are resistant to at least one of the drugs most commonly used to treat them.

- Persons infected with drug-resistant organisms are more likely to have longer hospital stays and require treatment with second- or third-choice drugs that may be less effective, more toxic, and/or more expensive.

For example, the staphylococcus, a common bacterium causing skin infections, used to be exquisitely sensitive to penicillin when the drug was first introduced. Twenty years later, penicillin was no longer anywhere near as effective against the staphylococcus. A new drug, called methicillin, was designed to combat the "staph bug," and it was widely used. Over time, strains of methicillin-resistant "super-staph" (MRSA) have also emerged.

At a recent government-sponsored conference on antibiotic resistance, some alarming data were presented on the rapid rise in resistance to antibiotics of some common bacterial causes of life-threatening illness and death. For example, the odds that staph aureus will be resistant to a once extremely useful antibiotic, methicillin, (MRSA) have increased from about 4%, in 1980, to over 55%, in 2000. Thus, clearly related to the

continued on page 10

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