

# Health Letter

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## Cost, Quality and Choice: Winning Less Expensive, Better Quality Health Care For America

*The following was submitted for publication in Health Letter by long-time Public Citizen member Clyde Winter. See also the following related piece by Don McCanne, M.D., President of Physicians for a National Health Program.*

While legislators and politicians and their families in Washington enjoy — at no cost, for the rest of their lives — the finest comprehensive medical care benefits package taxpayers can provide, one out of every six Americans has no medical care insurance. Over 30 percent of workers in agriculture, construction and household services are uninsured. One out of nine health care workers has no medical insurance. Two-thirds of all uninsured persons are employed workers and their families. Nearly half (42 percent) of all bankruptcies in the United States involve illness or medical debt. The uninsured die at a rate 25 percent higher, and thousands die yearly from lack of coverage.

During the booming nineties, health care costs skyrocketed while health care became a commodity (where the criterion for receiving care is ability to pay, rather than medical need) and the healing professions were being transformed into a profit-seeking industry. In 1985, three-fourths of HMO members were in non-profit plans.

By 1999, only one-third were enrolled in non-profit HMOs. While average premiums of investor-owned and not-for-profit plans are virtually identical, medical insurance plans designed to make profits spend almost 50 percent more on administration and profits, and correspondingly less on actual patient care. The number of non-medical administrators in the increasingly profit-oriented, market-driven system has grown ten times as fast as the numbers of physicians, nurses and other clinical care givers. As much as half the health care dollar is never applied to health care. It's consumed by administrative costs, marketing, profits, insurance brokers, disease management and utilization review compa-

nies, lawyers, business consultants, billing and collection agencies, information management firms, etc. Health insurance overhead alone now accounts for about one percent of the U.S. GNP.

Not only did costs go through the roof, but the proportion of those costs that were paid directly by the employee in employment-based plans doubled and tripled during the nineties. By 2000, elders in the U.S. were spending, on average, one-fourth of their total income just for medical care due to deductibles, co-payments, non-covered items and premiums that have been tacked on to Medicare by politicians and legislators. Medicare currently pays for only

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**BETTER HEALTH CARE**, from page 1 about half of all medical expenses of the elderly.

Quality of care is lower when the providing institution is there to make a profit. For-profit HMOs calculate a "medical loss ratio," which is the percentage of revenue they have collected that they have to actually spend on medical care. They seek to lower this ratio because their responsibility is to the shareholders, not the patients. When the "loss ratio" falls, their stock's value on Wall Street and the CEO's personal fortune typically rises. Increasingly, arbitrary rules and gatekeepers who are not your doctor or nurse — and are often not even medical professionals — determine whether to authorize procedures and treatments, even in emergencies. Employer-sponsored plans that are managed for profit view the employer, not the insured patient, as their customer. The HMO wins a contract by defining optimal care as that which minimizes costs. A doctor's "productivity" is evaluated and financially rewarded based on how little time he spends with each patient and how little his recommended treatment costs the plan. Patient outcomes are not even a factor in these productivity evaluations. A study published in the *Journal of American Medicine* found that for-profit HMOs nationwide scored worse than non-profit HMOs on all fourteen quality-of-care indicators. The largest quality differences were in the care of seriously ill patients. Because of inadequate access to mammograms, if all American women were enrolled in for-profit HMOs, the annual death toll from breast cancer would rise by thousands. For-profit HMOs in New York state selectively refer heart surgery patients to the hospitals with the highest surgical death rates.

One purported advantage of the U.S. system of health care is the smorgasbord of "choices" represented by the many insurance companies and agents, the lists of "preferred providers" (who prefers them,

anyway, and for what reasons?), all those for-profit HMOs, and the various previously unknown corporate predators gobbling up what remains of our old respected non-profit medical institutions and then each other. The choices we face in health care for ourselves and our loved ones are at once mind-boggling and frightening. We find ourselves one day, clutching a ream of insurance papers full of restrictive and exclusionary clauses, entering a hospital called something like "The Sisters of Mercy" that we suspect, with good reason, is owned by a group of investors expecting dividends for themselves of at least 20 percent per annum, whose chief executive is a ruthless corporate raider looking to take over all the hospitals with a five-state target region. How can we know whether the doctor, nurse or whoever is telling us everything they know about what is happening in an ailing body and what can be done about it, or whether she or he is telling us only what treatment the private insurer intends to provide?

But many Americans don't have to suffer those confusing and distressing choices. The uninsured and underinsured usually have no difficulty weighing their options and choices. Forty-two percent of all employees — and four out of five in small firms — are offered the "choice" of only one plan, which usually restricts them to a doctor and clinic chosen by The Plan. A lot of privately insured Americans change plans, but only one out of ten changes in order to hopefully get better care. Three out of every four who change are forced to by a job change or because their employer switches plans. There is, however, one important choice many Americans will be making regarding health care. Four out of ten terminally ill patients or their families report that the personal financial costs of the illness are a moderate to severe problem. Too often, an American's most taxing and lonely medical "choice" is between staying alive or

saving their family money.

Is there a better way? The solution is simple and proven. We need, we must have, **Single Payer National Health Insurance** that is:

1. **Universal** — all Americans would be fully and uniformly covered — no tiers for "commoners" and the elite;
2. **Portable** — coverage stays the same regardless of changes in employment, residence, age or marital status;
3. **Accessible** — medical services would be covered from any provider anywhere...no "preferred" providers;
4. **Comprehensive** — no denial of care for pre-existing conditions, "pre-approval," exclusions or cut-off ceilings;
5. **Publicly administered** — Oversight of effectiveness to be provided by public scrutiny, the democratic process and medical professional review, rather than corporate CEOs and accountants and their desire to maximize profits, dominate the market and rake in millions in bonuses, stock options, and golden parachutes.

And we need, we must have, medical care providers that can retain the commitment and the ability to serve, first and foremost, the traditions and ethical standards of their ancient and honorable profession.

The free-wheeling insurance and HMO giants have transformed U.S. health care because their arm-twisting drives providers (the traditional private practice physicians and the independent community-based hospitals directed largely by practicing doctors) into takeovers by for-profit corporations and mergers into mega-corporations, which then wrestle with the insurance companies for slices of the billions of health care dollars. The more health care dollars there are, the



bigger the pie. The fewer of those dollars that are actually spent on health care, the bigger the profit margins. The consequences to us of this development unique to health care are severe and adverse to cost containment, quality of care and choice in America.

U.S. spending on health care per person is *twice* that of all other modern industrialized nations. Switzerland, our nearest competitor in big spending, puts out 65 cents for every dollar we spend per capita. At the time that Universal Single Payer Health Care was first mandated in Canada, costs as a share of GDP were the same as costs in the U.S. But by 1995, Canada's health expenditures per person were only 55 percent of what America was spending. These countries' health care costs are way less than ours *because* their systems are publicly funded, universal and comprehensive. There are no legions of what we used to call paper shufflers, no determining eligibility, no chasing after payments from impoverished patients, no prior approval for medical treatment, no endless variety of complicated forms and procedures depending on which HMO or insurer, which species and permutation of health care "Plan," applies. Doctors and nurses can spend all their time on patient care, much less of their time on paperwork and none being monitored or struggling to understand and comply with payment and treatment directives from a myriad of insurers. Canadian hospitals spend 30 percent less on administrative costs than do U.S. hospitals.

The American employment-based, multiple-private-insurer system, full of dangerous gaps and loopholes, leaves American business holding the bag. A small business with few employees has no leverage negotiating with the insurers. To provide employees with truly good coverage (check the fine print) places the business at a severe disadvantage with the competitor who slyly provides junk insurance or none at all.

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in a nation is not  
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Associations and big corporations are also caught in the crunch. Fifteen years ago, Chrysler spent \$500 more to build a car in Detroit than it did to build one across the bridge in Ontario because of the cost difference of health care. That's another excuse for jobs to migrate overseas. And it's only gotten worse. Canada spends 10 percent of its GDP on health care costs while the U.S. spends 14 percent.

Quality of care is secondary to the profit motive in the U.S. system. All countries ration medical care. In Canada, this rationing depends on urgency of medical need. In the U.S., it depends on a) whether your particular insurance coverage even allows you to get in a particular service line, and b) whether you can pay to jump to the head of the line. All forms of managed care attempt to control costs by monitoring and controlling the treatment plans of physicians. Under Canada's national universal plan, doctors' clinical decisions are neither questioned nor monitored except by the College of Physicians and Surgeons. In Canada, there are 25 percent more nurses working per capita than in the U.S., where providers rely heavily on untrained "aides" and "assistants" for patient

care. After WWII, the U.S. led the world in life expectancy. By 1997, American women ranked 20th among industrialized nations in life expectancy, American men ranked 22nd and the U.S. ranked 24th in infant mortality. Canadian elders receive four times as many home or nursing home caregiver visits as do American elders. *Quality of medical care in a nation is not measured by what is procurable by the very wealthiest of individuals; it is measured by what is actually provided to all of the people.*

Paradoxically, citizens in countries that have publicly financed, universal national health insurance have much more individual choice in their medical care than do we Americans with our privatized, for-profit, multiple-insurers, employer-based system. Most people in the U.S. have a "choice" of one "Plan": that chosen by their employer. Preferred provider lists and required pre-approval restrict us to specialists, hospitals and treatment plans chosen neither by us nor by our doctor. If the HMO takes a hike, if our job changes or if the boss decides to sign a different contract, we may have to change our family doctor and get a whole new preferred provider list. Universal national health insurance lets you choose any doctor you want. The doctor and patient can refer to any specialist or hospital. And there is no pre-approval required of your doctor's treatment plan.

A Gallup poll found that 96 percent of Canadians prefer their health care system to the U.S. model. Despite all the propaganda here, a majority of Americans also prefer national health insurance. And regarding trust: a 1997 public poll published in the *New England Journal of Medicine* found that "health insurers and managed care companies were ranked 2nd and 3rd from the bottom, just above the tobacco industry."

Let's get what we need.



# Affordable Reform That Benefits Patients

*The following was written by Don McCanne, M.D., President of Physicians for a National Health Program.*

**T**he continuing rise in health care costs is proof that our existing system of competing health plans has been incapable of controlling costs. Decades of attempts to improve coverage through a hodgepodge of private plans and public programs have resulted only in higher costs and greater numbers of uninsured. Current proposals that build on our existing system promise only higher costs and the perpetuation of the profound administrative waste that is unique in the world. We spend more on paperwork in our health care system than we do for our entire military budget — almost \$400 billion.

Single-payer national health insurance, by contrast, would slow the growth of health-care costs well into the future. And it would ensure that everyone has access to comprehensive health care services. What do we really want out of our health care system?

- We want affordability. Placing our health care system on a single budget would provide a mechanism to finally corral health care costs for all of us.
- We want our health insurance

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dollars to be spent on patients, rather than private health plan bureaucracies. By eliminating administrative waste caused by the health plans and the costly burden they place on the system, we would free up more than enough to pay for coverage of the uninsured and truly comprehensive benefits for all.

- We want our health insurance always to be there. With a universal insurance program, we would never lose coverage because of a change in employment, early retirement or a financial setback that makes premiums unaffordable.
- We want to be free to choose our physicians and hospitals instead of

being penalized for failing to use the provider chosen by the insurance company.

- We want to have access to care whenever we need it rather than when and where the insurance company dictates.

The marketplace will not serve us well in health care if we depend on health plans. They would continue to compete based on the price of their premiums. But with rising costs, plans can keep their premiums competitive only by shifting costs to patients in the form of fewer benefits and greater out-of-pocket payments. This would threaten the financial security of those with the greatest health care needs.

On the other hand, competition based on quality would be beneficial. Since we would have free choice of doctors and hospitals, the providers themselves would be motivated to compete for patients based on the quality of their services.

A single-payer system, funded at our current level of spending, would provide high-quality, comprehensive, affordable health care for everyone. But we can achieve this only if we throw out the wasteful, ineffective middlemen — the health plans — and spend the money on patients instead.

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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# The Dangers of Some Screening Tests

Disease screening refers to performing tests to determine whether a person has a disease or the potential to develop a disease when, at the time of testing, the person does not have any obvious signs or symptoms of the disease. The notion is that action can

be taken early to prevent or mitigate a problem. With modern technology, many tests are available for disease screening. A well-known example is the PAP test, which detects abnormalities in cervical cells when they are treatable, well before they develop into cervical cancer, but before

the woman experiences any discomfort. First, it is important to note that the following discussion does **not** pertain to those instances where a) it is known that something is wrong with the patient, and the blood testing is done to pinpoint the problem, *continued on page 6*

## A Free Ride For Bad Doctors

*This Op-Ed by Sidney Wolfe, M.D. appeared in the March 4, 2003 edition of the New York Times.*

The death of J sica Santill n, the 17-year-old given a heart and lung transplant last month from an incompatible donor, has become the latest argument in Congress against President Bush's plan to limit malpractice damage awards. With doctors in several states staging work stoppages to protest the soaring costs of premiums, the plan to put caps on pain-and-suffering payouts had been picking up steam.

Yet in all the discussion of tragic cases and dollar amounts, a major cause of the malpractice problem is ignored: the failure of state medical boards to discipline doctors.

The fact is, only a small percentage of doctors account for most of the money paid out in malpractice cases. From 1990 to 2002, just 5 percent of doctors were involved in 54 percent of the payouts — including jury awards and out-of-court settlements — according to the National Practitioner Data Bank of the Department of Health and Human Services. (The data bank allows hospitals and medical boards to see the records of individual doctors but, thanks to pressure from the American Medical Association, Congress forbids it to release information to doctors or the public.)

Of the 35,000 doctors with two or more payouts during that period,

only 8 percent were disciplined by state medical boards. Among the 2,774 doctors who had made payments in five or more cases, only 463 — one out of six — had been disciplined.

Is it any coincidence that the states least likely to discipline doctors are among those with insurance crises? Pennsylvania — where the governor had to intervene to keep doctors from going out on strike over malpractice insurance costs — has disciplined only 5 percent of the 512 doctors who had made payments in malpractice suits five or more times, the lowest percentage of any state. (Arizona, for example, has disciplined nearly half of the doctors in this category.)

And while Pennsylvania has 5.3 percent of the doctors in the United States, they make up 18.5 percent of American doctors with five or more malpractice payments. One doctor there paid 24 claims between 1993 and 2001 totaling more than \$8 million (one was for operating on the wrong part of the body; another was for leaving a "foreign body" in the patient) yet was never disciplined by Pennsylvania authorities.

The state with the next highest overrepresentation of doctors with five or more payouts is West Virginia, where doctors went on strike last month. It has 0.57 percent of the country's physicians, but they make up 1.69 percent of American doctors who have had made malpractice payments five or more

times. Only one-quarter of the state's doctors with five or more payouts has been disciplined by the medical board.

In New York, another state with a pending malpractice crisis, the number of doctors who have had five or more malpractice payments is two and one-half times higher than would be expected from the number of doctors licensed. Yet only 15 percent of these 698 doctors have been disciplined by the state board.

Amid the uproar about malpractice premium increases, there is a deadly silence from physicians' groups on the crisis of inadequate doctor discipline. The problem is not the compensation paid to injured patients, but an epidemic of medical errors. If medical boards, which are state agencies, are unwilling to seriously discipline doctors who repeatedly pay for malpractice — including revoking medical licenses from the worst offenders — then legislatures must step in and change the way the boards operate.

Congress should also rethink the secrecy surrounding the practitioner data bank. While a few states release some data to the public, most Americans have no way of finding out their doctors' backgrounds. What patient would not like to discover the malpractice history of a potential doctor, especially if he is among the 2,774 in the United States who have had five or more payouts?



# SCREENING TESTS, *from page 5*

i.e., for diagnosis, or b) the blood testing is being done to monitor a known disease or problem, or to treat for the disease, i.e., as part of treatment.

As attractive as the concept of disease screening is, problems can occur. To understand the problems, some terminology used by epidemiologists needs to be explained. Consider Table 1, which compares the result of the test to what is in fact true. It is possible that the test gets it right, and the patient actually does or does not have the disease. But the test also can be wrong in one of two ways: it can say the patient has the disease when he or she does not (a false positive) or it can fail to detect the disease when it is present (a false negative).

When a patient learns that a test is abnormal (positive for a given disease), he or she needs to know what the likelihood is that the test is a true positive as opposed to a false positive. Epidemiologists call this the Positive Predictive Value, or the percentage of all positive tests that are true positive tests. But here is the rub: the Positive Predictive Value of a test is quite affected by the percentage of people in the population who have the disease.

In Table 2, we consider a population of 100,000 people, of whom 50,000 (50 percent) truly have the condition for which you are testing. Assume that the test always detects the condition when it is present (no false negatives), but five percent of the time it says the condition is present when it is not (false positives). The total number of positive tests will be the true positives (50,000) plus the false positives (five percent of the remaining 50,000 or 2,500). In this example, the positive predictive value is  $50,000 / (50,000 + 2,500)$ , or 95.2 percent. This is excellent test performance. It means that if you test positive, there is a strong likelihood that the finding is real.

But what if only one percent of the population actually has the condition? (See Table 3.) This is more often the case when screening

**Table 1: Possible outcomes in testing for disease**

		In Reality:	
		Person has disease	Person does not have disease
Test Says:	Person has disease	True Positive	False Positive
	Person does not have disease	False Negative	True Negative

**Table 2: Test performance when 50 percent of a population of 100,000 people has the disease**

		In Reality:	
		Person has disease	Person does not have disease
Test Says:	Person has disease	True Positive 50,000 persons	False Positive 2,500 persons
	Person does not have disease	False Negative 0 persons	True Negative 47,500 persons

Positive Predictive Value =  $50,000 / (50,000 + 2,500) = 95.2$  percent

**Table 3: Test performance when one percent of a population of 100,000 has the disease**

		In Reality:	
		Person has disease	Person does not have disease
Test Says:	Person has disease	True Positive 1,000 persons	False Positive 4,950 persons
	Person does not have disease	False Negative 0 persons	True Negative 94,050 persons

Positive Predictive Value =  $1,000 / (1,000 + 4,950) = 16.8$  percent

is done. Then the number of true positives is one percent of 100,000 or 1,000. But the number of false positives is still five percent of the remaining 99,000 or 4,950. The positive predictive value is only 16.8 percent ( $1,000 / (1,000 + 4,950)$ ). This means that most likely your positive test does not reflect true disease.

All of this is important to remember when getting blood tests, particularly when numerous blood tests are run simultaneously. With modern technology, many different tests can be run automatically from very little blood, drawn from just one puncture of a vein. Such blood test screening is commonly performed as part of a routine physical examination. This benefits the patient in reducing the

number of "sticks," the amount of blood taken and the cost per test.

But running so many tests for disease-screening purposes presents certain problems, and the false positive/Positive Predictive Value problem is one of them.

The multiple blood tests obtained from one "stick" are often referred to as a "panel" of tests. A routinely used blood test panel for screening is the Comprehensive Metabolic Panel (CMP), consisting of about 14-20 tests. The CMP usually measures kidney and liver functioning and glucose and electrolyte levels. Electrolytes are important in nerve and muscle function; examples are sodium, potassium, calcium and chloride. The multiple tests in the



CMP are **not** specific to one body organ. To get more specific, the physician would have to order additional tests. This requires more effort from the physician and perhaps more cost.

Let us consider a case where the physician is using the panel for screening purposes; he or she expects that it is not likely that you have any of the conditions (akin to Table 3). It is important to remember that a "normal" result is a statistical concept. The normal range for a test is usually based on a range that covers 95 percent of the test values in normal people. This means that on any one test, five percent of normal people will have abnormal values (false positives). This is the same rate of false positives we used in the examples in Tables 2 and 3, so you can see how misleading the results can be with just a single blood test.

The problem is magnified when multiple tests are ordered. In fact, one can calculate that for a panel with 14 tests or more, it is more likely than not that at least one of the tests will be falsely positive (how many will be truly positive will depend on whether you actually have the condition for which you are being tested).

If a physician follows up on every single "abnormal" test result, you may find yourself undergoing a cascade of unnecessary, costly and even harmful tests. An example is an elevated alkaline phosphatase (a component of the CMP that is not infrequently elevated because it is found in so many body tissues). This could lead to the physician ordering an ultrasound of the gallbladder. If the ultrasound yields a false positive (even radiological tests are imperfect), the patient could undergo unnecessary surgery.

Laboratories usually have "panic"

values for important tests — values that are so low or high that they are not likely false positives and could represent an immediate danger to the patient. In such cases, the laboratory must notify the physician immediately. However, if the laboratory result is outside of the normal range but not markedly so, and there are no overt signs or symptoms of a problem, it is often better to repeat the test.

In light of the potential pitfalls of multiple blood test panels, the following outlines procedures you can

*One can calculate that for a panel with 14 tests or more, it is more likely than not that at least one of the tests will be falsely positive.*

follow with your physician to receive optimal benefits from the tests.

1. Before ordering any blood tests, review both your family and personal medical histories for diseases and problems. Also review the diseases that are common for your age and sex.

The U.S. Agency for Health Care Research and Quality (AHRQ) has a Web site ([www.ahrq.gov](http://www.ahrq.gov)) that provides epidemiological reviews of the usefulness of various screening tests and other preventive measures for common diseases/problems (click on "Preventive Services" at

the Web site).

2. Determine which tests you really need. Then ask the physician whether it would be cheaper to have the laboratory run only the individual tests, or the panel that includes the tests.
3. Ensure that the physician is taking the expected prevalence of the disease into consideration when interpreting your test results.

Following the preceding steps will alert both you and your physician as to which of the blood test results are worth follow-up.

There are other factors that can adversely affect any of the tests and cause them to give an inaccurate reading:

1. Poor blood-drawing technique. Red blood cells can burst as a result of this, releasing potassium and thus showing an abnormally high potassium reading.
2. Incorrect storage and preparation of the blood sample.
3. Faulty blood-testing equipment. Under a law called CLIA (Clinical Laboratory Improvement Amendments), the government seeks to "ensure quality laboratory testing." By going to [www.cms.gov/clia](http://www.cms.gov/clia) and scrolling down to "Laboratory Registry," you can identify whether the U.S. government (Centers for Medicare and Medicaid Services) has taken any adverse action against your laboratory.

Finally, none of your testing will be worthwhile unless your physician discusses the results with you. You should request a copy of your laboratory results for your personal records.



# Product Recalls

*February 12, 2003 — March 12, 2003*

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, 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](http://www.fda.gov).

### Name of Drug or Supplement; Class of Recall; Problem

**Aerzoin**, Skin Conditioner For Tape & Cast Dressings, 3.5-oz can and **Kenzoin**, Skin Conditioner For Tape & Cast Dressings, 4-oz can; Class III; Failure to comply with Good Manufacturing Practice Regulations including performance of finished product assays & manufacturing validation

**Clindamycin Phosphate Topical Solution**, 1-oz and 2-oz bottles, Rx Only; Class III; Superpotency

**Codimal DM Syrup for Cough/Colds**, 118mL (4 fl oz) and 473mL (1 pint) bottles; Class III; Cross contamination: product contains traces of iron from another oral iron product

**Diltia XT Extended Release Capsules**, 120 mg, 100- and 1000-capsule bottles, Rx only; Class III; Dissolution Failure: four-hour time point (12-month stability station)

**Feen-A-Mint Laxative Tablets**, 5mg, 10-tablet carton; Class III; Disintegration: failure due to tablet softening

**Fluoracaine, Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution**, Sterile, Rx Only, 5 mL glass screw cap vial with black propylene cap and sterile dropper; Class II; Container/closure integrity problems, leaking containers

**Fluress, Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution**, Sterile; Class II; Container/closure integrity problems, leaking containers

### Lot #: Quantity and Distribution; Manufacturer

Numerous lots; 102,864 cans distributed nationwide; Pel Associates, Inc., North Branch, New Jersey

Lot 24667 exp. 04/2004 and sub-lots 24667A, 24667C and 24667E; 7,734 1-oz and 6,315 2-oz bottles distributed in Pennsylvania, New York, Missouri, Florida, Ohio, California and Puerto Rico; Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois

Lots 1125602 (4 fl oz) and 1125601 (1 pint); 706 4-fl oz bottles and 23,683 1-pint bottles distributed nationwide and throughout the Americas; Schwarz Pharma Manufacturing, Seymour, Indiana

Numerous lots; 132,181 100-capsule and 6,080 1000-capsule bottles distributed nationwide; Andrx Pharmaceuticals, Inc., Fort Lauderdale, Florida

Lot 1-EGN-4 exp. 01/2003; 109,728 packages distributed nationwide; Schering-Plough HealthCare Products/DBA Bain de Soleil Co., Cleveland, Tennessee

Numerous lots; 129,594 bottles distributed nationwide and internationally; Akorn, Inc., Decatur, Illinois

Numerous lots; 222,400 bottles distributed nationwide and internationally; Akorn, Inc., Decatur, Illinois



## D R U G S   A N D   D I E T A R Y   S U P P L E M E N T S   *cont.*

### *Name of Drug or Supplement; Class of Recall; Problem*

**Humalog Pen** disposable insulin delivery system, 3 mL, 100 units per mL, Rx only; Class II; Drug cartridges may be cracked or broken

**Hydrocodone Bitartrate and Acetaminophen Tablets,** 10mg/500 mg, Qualitest, Rx only, 1000-tablet bottles; Class III; Tablet hardness failure

**Hydrocodone Bitartrate and Acetaminophen Tablets,** 5mg/500mg, 100-count bottle, Rx only; Class III; Mislabeling: label incorrectly printed with Scheduled Drug Classification as CIV instead of correctly as CIII

**Levothyroxine Sodium,** 100 mcg (0.1mg) tablets, Rx only, 100- and 1,000-count bottles; Class III; Stability: product may not maintain potency through labeled expiration date

**Micardis Tablets,** 20 mg, 28 tablets, Rx only; Class III; Container defect: loss of integrity of air tight seal on blister cards

**Motrin IB,** 200mg coated caplets, 2-count single-dose packets, and **DayQuil LiquiCaps,** 2-count unit dose packages; Class III; Mispackaging: packets of Motrin IB incorrectly repackaged in hanging card packages labeled to contain DayQuil LiquiCaps

**Natural Nasal Decongestant with Echinacea & Valerian, Adult Nighttime Cold Formula, Tom's of Maine,** 4-fl oz (112ml) bottles; Class III; Misbranded: dosing instructions for adults/children 12 years and older will only provide half required amount of active ingredient

**Natural Nasal Decongestant with Echinacea & Valerian, Children's Nighttime Cold Formula, Tom's of Maine,** 4-fl oz bottles (112 mL), Cherry flavor; Class II; Misbranded: dosing instructions for children ages 2 to 6 will provide excessive amounts of active ingredient

**Natural Nasal Decongestant with Echinacea, Adult Daytime Cold Formula, Tom's of Maine,** 4-fl oz (112ml) bottles; Class III; Misbranded: dosing instructions for adults/children 12 years and older will only provide half required amount of active ingredient

**Natural Nasal Decongestant with Echinacea, Children's Daytime Cold Formula, Tom's of Maine,** 4-fl oz bottles, Cherry Flavor; Class II; Misbranded: dosing instructions for children ages 2 to 6 will provide excessive amounts of active ingredient

**Nature-Throid NT-2 (Thyroid),** 129.6 mg, 100-tablet bottles, Rx only; Class II; Mislabeling: bottles labeled Nature-Throid NT-2 (129.6mg) actually contain Nature-Throid NT-1 (65mg)

### *Lot #: Quantity and Distribution; Manufacturer*

Lot FF2S19C exp. 08/01/2004; 12,825 bottles distributed nationwide; Eli Lilly and Company, Indianapolis, Indiana

Lot 142081A; 1,459 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina

Lot 062121C; 1,079 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina

Numerous lots; 13,168 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina

Lot 106909A exp. 11/2003 and 205752A exp. 08/2004; 264 boxes distributed nationwide; Boehringer Ingelheim Roxane Laboratories, Columbus, Ohio and Boehringer Ingelheim Pharma KG, Ingelheim, Germany

Lot FCC035 exp. 03/2005; 1,470 units distributed nationwide; Navajo Manufacturing Company, Inc., Denver, Colorado

All lots; 8,072 bottles distributed nationwide; Tom's of Maine, Inc., Kennebunk, Maine

All lots; 10,188 bottles distributed nationwide; Tom's of Maine, Inc., Kennebunk, Maine

All lots; 19,738 bottles distributed nationwide; Tom's of Maine, Inc., Kennebunk, Maine

All lots; 6,788 distributed nationwide; Tom's of Maine, Inc., Kennebunk, Maine

Lot B036N exp. 03/2005; 360 bottles distributed nationwide; RSJ, Inc., Phoenix, Arizona

*continued on page 10*



## DRUGS AND DIETARY SUPPLEMENTS *cont.*

### *Name of Drug or Supplement; Class of Recall; Problem*

**Premarin Tablets** (conjugated estrogens tablets), 0.625 mg, packages of 100 and bottles of 1,000, Rx only; Class III; Dissolution failure: by manufacturer

**Rhinaris Lubricating Nasal Mist**, non-medicated, .33-fl oz (10 mL) and 1-fl oz (30 mL) bottles; Class II; Microbial Contamination: *Pseudomonas fluorescens*

**Toprol-XL (Metoprolol Succinate) Tablets**, 100 mg, 90-tablet bottles; Class II; Mislabeling: bottles labeled 100 mg contain 50-mg tablets

### *Lot #: Quantity and Distribution; Manufacturer*

Lots 1A03925 exp. 12/2002, 1A03960 exp. 05/2005 and 1B00084 exp. 05/2005; 26 packages and 3,870 bottles distributed nationwide and in Puerto Rico; Recalled by Amerisource Health Services Corp. Columbus, Ohio, Manufactured by Ayerst Laboratories Inc., A Wyeth-Ayerst Company, Philadelphia, Pennsylvania

Lot 209281 exp. 05/2007 and 209280 exp. 05/2007; 10,000 .33-oz and 1,345 1-oz bottles distributed nationwide; Pharmascience, Inc., Tonawanda, New York and Montreal, Canada

Lot LN066233 exp. 12/19/2003; 418 bottles distributed nationwide; Caremark Pharmaceutical Services, Vernon Hills, Illinois

## 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](http://www.cpsc.gov).

### *Name of Product; Problem*

**Bamboo Stick Sparklers**; Handles can catch fire, burn, disintegrate and emit burning fragments, presenting fire hazard and risk of burn injury

**Busy Bug Plush Toys**; Antennae can be chewed or pulled off, posing a choking hazard

**Children's Board Book Sets**; plastic snaps on cardboard box can detach, posing a choking hazard

**Computer Monitors**; Monitor's circuit board can overheat and smoke, posing fire hazard

**Fondue Pots**; Plastic handles can melt and crack during heating on range top, posing burn and fire hazards

**Fun Buckets**, add-on option for backyard play sets; 6- to 8-foot free-hanging rope can become entangled around child's neck, presenting strangulation hazard

### *Lot #: Quantity and Distribution; Manufacturer*

Multicolored cardboard box with six sparklers per box and "LB-N011-7" printed on package; 72,000 boxes sold nationwide between June 2002 and December 2002; Fireworks of Alabama, Inc., Adamsville, Alabama (800) 289-5569

Small plush bug with antennae with orange fabric ends, blue stuffed face and red musical nose, UPC code 778267862920; 11,200 sold nationwide between August 2002 and January 2003; The Betesh Group, New York, New York (866) 473-0118

Boxed 4-book sets with children's characters on front of box, colored plastic handle and plastic snaps; 360,000 sold nationwide between August 2002 and January 2003; Random House Inc., New York, New York (800) 805-8534 [www.randomhouse.com](http://www.randomhouse.com)

G51 and G51t monitors model numbers 6541-02N, 6541-02E, 6541-02S, 6541-Q0N, 6541-Q0E and 6541-Q0SIBM; 56,000 sold nationwide between June 1997 and December 1998; IBM, Armonk, New York (866) 644-3155 [www.ibm.com/pc/g51recall](http://www.ibm.com/pc/g51recall)

Model number 82-384 sold under brand name "Trudeau"; 45,200 sold as part of 17-piece set at Bed, Bath and Beyond stores between August 2001 and July 2002; Trudeau Corp., Woodridge, Illinois (877) 659-4844 [www.trudeaucorp.com](http://www.trudeaucorp.com)

14-inch-deep yellow or green vinyl buckets with black nylon strap attached to rope and sold with heavy wood bracket to attach to roof of play set fort; 1,400 sold nationwide between February 1998 and February 2003; Playnation Play Systems, Kennesaw, Georgia (770) 792-9300 [www.playset.com](http://www.playset.com)



Name of Product; Problem	Lot #: Quantity and Distribution; Manufacturer
<b>Kitchen Gourmet Hot Pots;</b> Bottom of hot pot can separate from top, posing serious burn hazard	White plastic, pitcher-shaped hot pots with date code of 0702 on bottom of pot and box; 37,000 sold at Walgreens nationwide between September 2002 and January 2003; Atico International USA Inc., Ft. Lauderdale, Florida (800) 645-3867 <a href="http://www.aticousa.com">www.aticousa.com</a>
<b>Makita Electric Orbit Sanders;</b> Pads on sanders can break apart during use and strike operator, posing an injury hazard	Model numbers BO5000 and BO5001; 350,000 sold nationwide between April 1992 and February 2003; Makita U.S.A. Inc., La Mirada, California (800) 462-5482
<b>Novelty Lighters;</b> No child-resistant mechanism	Refillable, butane gas-fueled, metal dolphin-shaped lighters in three models: dolphin with large ball labeled "1988.8 Young's Wholes 14.9," single dolphin labeled "00005011 \$14.00 EA" and two dolphins with ball and no label; 500 sold in Oregon and Southwest Washington between 1996 and October 2001; Young's J.K. Inc., Portland, Oregon (503) 998-9801
<b>Riding Lawn Tractors;</b> Fuel tank can crack and leak, posing burn and fire hazard	Murray and Stanley brand with numerous model numbers; 270,000 sold nationwide between November 2000 and January 2003; Murray Inc., Brentwood, Tennessee (800) 876-1634 <a href="http://www.murray.com">www.murray.com</a>
<b>Skil Warrior Drill Battery Chargers;</b> Transformer inside charger can overheat, charger housing can melt and deform, possibly igniting flammable materials near or on charger	Numerous model numbers of 9.6-volt, 12-volt, 14.4-volt and 18-volt chargers sold with or as accessories for Skil Warrior drills; 2 million sold nationwide between July 1994 and February 2003; Robert Bosch Tool Corp., Chicago, Illinois (800) 661-5398 <a href="http://www.skil.com">www.skil.com</a>

**OUTRAGE, from page 12**

different compound, according to FDA guidelines."

"Finally, they tested and proved the hypothesis that the American public could be duped into paying far more for things available in less costly, but basically identical, formulations simply by employing colorful ad campaigns and effective direct-to-consumer marketing techniques," he concluded.

Indeed, study after study since Nexium's release has indicated that Nexium® benefits the executives and shareholders of AstraZeneca significantly more than do generic omeprazole or, for that matter, any of the other FDA-approved proton-pump inhibitors, with a *p-value* of <.005.

"It's truly a miracle drug," said Patsy Goldberg, a long-time esophagitis sufferer. "Imagine that — a medica-

*Study after study since Nexium's release has indicated that Nexium® benefits the executives and shareholders of AstraZeneca significantly more than do generic omeprazole or, for that matter, any of the other FDA-approved proton-pump inhibitors.*

tion that helps my acid reflux about the same as a cheaper generic would, and allows AstraZeneca to keep making money off me at the same time!"

Researchers at AstraZeneca are

currently hard at work "discovering" the R-isomer of omeprazole, with which they plan to overcharge the general public as soon as the patent for Nexium® runs out in 2014.



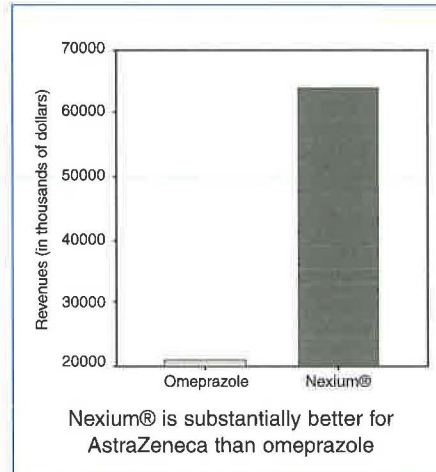
# Nexium® Offers Unique Advantage Over Generic Omeprazole

Only proton-pump inhibitor proven to enrich AstraZeneca

*The following is a parody that appeared in the August 1, 2001 issue of Q Fever!, a medical humor Web site (www.qfever.com).*

**W**ILMINGTON, DE — Nexium® (esomeprazole), the newest proton-pump inhibitor approved by the FDA for peptic ulcer disease, offers a unique advantage over the generic form of Prilosec (omeprazole), said a panel of industry experts this Wednesday.

Namely, Nexium®, which is simply the *L*-isomer of omeprazole, is now the only proton-pump inhibitor definitively shown to enrich AstraZeneca, the pharmaceutical



corporation that lost its U.S. patent for omeprazole in April 2001.

Experts in the healthcare community attribute the unmatched ability of Nexium® to benefit AstraZeneca to a remarkable series of scientific discoveries made at the company's research centers during the mid-to-late 1990's.

"First, they discovered that when they lost the patent for omeprazole, they wouldn't be making any money from it anymore," says Dr. George Papadopolous, a pharmacist in Wilmington.

"Then, they realized that omeprazole, like many chemical substances, has both an *L*- and an *R*- isomer, each of which is technically *[winks]* a

*continued on page 11*

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