

Health Letter

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Insufficient Credits

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As air leaks out of the economic balloon, the number of Americans without health insurance will rise. For two decades, the number—now more than 45 million—has been steadily growing, as it has during all but the last of our eight years of unprecedented prosperity. There are only two large payers for health insurance: government and private employers. Both have large gaps in whom they cover. The federal government, through Medicare, does insure nearly everyone over age 65; but the state-run Medicaid system, along with the four-year-old State Children's Health Insurance Program (SCHIP), covers only a fraction of the poor—children and some parents—using very stringent criteria.

Employer-sponsored insurance is spotty in the best of times. Companies may or may not offer it, and workers may or may not accept it. During full employment, employers must compete for workers, so they have an incentive to offer health benefits, at least to skilled employees. In the year 2000, which will probably turn out to be the high watermark of our current employer-based system, nearly all large companies and those with highly paid workers offered health insurance. But about a third of small companies (those with fewer than 200 employees) did not; nor did many companies—

large as well as small—with temporary or hourly-wage earners.

In firms that did offer insurance, one in five workers (mainly new employees and part-time and temporary workers) were considered "ineligible." And of those considered eligible, another one in five turned down insurance because they could not afford to pay their share of the premiums (usually about 10 percent to 30 percent of the total cost). Thus, only about half of American workers received employer-sponsored health coverage.

Still, until this year most employers offered health benefits and even absorbed the rapid increases in premiums that began in 1998 after a few years of slowed inflation. But premiums charged by insurers are now rising at double-digit rates. So far, most em-

ployers have not passed these increases directly to their workers. Instead, they have avoided higher premiums by increasing the workers' out-of-pocket costs through higher deductibles and co-payments.

But with the slowdown in the economy and rising unemployment, the balance of power between employers and workers will shift. Since the employer-sponsored system is voluntary, some employers will drop health benefits altogether. A tough patients' rights bill would add to this erosion, because it would drive up premiums.

Employers who continue to offer benefits will take steps to reduce their outlays. One way is to pass along higher health insurance costs to employees by raising out-of-pocket charges. Another is to reduce the ser-

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vices covered. Another is to shift to stringently "managed" plans. Still another is to contribute only a fixed amount toward the premium—known as a "defined contribution"—and require workers to pay the rest. Often billed as a method to increase workers' options, this is really inflation protection for employers. Obviously, the more workers have to pay, the more likely they will be to refuse coverage when it is offered. Employers are resorting to all of these devices. Thus, the combination of rising unemployment and rising premiums will swell the ranks of both the underinsured and the uninsured, as employers drop coverage or more workers find they can't afford it.

Faced with the likelihood of a large increase in the number of Americans without health insurance, many policy makers and interest groups are coalescing around the same solution: refundable tax credits to enable the uninsured to purchase private insurance. (A refundable tax credit is like a cash subsidy.) In insurance terms, this is essentially a defined contribution, and there are a number of variations on the theme. In his election campaign, Bush called for tax credits of up to \$1,000 for individuals earning below \$45,000 a year and \$2,000 for families earning below \$60,000 a year. Others have called for larger credits that would phase out at higher incomes. Most proposals would require recipients to purchase insurance in the private market, without any regulation of premiums or benefits. Most also contain no provision to adjust the tax credit for inflation in health care premiums. Some would limit the program to those not eligible for other government programs or employer-subsidized coverage, but others would offer credits to all low-income workers who turn down employer coverage or need help to pay their share of the premiums.

Tax credits for the uninsured are a bad idea for several reasons. First, even the most generous of the proposed tax credits would not buy an adequate policy. According to the General Accounting Office, the average cost of a nongroup health insurance plan for a family of four is \$7,352 per year. Even with a \$3,600 tax credit (the most

generous proposed), \$3,752 would be left for the family to pay out of pocket—or 12.5 percent of a \$30,000 income. With Bush's \$2,000 credit, the out-of-pocket expense would be \$5,352, or nearly 18 percent of a \$30,000 income. Such outlays would be impossible for the very people who most need coverage. So right from the start, the idea is empty. And without adjustments for inflation in health costs, the shortfall would grow larger over time.

Second, the influx of federal money would probably cause premiums to rise even faster than current projections. Unless premiums are regulated (which nobody proposes), tax credits for the uninsured would be a windfall for the insurance industry.

Third, tax credits would tend to drive out other types of coverage. Employers could use them as an excuse to drop health benefits altogether or shrink them further. That would be particularly likely if premiums rose steeply as a result of the tax credits. Similarly, parents of children eligible for Medicaid or SCHIP might opt instead for tax credits to cover the entire family. Prohibitions on such shifting would be difficult to enforce.

Fourth, most of the tax credit proposals require individuals to fend for themselves in the notoriously treacherous market for individual coverage. Some companies would likely offer cut-rate plans for the amount of the tax credits, but those plans would have very large out-of-pocket payments and very narrow benefits. Even with regulation, policing this market would be a nightmare.

Finally, complex administrative requirements, including the need to monitor the insurance market and ensure that criteria for eligibility are met, would probably generate a huge and expensive new government bureaucracy. That would siphon off still more of the U.S. health dollar for overhead, which is already an exorbitantly high fraction of the total.

Yet despite its fatal flaws, the tax credit idea enjoys surprising support from the political right, the center, and even the near left. For example, Senator Jim Jeffords (while he was still a Republican) introduced a bill along

the lines of the Bush plan that was co-sponsored by Democrats John Breaux of Louisiana and Blanche Lincoln of Arkansas, together with Republicans Lincoln Chafee of Rhode Island, Bill Frist of Tennessee, and Olympia Snowe of Maine. In the House, versions of tax credit bills have been sponsored by liberal Democrats Pete Stark of California (whose plan did provide for regulation of benefits) and Jim McDermott of Washington (the only plan to peg credits to premiums), as well as by conservative Republicans Dick Armey of Texas (the House version of the Jeffords bill) and Charlie Norwood of Georgia (a plan permitting reduced credits for individuals eligible for employment-based coverage). And outside the halls of Congress, the idea has created even stranger bedfellows. Organizations more often at odds than in accord, like the American Medical Association, the Health Insurance Association of America (HIAA), Families USA, and the American Hospital Association, have signed on to tax credits as at least a partial solution to the problem of the uninsured.

It's easy to see why conservatives would like the tax credit solution. It's a part of their creed that nearly any problem can be solved by an adjustment in taxes. And they are committed to market solutions, however unworkable they might be. As for the political center, providing tax credits sounds like a good "centrist" thing to do: set up a "partnership" in which government policy creates incentives for market solutions. But why does the idea appeal to people who should know better—good liberals like Ron Pollack, executive director of Families USA, and Congressman Jim McDermott, a longtime champion of a single payer health care system?

One answer is that they see it as a harmless bargaining chip to be offered in return for an expansion of government programs such as Medicaid and SCHIP. Another is that after the defeat of the Clinton health care plan in 1994 and the general ascendance of market ideology, they no longer believe that it is realistic to push for comprehensive reform. The only way to expand coverage, they now believe, is by incremen-

talism—nibbling at the edges—which necessarily requires a lot of political horse-trading. Pollack joined with Chip Kahn, then president of the HIAA, to publish an article in the January/February issue of *Health Affairs* arguing for such incremental quid pro quos. In welcoming the federal budget resolution's inclusion of \$28 billion to extend health coverage for the uninsured, Pollack later said: "Expanding Medicaid and [S]CHIP programs in conjunction with tax credits to assist working families will significantly reduce the number of uninsured Americans."

McDermott joined with conservative Republican Congressman Jim McCrery of Louisiana to stage a conversation on the subject at the request of journalist Matthew Miller, who reported on it in the October 2000 issue of *The Atlantic Monthly*. Both McDermott and McCrery are members of the House Ways and Means Subcommittee on Health. A passionate crusader for middle-ground solutions, Miller got the unlikely pair to agree that the tax credit idea is a feasible second choice (to a single payer system, for McDermott; to the market, for McCrery) and a good compromise. McCrery candidly stated that his purpose was to stave off a move toward a single payer system, a move he thought would be inevitable as the current system deteriorates. As for McDermott, he recently told me that he just wanted to show "that the emperor has no clothes"—in other words, that nothing short of a single payer system would cover anywhere near the entire population.

But tax credits are not harmless, and it's not just a matter of watching them fail and then starting over from the same point. Paradoxically, tax credits would actually increase the number of uninsured. That is because they would drive up prices and undermine the employment-based system without putting anything workable in its place. In short, the damage done in demonstrating that the "emperor has no clothes" would be great, and small expansions in public programs would not compensate for the harms.

Tax credits are just an extreme example of the problem with incremental improvements to our fragmented, mar-

ket-driven system. There is simply no way to fix a piece of the system without creating unintended ripple effects. Push in here and it pops out there. We should have learned that lesson from our disastrous experiment with market-driven managed care. Both employers and the managed care companies competing for employers' business have every incentive to keep premiums as low as possible. But the surest way to do that is by limiting services.

Managed care companies, for example, often refuse insurance to employers with workers at unusually high risk of getting sick—say, because they are older than average or many of them have chronic conditions of one sort or another. Instead, they direct their marketing efforts toward young, well-educated workforces, because they are healthier. And when they do agree to provide insurance, they may refuse to cover certain expensive conditions or services. These practices—known as "cherry-picking"—have become the hallmarks of managed care. Employers and managed care companies also discourage the use of medical care through high deductibles and co-payments and by erecting so many bureaucratic roadblocks to obtaining care that workers often prefer to pay out of pocket or do without. For health plans to avoid actually delivering medical care requires a degree of ingenuity and a lot of overhead expense. But the expense is apparently worth it. Managed care companies boast to investors about their low "medical loss ratios"—the amount they spend on medical care. The lower the ratio—and it may be as low as 70 percent—the more the companies keep in profits and administrative salaries.

Incremental attempts to deal with these abuses have failed or backfired for the simple reason that employer-sponsored coverage is purely voluntary and there is no regulation of premiums and benefits. Thus, recent legislative initiatives to provide remedies—such as requiring at least 48 hours' hospitalization for childbirth and enacting other patient-protection measures—can lead to the unintended consequences of managed care companies

raising premiums and employers shrinking benefits or dropping them altogether. The same will be true for tax credits. Premiums will rise, the benefit package will shrink, and more employers will drop coverage.

The fact is, our private-employer-based health care system is a failure. It pits the economic interests of managed care companies and employers against the health needs of patients, and it is woefully inefficient because of its huge overhead expenses, many of which are aimed toward limiting services. Dealing with the effects rather than the underlying causes of the system's failures is not only futile, it is harmful.

Compare the tax credit idea with Medicare (which is a public, single payer system embedded in the private, market-based system). Medicare offers defined benefits, not defined contributions; that is, all beneficiaries are entitled to certain services. The program provides a uniform set of benefits to nearly everyone who qualifies, and it does so far more efficiently than the private sector's employment-based system. Furthermore, by regulating prices as well as benefits, Medicare limits what providers charge. Certainly, Medicare has plenty of room to improve. It could make the benefit package more appropriate for seniors and it could control inflation better (although it does better on this score than the private sector). But the essential mechanisms for doing both are in place.

No system can work if it doesn't cover virtually everyone automatically and regulate prices as well as benefits. No matter how many ways we try to shift costs and plug holes, we will sooner or later have to face that fact. Otherwise, we continue to chase a rapidly receding quarry: health care that is both adequate and affordable. Precisely what makes the tax-credit idea attractive to conservatives—the preservation of the private market—is what will doom it in practice. We had better come up with another solution, because the problem is about to get a lot bigger. Universal Medicare, anyone?

Drugs for Possible Exposure to Anthrax: What Makes Sense?

With each new day come new reports of exposures, possible exposures and what turn out to be fake exposures to anthrax. Originally coming from Florida, reports are now emanating from other states including New York, Nevada and the District of Columbia. Although it is likely that the majority of scares about anthrax will not turn out to actually involve the potentially lethal bacteria, public concern and fear is quite understandable since, at this writing, there has been one death in Florida in a man exposed to anthrax and several who have become ill.

The main scenario that has fueled public concern is one in which people have been or believe they have been exposed to anthrax and are desperate to prevent their possible exposure from causing them to contract the disease. Thus, they seek to be treated before any symptoms begin. Given that the anthrax disease is not at all communicable from person to person, the route of this exposure would have to be spores—the dormant form of the bacteria—either inhaled, which can lead to the pulmonary type of anthrax or touched, leading to the variety of anthrax which affects the skin. Less likely is ingestion that could lead to the more unusual gastrointestinal form of the disease. (See the box discussing anthrax background at the end of this article.)

Debate has centered on what antibiotic people should take after possible exposure to anthrax spores has occurred. This type of treatment is referred to as post-exposure prophylaxis. Fueling the rush of people to stockpile ciprofloxacin (CIPRO), the antibiotic most often mentioned as a way of preventing disease in people who may have been exposed to anthrax spores, are misperceptions resulting from a lack of information. This has included the idea that only ciprofloxacin is effective in prevention of disease in

those exposed.

A September 1999 U.S. Army report, titled *Medical Management of Biological Casualties Handbook*, recommended that, for people who have been or may have been exposed to anthrax spores, **“prophylaxis with ciprofloxacin (500 mg orally twice a day) or doxycycline (100 mg orally twice a day) is recommended.”** [Emphasis added]

For obvious ethical reasons, no human experiments were the basis for this recommendation but experiments on monkeys at Ft. Detrick in the early 1990s found that a 30-day post-exposure prophylaxis regimen with doxycycline or ciprofloxacin was approximately 90 percent effective in preventing anthrax in animals exposed one day before starting the drug to high concentrations of anthrax spores in the air. The current recommendation of 60 days treatment for exposed people was probably based on this animal study because the two drugs were, in fact, 100 percent effective in preventing anthrax during the 30 days they were still being used and the cases which occurred (one each in the doxycycline and ciprofloxacin groups) were between the discontinuation of the drugs after 30 days and 60 days after exposure to the anthrax spores.

Unlike ciprofloxacin, which is still on patent to Bayer and which costs over \$500 for a recommended 60-day course of treatment, doxycycline is available in a generic form and costs less than one-tenth as much, approximately \$50, for 60 days of treatment.

Another issue about which there has not been clarity in the media is that a distinction must be drawn between the treatment of an established anthrax infection and the prevention of anthrax infection after inhaling or otherwise having contact with anthrax spores: post-exposure prophylaxis. The U.S. Food and Drug Administration (FDA)

has approved five drugs for the treatment of established anthrax infection: ciprofloxacin (CIPRO); tetracycline (various generics); minocycline (MINOCIN and various generics); doxycycline (VIBRAMYCIN and various generics); and penicillin (various generics). However, only ciprofloxacin, a member of the fluoroquinolone family of antibiotics, has been approved by the FDA for the post-exposure prophylaxis. There is apparently a current effort to expedite the FDA approval, for post-exposure prophylaxis, of doxycycline and penicillin. (Penicillin was less effective in the Ft. Detrick study.)

In the late 1990s, the government approached Bayer, the manufacturer of ciprofloxacin, and urged it to seek FDA approval for post-exposure prophylaxis. This may have been because Cipro is the only one of the candidate drugs still under patent and whose manufacturer therefore had an incentive to seek such approval. Following an FDA advisory committee meeting on July 28, 2000 at which the Ft. Detrick monkey study was heavily relied upon, the FDA gave its approval for Cipro for this purpose.

The use of appropriate antibiotics for post-exposure prophylaxis in the event of possible exposure to anthrax spores is unequivocally warranted, as the benefits of the drug would clearly outweigh its risks. However, if a substantial number of people take a drug in the absence of exposure to anthrax spores, there will be a finite number of individuals who will needlessly suffer substantial morbidity from the drug. There are additional concerns about creating other bacteria (most likely not anthrax) resistant to the antibiotics.

The FDA-approved professional product labeling, or “package insert,” for ciprofloxacin and doxycycline list several contraindications and a number of potentially serious adverse effects associated with the use of these drugs.

Adverse Effects of CIPRO and Doxycycline

Ciprofloxacin

The safety and effectiveness of ciprofloxacin in pediatric patients and adolescents less than 18 years of age, pregnant women, and lactating women have not been established. The drug should not be used routinely in these groups except for post-exposure prophylaxis for anthrax.

The following adverse reactions have been documented with ciprofloxacin:

- Fatal reactions in patients receiving ciprofloxacin with the asthma drug theophylline (SLO-BID, THEO-DUR, QUIBRON-T-SR).
- Pseudomembranous colitis (inflammation of the bowel) ranging in severity from mild to life-threatening.
- Achilles and other tendonitis and tendon ruptures requiring surgical repair or resulting in prolonged disability.
- Neuropsychiatric adverse reactions such as nervousness, agitation, insomnia, anxiety, nightmares or paranoia.
- Severe sunburn (phototoxicity).

- Convulsions.

Doxycycline

The following adverse reactions have been documented with doxycycline:

- Doxycycline and other tetracycline drugs used during the last half of pregnancy, infancy and childhood through the age of eight years may cause permanent discoloration of the teeth.
- Phototoxicity: In some people using this drug, simultaneous exposure to sunlight may cause a skin rash.
- Reduced effectiveness of oral contraceptives.
- Greater risk of bleeding among patients taking the blood thinner warfarin (COUMADIN).

What You Can Do

- 1) Use doxycycline (100 mg twice a day) or ciprofloxacin (500 mg twice a day) to prevent anthrax only if you have had a reasonably probable exposure to anthrax spores. The best current evidence is that they are equally effective in preventing anthrax in people who have

been exposed.

- 2) If after bacterial tests are done on the powder or other substance(s) to which you may have been exposed, it turns out not to have been anthrax, the antibiotics should be immediately discontinued.
- 3) If anthrax exposure is confirmed, it is essential that you continue taking the antibiotic for the full 60 days in order to reduce, if not eliminate, the possibility of developing active disease.
- 4) In order to protect the national supply of drugs, you should not ask your physician for ciprofloxacin or other antibiotics to prevent anthrax infection in the absence of your possible exposure to anthrax spores. Any antibiotics needed for post-exposure prophylaxis should be made available by public health authorities when and where they are needed.

Anthrax Background

Anthrax is primarily a disease of farm animals, with cattle, sheep and horses being the animals usually infected. Human infections may be contracted by contact with contaminated hair, wool, hides, flesh, blood and excreta of infected animals and from manufactured products such as bone meal. Until recently, human cases have been extremely rare.

Anthrax is an unusual bacterium. Unlike most bacteria, it forms spores, which are extremely hardy—they can persist in some soils for decades. These spores are a dormant form of the bacterium and are resistant to antibiotics. In the body, anthrax spores are consumed by special white blood cells called macrophages, which carry the spores into the lymphatic system. In the macrophages the spores can be transformed into actual bacteria which can invade the blood system, producing a toxin. Several antibiotics can treat the bacteria, but untreated anthrax can lead to rapid death.

There are three distinct anthrax syndromes seen in humans, all contracted from exposure to anthrax spores: 1) cutaneous (skin) anthrax, contracted through scratches or abrasions of the skin; 2) inhalational (breathed) anthrax; and 3) gastrointestinal anthrax, from eating insufficiently cooked infected meat.

The cutaneous form (until now, 95 percent of U.S. anthrax infections) occurs most frequently on the hands and forearms of persons working with infected livestock. A local skin infection can lead to bacteria entering the blood stream, which can be fatal. Within a week of exposure, a painless black scab appears, surrounded by swelling and small purplish blisters. Cutaneous anthrax resolves without complications or scarring in 80–90 percent of patients who receive antibiotics for treatment.

Inhalational anthrax, known as Woolsorters' disease, is a rare infection contracted by inhalation of anthrax spores. It occurs mainly among workers handling infected hides, wool, and furs. Infection spreads from the lungs to the rest of the body, typically 10 days (but as long as six weeks) after exposure. In people who have already become significantly symptomatic, it is usually fatal, even with aggressive antibiotic treatment. This form represents the major terrorist threat at this time. The gastrointestinal form has never been reported in the U.S.

An Epidemic of Lung Disease Caused by a Quarter-Century of Government Inaction

Consider this scenario: take a marble-sized sphere of the metal beryllium. Then don appropriate protective gear and finely grind up the sphere, dispersing the minute dust particles uniformly in a box six feet high, a mile wide and a mile long. That represents the maximum concentration of beryllium in a workplace atmosphere currently allowed by the Occupational Safety and Health Administration (OSHA): 2 micrograms per cubic meter of air.

Seems pretty strict, right? Wrong. Workers exposed to beryllium levels about one-hundredth that high for less than 50 days have come down with a debilitating, sometimes fatal disease called chronic beryllium disease (CBD). Twenty-four years ago, OSHA promised to lower occupational exposure limits; and today most U.S. workers exposed to beryllium are still waiting for action.

Beryllium is a remarkable metal. Its oxide is resistant to corrosion and high temperatures and its alloys are extremely light and hard. An alloy of 2 percent beryllium with 98 percent copper is six times stronger than pure copper. Consequently, it is a prized metal, used in such diverse products as ceramics, aircraft parts, dental prostheses, golf clubs, missile guidance systems and many other precision instruments. Upwards of 30,000 workers are exposed annually, a number that is increasing as beryllium's use in the electronics industry expands.

Consumers are not generally exposed to beryllium. However, anyone involved in the cutting, drilling, sawing or other processing of beryllium can inhale the dust or fumes. While usually described as originating in nuclear facilities and ceramics factories, cases of CBD are now starting to crop up among scrap metal workers and dental technicians who handle beryllium. The first stage of disease, a kind of allergic reaction called sensitization, occurs in

about 1 to 3 percent of workers per year. Each year, 10 to 19 percent of these sensitized workers actually develop the disease. The main symptom is growing breathlessness, leading ultimately to dependence on an oxygen tank and even death.

Originally, beryllium was known to cause an acute toxic reaction called acute beryllium disease. A standard of 2 micrograms per cubic meter, first adopted by the Atomic Energy Commission on the basis of a conversation between a researcher and a beryllium industry representative during a taxicab ride in 1949, effectively put an end to that scourge. But better diagnostic techniques and exposure measurements soon showed that the standard was inadequate to prevent CBD.

In 1977, OSHA proposed lowering the exposure limit from 2 to 1 micrograms per cubic meter. But opposition from the Department of Defense, which argued that such a restriction would endanger national security due to an interrupted beryllium supply, effectively applied a bureaucratic guillotine to that proposal. Subsequently, the International Agency for Research on Cancer labeled beryllium a lung carcinogen.

By 1999, even the foot-dragging OSHA admitted that its standard was inadequate. OSHA head Charles Jeffress stated then that "our current permissible exposure limits for beryllium in the workplace now appear to be too high to prevent chronic beryllium disease."

But even as the agency principally charged with protecting U.S. workers sat on its hands, other government agencies were taking action. In January 2000, exposure limits for workers covered by the Department of Energy (DOE) were lowered to 0.2 micrograms per cubic meter, one-tenth what OSHA permits all other workers.

On Labor Day, Public Citizen and the Paper, Allied-Industrial, Chemical

& Energy Workers International Union (PACE) filed a petition with OSHA to reduce its exposure limits to equal those already established by the DOE. We also asked for annual blood tests to detect sensitization to beryllium and removal of sensitized workers from ongoing exposure, without any reduction in pay or benefits. To date, we have had no response from the agency. The full petition can be viewed at <http://www.citizen.org/publications/release.cfm?ID=7052> or by writing to Public Citizen's Health Research Group, 1600 20th St., NW, Washington DC 20009 and asking for publication #1587.

Just two years earlier, on Labor Day 1999, Public Citizen published a report on OSHA enforcement actions since the agency's inception in 1971 (<http://www.citizen.org/publications/release.cfm?ID=6693>). Our report showed that the Clinton administration was, depending on which measure of enforcement you examined, either no better than the first Bush administration, worse than the first Bush administration, or the worst in the history of the agency. Moreover, it had the ignominious distinction of proposing no new chemical standards in its eight years in office (at least 17 were proposed between 1971 and 1993, almost one per year).

It is hard to see how the present Bush administration could do worse, but these days one should never say "never." To make your opinion known, write a letter supporting the Public Citizen/PACE petition to John Henshaw, MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Occupational Safety & Health Administration, Office of Public Affairs, Room N3647, 200 Constitution Avenue, NW, Washington, D.C. 20210 (fax: 202-693-2106). Please send a copy to us at Public Citizen's Health Research Group at the address above.

Product Recalls

September 11—October 10, 2001

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 & 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 reasonable 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.

Class I Recall

Name of Drug or Supplement; Class of Recall; Problem

Acetaminophen Pain Reliever for Children, cherry flavored; Super-potent; Good Sense brand liquid, Kroger brand suspension liquid, and Hy-Vee brand suspension liquid

Lot #: Quantity and Distribution; Manufacturer

Lot #1AD0228; 7,788 units distributed nationwide; Perrigo Company Allegan, Michigan

Name of Drug or Supplement; Class of Recall; Problem

Premarin Tablets (conjugated estrogen tablets) 1.25 mg bottles of 5,000; Class III; Dissolution failure

Lot #: Quantity and Distribution; Manufacturer

Lot numbers 9010249 and 9010403 EXP 9/03; 2,070 bottles distributed in Alabama, Florida, New Jersey, New York, Ohio, Tennessee and Texas; Ayerst Laboratories, Rouses Point, New York

Tegretol® (carbamazepine) 200 mg tablets, in bottles of 100 and 1000 tablets, Rx product; Class II; Dissolution failure; These are extensions to the original 9/18/00 and 11/27/00 recall of over 172,000 bottles of Tegretol

Lot numbers 179D5121, 179D5216, 232E9126, 205D6684, and 206D6684; 25,125 bottles distributed nationwide and in Puerto Rico; Novartis Pharmaceuticals, Corp., Suffern, New York

Temodar Capsules (temozolomide) 250mg, 20 capsules per bottle; Class II; Under-filled capsules

Lot 9-PHT-4, EXP 8/02; 738 bottles distributed nationwide; University of Iowa—College of Pharmacy, Iowa City, Iowa. Recalled by Schering Corp., Kenilworth, New Jersey

TRAV-L-TABS (meclizine HCl) 25 mg per tablet, 60 tablets per bottle; Class III; Production validation deviation (extended holding times for powdered ingredients)

Lot numbers 191002 EXP 9/01, and 191111 EXP 10/01; 770 bottles distributed in Idaho, Illinois, Nebraska, and Wisconsin; Wendt Laboratories, Inc., Belle Plaine, Minnesota

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 1-800-638-2772. The CPSC web site is <http://www.cpsc.gov>.

Name of Product; Problem

All-Terrain Vehicles (youth); Drive chain could come off the sprockets and lock the rear axle, causing the driver to lose control of the ATV

Bicycle Rims; Rims can unexpectedly fail during normal use, posing risk to riders

Butterfly Baby Toys; Antennae contain wire that can pass through the fabric, causing cuts and scratches

Computer AC Adapters; Adapters can overheat, posing a fire hazard

Circular Saws; Recall to repair; Lower blade guards can stick in the open position, posing a risk of serious injury to the operator and bystanders

Drain Cleaner; Bottles can leak, allowing contents to come into contact with consumers, causing irritation and burns to the skin and eyes

Electric Blankets; Plug that connects the detachable control switch to the blanket can become loose—poor electrical contacts can overheat, posing a fire hazard

Gas Ranges; Recall to repair; During the broil and self-clean modes, the range can emit high levels of carbon monoxide (CO), presenting the potential for CO poisoning to consumers. Additionally, during the broil and self-clean modes, the temperature of the storage drawer can become extremely high, presenting the risk of burn injuries to consumers

Glass Cleaner and Washer Fluid; Products contain methyl alcohol (also known as methanol), a toxic substance and are not sealed with child-resistant closures as required by federal law

Lot #: Quantity and Distribution; Manufacturer

2002 model year Suzuki "QuadMaster 50" ATVs designed for children 6 to 12 years old; 7,400 sold nationwide from March through August 2001; American Suzuki Motor Corp., Brea, California (714) 572-1490

Salsa Alto models, with black anodized finish, labeled "Salsa" and "Salsa Alto" in yellow, red and white, sold individually or built into wheels with Shimano Deore or Deore XT hubs; 500 sold nationwide from January through August 2001; Salsa Cycles, Bloomington, Minnesota (877) 887-2572 www.salsacycles.com

Carter's Activity Butterflies with 3-inch long bendable antennae model number 50052; 21,000 sold nationwide from February through August 2001; Kids II, Alpharetta, Georgia (877) 325-7056 www.kidsii.com

Model series PPP003SD, PPP003 and PP2012, sold individually and with the following computers: Armada M300, 3500, M700, E500s, E500, V300, 100s, 110, Prosignia 170, 190, Notebook 100; 594,000 sold worldwide from September 1998 through July 2001; Compaq, Houston, Texas (888) 302-7689 www.compaq.com

Models CSB120, CSB130, CSB1308, CSB130K, CSB130JS; 125,000 sold from October 1998 through July 2001; Ryobi Technologies Inc. (RTI), Anderson, South Carolina (800) 867-9624

Zep and Enforcer brands of 10 Minute Hair Clog Remover and Drain Care Professional Strength Drain Opener Clog Remover; 1.1 million bottles sold nationwide from January through August 2001; National Service Industries Inc. (NSI), Atlanta, Georgia (888) 805-4357 www.zepcommercial.com or (800) 241-5656 Ext. 686 www.enforcer.com

Controlled Comfort, EH 2000, Starbright, Staywarm, Supreme 21, Warm Comfort, serial numbers A001A to C210C; 394,000 sold nationwide from August 1999 through July 2001; Biddeford Textile Corp., Biddeford, Maine (877) 217-6294 www.blanketrecall.com

Amana Big Oven, Model ACF3315A (T) (K) Serial Nos. 0005 thru 0103 (First 4 digits of the 10 digits), Model ACF3335A (W) (C) (B) (S) Serial Nos. 0005 thru 0107, Model ACF3375A (W) (C) (B) (S) Serial Nos. 0006 thru 0107; 50,000 sold nationwide from May 2000 through July 2001; Maytag Corp., Newton, Iowa (800) 266-3535 www.amana.com

Rain-X products: Super Glass Cleaner Concentrate, Plus Washer Fluid Concentrate and Fluid Additive; 1.1 million containers sold nationwide from September 1998 through August 2001; Blue Coral, Cleveland, Ohio (800) 416-1600 www.bluecoral.com or www.rain-x.com

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Colds: How to Treat Them

The following article is updated from our 1999 best selling book, *Worst Pills, Best Pills* which can be purchased on our web site at www.worstpills.org or by sending \$16 to Public Citizen Publications, 1600 20th Street, NW, Washington, DC 20009

The viral infection we call "the common cold" can usually be treated without any professional help by rest and plenty of liquids, occasionally aided by the use of simple over-the-counter (nonprescription) remedies for relief of certain symptoms. There are no drugs that can kill the viruses that cause colds.

A cold cannot be "cured," except by time, but you are less likely to catch a cold if you do not smoke, since smoking paralyzes the hair-like cells (cilia) that clean out the body's airways. Colds are usually spread by hand more often than they are spread through the air. It's a good idea to prevent the spread of viruses by trying not to touch your eyes, mouth, and nose, and by washing your hands frequently when you

are ill or with an ill person.

Certain other illnesses appear similar to colds, but warrant medical advice. If you have a high fever (above 101°F or 38.3°C) accompanied by chills and you are coughing up thick phlegm, or if coughing or breathing deeply causes sharp chest pain, you may have pneumonia. You should call your doctor for diagnosis and appropriate treatment.

The safest, best, and least expensive way to care for a cold is to not take anything at all and let the illness run its short, usually self-limiting course. If necessary, purchase single-ingredient products to treat the individual symptoms that you have.

What Is the Common Cold?

The common cold is a viral infection of the upper respiratory tract (nose, throat, and upper airways), resulting in inflammation of the mucous membrane lining of those areas. The most common symptoms are runny nose, sneezing, and a sore throat.

How to Treat a Cold

Nondrug Measures

A cold is best treated without drugs by drinking plenty—at least 8 to 10 full (eight-ounce) glasses per day—of non-alcoholic liquids (especially warm or hot liquids), getting enough rest, and not smoking.

Drugs to Use

If symptoms do not respond to these nondrug measures and interfere with normal activities, the following products are safe and effective. Please note that all of the drug products we recommend for treating various cold symptoms—stuffy nose, fever, non-productive cough—are available without a prescription (over-the-counter, OTC). None of the prescription cough or cold drugs among the 456 most-prescribed drugs for older adults is recommended; 14 of the 15 drugs are classified as *Do Not Use*.

For a runny nose: No OTC or prescription drug is appropriate. A runny nose promotes drainage and should not be treated with medication. If it

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CONSUMER PRODUCTS cont.

Name of Product; Problem

Hunting Treestands; Cables can break, causing the treestand to fall to the ground, posing an injury hazard to consumers

Toy Toolboxes; Carrying handle can break, creating small parts and a sharp plastic edge that pose a choking and laceration hazard

Utility Wall Cabinet; Cabinets can detach from wall and fall

Window Latches; Recall to repair; Latches on the lower sash of the window can unexpectedly open, posing a potential injury hazard

Lot #: Quantity and Distribution; Manufacturer

HVTS-100 Wildcat, HVTS-101 Wildcat with camo seat, HVTS-102 Wildcat Comfort Zone, HVTS-104 Wildcat Swivel Seat, HVTS-300 Big Daddy, HVTS-302 Big Daddy Comfort Zone, HVTS-400 Big Horn Ram, HVTS-402 Hoot Owl, HVTS-500 Timber Ghost, HVATS-3000 Big Daddy Lite, and HVATS-4020 Comfort Zone Swivel Seat; 30,000 sold nationwide from March through August 2001; Hunter's View Ltd., Peoria, Illinois (888) 878-0440

Soft-shelled, plastic, green box with a yellow handle and raised letters that read John Deere; 11,600 sold nationwide from June through September 2001; Racing Champions Ertl, Inc., (RCE), Dyersville, Iowa (866) 898-4999

Premier and Four Seasons brand, 54 inches wide by 24 inches high; 187,000 sold at Home Depot Stores from July 2000 through May 2001; Mill's Pride, Waverly, Ohio (877) 677-6777

Andersen 200 Series Tilt-Wash Double-Hung Window; 400,000 sold nationwide from May through August 2001; Andersen Corporation, Bayport, Minnesota (888) 888-7020 www.andersenwindows.com

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lasts longer than a week, call your doctor.

For a stuffy nose: If your nose is blocked, especially if you can't breathe through it, use nose drops or spray containing oxymetazoline hydrochloride (Afrin, for example), xylometazoline hydrochloride (Otrivin Nasal Spray, for example), or phenylephrine hydrochloride (Neo-Synephrine nose drops and nasal spray, for example). Buy a less expensive generic or store brand product of any of these if it is available. Do not use these drugs for more than three days.

For fever, headaches and body aches: Use aspirin or acetaminophen, if needed.

For a cough: A productive cough (when you are coughing something up) should not be treated. If you have an unproductive (dry) cough that keeps you from sleeping, use dextromethorphan, available in Hold, St. Joseph's Cough Syrup for Children, or Sucrets Cough Control Formula. Buy a less expensive generic or store brand dextromethorphan product if it is available.

Cold Remedies (Not to Use)

Oral nasal decongestants (pills or syrup): We do not recommend the use of any nasal decongestants that are taken by mouth for treatment of a cold, although a Food and Drug Administration (FDA) panel has found three ingredients safe and effective. These ingredients are in the OTC drugs Afrinol, Actifed and Sudafed, and 12 of the 18 prescription cough and cold drugs presented in this book. The reason we do not recommend them is that they all contain large amounts of amphetamine-like drugs which can increase your heart rate and blood pressure. In addition, they can make you jittery and keep you awake. By using nose drops or spray, for one to three days (no more), you get less than 1/25th as much of these drugs—and just in your nose where they are needed, instead of throughout your system as you do when you take these drugs by mouth. This is now underscored by the recent ban of one of the most widely used oral

decongestants, PPA or phenylpropanolamine because it causes strokes and other life-threatening or fatal adverse reactions.

Antihistamines: Although the FDA has tentatively approved these drugs, we do not recommend the use of the following for treatment of a cold, largely because they are ineffective for this purpose: Chlor-Trimeton and Dimetane (OTC) or any of the prescription antihistamines.

The most widely read book on drugs, a standard reference for doctors called *The Pharmacological Basis of Therapeutics*, says this about the use of antihistamines for treating the common cold: "Despite early claims and persistent popular belief, histamine-blocking drugs [antihistamines] are without value in combating the common cold." Antihistamines also have a sedative effect.

Another reason to avoid unnecessary use of antihistamines is that older adults are more sensitive to their adverse effects.

Eight of the 15 prescription cough and cold drugs that are in this book contain an antihistamine and are therefore classified as *Do Not Use*. They include Chlor-Trimeton 12 Hour, Ornade, Trinalin, Actifed,* Dimetapp,* Tavist-D, Naldecon, and Tussionex. These eight also contain an oral decongestant.

Commonly used oral OTC cold remedies that contain an antihistamine, and a decongestant, a combination that we label *Do Not Use* include Alka-Seltzer Plus, Chlor-Trimeton Decongestant, Comtrex, Contac, Contac Severe Cold Formula, Coricidin, Coricidin-D, CoTylenol, Dimetane Decongestant, Dristan Advanced Formula, Drixoral, Maximum Strength Tylenol Sinus Medication, Nyquil, Pyrroxate, Sinarest, Sine-Aid, Sine-Off, Sinutab, Sudafed Plus, Triaminic Syrup, Triaminic Tablets, and Vicks Formula 44D.

Cough: A Necessary Evil

Your lungs clean themselves constantly in order to maintain efficient breathing. Mucus normally lines the walls of the lungs and captures foreign particles, such as inhaled smoke and

infecting virus particles. Hair-like cells (cilia) push this out of the lungs. Coughing adds an additional, rapid-fire means of removing unwanted material from the lungs.

A cough is beneficial as long as it is bringing up material, such as sputum (phlegm), from your airways and lungs. This is called a productive cough and is often seen with colds, bronchitis, and pneumonia. A dry, hacking, non-productive cough, on the other hand, can be irritating and keep you awake at night. Cough can also be part of a chronic condition, such as asthma or emphysema, or it may be caused by cigarette smoking.

Cough resulting from a chronic condition should be evaluated by your doctor. You should also seek medical advice if your sputum (phlegm) becomes greenish, yellowish, or foul smelling, if your cough is accompanied by a high fever lasting several days, if coughing or breathing deeply causes sharp chest pain, or if you develop shortness of breath. Any of the symptoms may indicate pneumonia. Anyone who coughs up blood should call a doctor.

Types of Coughs

A *productive cough* is useful in helping you to recover from a cold or flu. You should do what you can to encourage the clearance of material from your lungs by "loosening up" the mucus. This is the purpose of an expectorant, which thins secretions so that they can be removed more easily by coughing (or "expectoration"). The best expectorant is water, especially in warm liquids such as soup, which thins the mucus and increases the amount of fluid in the respiratory tract. A moist environment also helps this effort. You should drink plenty of liquids and if you can, moisten the air in your home with a humidifier or plain water steamed by a vaporizer. A pan of water on the radiator can help in the winter.

A *nonproductive cough*, a dry cough bringing up no mucus, may be treated with a cough suppressant, also called an antitussive. A cough that keeps you up at night or is extremely exhausting may also call for the use of one of these

* available OTC as well

agents. Cough suppressants should be used in a single-ingredient product. Rest and plenty of fluids are also in order.

Cough Remedies (Not to Use)

As mentioned above, the only time a cough medicine should be used is to suppress a nonproductive cough preventing sleep or other activities. The only drug recommended is single-ingredient dextromethorphan. Codeine, present in many prescription cough medicines, is not recommended for coughs. It is addictive and likely to cause constipation, especially in older adults.

Another ingredient in prescription (and OTC) cough products that we recommend against using is the expectorant guaifenesin (in all Robitussin products). We believe guaifenesin lacks evidence of effectiveness in loosening secretions (in, for example, Entex, Entex LA, and Robitussin).

Fever, Headache, and Muscle Aches

Fever, headache, and muscle aches are sometimes companions of the common cold. They are best treated without drugs, with rest and adequate fluids

Seek Medical Help When Any of the Following Occur:

- A fever greater than 101°F (38.3°C) accompanied by chills and coughing up thick phlegm (especially if greenish or foul smelling);
- Sharp chest pain when taking a deep breath;
- Cold-like symptoms that do not improve after seven days;
- Any fever greater than 103°F or 39.4°C;
- Coughing up blood;
- A painful throat with any of the following
 - 1) Pus (yellowish-white spots) on the tonsils or the throat
 - 2) Fever greater than 101°F (38.3°C)
 - 3) Swollen or tender glands or bumps in the front of the neck
 - 4) Exposure to someone who has a documented case of strep throat
 - 5) A rash that came during or after a sore throat
 - 6) A history of rheumatic fever, rheumatic heart disease, kidney disease, or chronic lung disease such as emphysema or chronic bronchitis.

or with plain aspirin or acetaminophen. (A generic or store brand is as effective as heavily advertised brand names like Genuine Bayer, Datril, and Tylenol and generally costs less.)

Never give aspirin to a feverish person under 40 years old: he or she may have influenza rather than a cold. There is strong evidence that young people who take aspirin when they have flu (or chicken pox) have a greatly in-

creased risk of later getting Reye's Syndrome. This is a rather rare but potentially fatal disease that often leaves its victims impaired for life, if they survive.

Call your doctor if a fever climbs above 103°F (39.4°C), or if a fever at or above 100°F (38°C) lasts for more than four days. Under either of these circumstances, the patient probably does not have a cold.

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company also offered a doctor \$65,000 in an "educational grant" if he would reverse his decision to recommend only Zoladex at his HMO. And it feted doctors with junkets to expensive golf and ski resorts and by picking up cocktail party bar tabs.

All this levity and high jinks came to a crashing end this October, when the

Justice Department revealed the details of the scams and the terms of its settlements with the companies. Abbott and Takeda agreed to pay \$875 million to settle fraud charges stemming from the kickback schemes—the largest health care fraud settlement in U.S. history. One physician and six company employees were indicted, adding to the four urologists who had

pleaded guilty previously.

Acting rapidly to erase the stain on its members, the American Urological Association, with 9,000 members, has announced a campaign to ensure that urologists do not run afoul of federal billing standards again. There's only one hitch: the campaign is partially underwritten by a \$1 million grant from Pharmacia, another drug company.

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The Lupron Loophole—and the Doctors Who Exploited It

As white collar (or in this case white coat) scams go, it was one of the most brazen. A drug company provides an expensive, potentially life-saving drug free of charge to doctors, who promptly turn around and bill the government and private insurers at the exorbitant rate usually charged by the company. The profits go straight into the pockets of the doctors.

And who foots the bill? You, through your taxes and co-payments to reimburse doctors for their grossly inflated charges to the Medicare program. And you, through higher premiums in private insurance schemes.

Like so many crooked schemes in U.S. health care, this one has its roots in one of the greatest social frauds of

our time—the failure of the government to provide universal health insurance. Even the Medicare program for seniors, which in some ways resembles a national health insurance system, has enormous gaps, not the least of which is the failure to cover almost all outpatient drugs.

But there is one exception to this lack of Medicare reimbursement—and it was this exception that was exploited by Lupron's manufacturers, Abbott Laboratories and Takeda Chemical Industries, organized together as TAP Pharmaceuticals. The government does reimburse for outpatient drugs if they are administered by a physician. Lupron, which is a treatment for prostate cancer that must be administered by injection, conveniently fits the bill.

The manufacturer establishes a price for the physician to charge, and the government obligingly pays 80 percent of that, with patients picking up the rest.

But what if doctors received the drug for free or at a deep discount? First, they would be able to pocket the entire manufacturer's price or a tidy fraction of it. Second, they would be more likely to prescribe Lupron, rather than its less expensive competitor Zoladex. To use a hackneyed phrase, it's a "win-win" situation—unless you happen to be a patient or a taxpayer.

But the companies didn't stop there. Just in case the bilking of hundreds of cancer patients wasn't enough to induce doctors to prescribe Lupron, the

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