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Information concerning the deficiencies of U.S. medical care has been accumulating. The fact that more than 40 million people have no health insurance is well known. The high cost of the health care system is considered to be a deficit, but seems to be tolerated under the assumption that better health results from more expensive care, despite evidence from a few studies indicating that as many as 20 percent to 30 percent of patients receive contraindicated care. In addition, with the release of the Institute of Medicine (IOM) report "To Err Is Human," millions of Americans learned, for the first time, that an estimated 44,000 to 98,000 among them die each year as a result of medical errors.

The fact is that the U.S. population does not have anywhere near the best health in the world. Of 13 countries in a recent comparison, the United States ranks an average of 12th (second from the bottom) for 16 available health indicators. Countries in order of their average ranking on the health indicators (with the first being the best) are Japan, Sweden, Canada, France, Australia, Spain, Finland, the Netherlands, the United Kingdom, Denmark, Belgium, the United States, and Germany. Rankings of the United States on the separate indicators are:

- 13th (last) for low-birth-weight percentages
- 13th for neonatal mortality and infant mortality overall
- 11th for postneonatal mortality
- 13th for years of potential life lost (excluding external causes) continued on page 2
poor health in the United States is undoubtedly complex and multifactorial. From a health system viewpoint, it is possible that the historic failure to build a strong primary care infrastructure could play some role. A wealth of evidence documents the benefits of characteristics associated with primary care performance. Of the seven countries in the top of the average health

Of 13 countries in a recent comparison, the United States ranks an average of 12th

ranking, five have strong primary care infrastructures. Although better access to care, including universal health insurance, is widely considered to be the solution, there is evidence that the major benefit of access accrues only when it facilitates receipt of primary care. The health care system also may contribute to poor health through its adverse effects. For example, U.S. estimates of the combined effect of errors and adverse effects that occur because of iatrogenic damage not associated with recognizable error include:

- 12,000 deaths/year from unnecessary surgery
- 7000 deaths/year from medication errors in hospitals
- 20,000 deaths/year from other errors in hospitals
- 80,000 deaths/year from nosocomial infections in hospitals
- 106,000 deaths/year from nonerror, adverse effects of medications

These total to 225,000 deaths per year from iatrogenic causes. Three caveats should be noted. First, most of the data are derived from studies in hospitalized patients. Second, these estimates are for deaths only and do not include adverse effects that are associated with disability or discomfort. Third, the estimates of death due to error are lower than those in the IOM report. If the higher estimates are used, the deaths due to iatrogenic causes would range from 230,000 to 284,000. In any case, 225,000 deaths per year constitutes the third leading cause of death in the United States, after deaths from heart disease and cancer. Even if these figures are overestimated, there is a wide margin between the numbers of deaths and the next leading cause of death (cerebrovascular disease).

One analysis overcomes some of these limitations by estimating adverse effects in outpatient care and including adverse effects other than death. It concluded that between 4 percent and 18 percent of consecutive patients experience adverse effects in outpatient settings, with 116 million extra physician visits, 77 million extra prescriptions, 17 million emergency department visits, 8 million hospitalizations, 3 million long-term admissions, 199,000 additional deaths, and $77 billion in extra costs (equivalent to the aggregate cost of care of patients with diabetes).

Another possible contributor to the poor performance of the United States on health indicators is the high degree of income inequality in this country. An extensive literature documents the enduring adverse effects of low socioeconomic position on health; a newer and accumulating literature suggests the adverse effects not only of low social position but, especially, low relative social position in industrialized countries. Among the 13 countries included in the international comparison mentioned above, the U.S. position on income inequality is 11th (third worst). Sweden ranks the best on income equality (when income is calculated after taxes and including social transfers), matching its high position for health indicators. There is an imperfect relationship between rankings on income inequality and health, although the United States is the only country in
a poor position on both.

An intriguing aspect of the data is the differences in ranking for the different age groups. U.S. children are particularly disadvantaged, whereas elderly persons are much less so. Judging from the data on life expectancy at different ages, the U.S. population becomes less disadvantaged as it ages, but even the relatively advantaged position of elderly persons in the United States is slipping. The U.S. relative position for life expectancy in the oldest age group was better in the 1980s than in the 1990s. The long-existing poor ranking of the United States with regard to infant mortality has been a cause for concern; it is not a result of the high percentages of low birth weight and infant mortality among the black population, because the international ranking hardly changes when data for the white population only are used.

Whereas definitive explanations for the relatively poor position of the United States continue to be elusive, there are sufficient hints as to their nature to provide the basis for consideration of neglected factors:

(1) The nature and operation of the health care system. In the United States, in contrast to many other countries, the extent to which receipt of services from primary care physicians vs. specialists affects overall health and survival has not been considered. While available data indicate that specialty care is associated with better quality of care for specific conditions in the purview of the specialist, the data on general medical care suggest otherwise. National surveys almost all fail to obtain data on the extent to which the care received fulfills the criteria for primary care, so it is not possible to examine the relationships between individual and community health characteristics and the type of care received.

(2) The relationship between iatrogenic effects (including both error and nonerror adverse events) and type of care received. The results of international surveys document the high availability of technology in the United States. Among 29 countries, the United States is second only to Japan in the availability of magnetic resonance imaging units and computed tomography scanners per million population. Japan, however, ranks highest on health, whereas the United States ranks among the lowest. It is possible that the high use of technology in Japan is limited to diagnostic technology not matched by high rates of treatment, whereas in the United States, high use of diagnostic technology may be linked to the "cascade effect" and to more treatment. Supporting this possibility are data showing that the number of employees per bed (full-time equivalents) in the United States is highest among the countries ranked, whereas they are very low in Japan far lower than can be accounted for by the common practice of having family members rather than hospital staff provide the amenities of hospital care.

How cause of death and outpatient diagnoses are coded does not facilitate an understanding of the extent to which iatrogenic causes of ill health are operative. Consistent use of "E" codes (external causes of injury and poisoning) would improve the likelihood of their recognition because these ICD (International Classification of Diseases) codes permit attribution of cause of effect to "Drugs, Medicinal, and Biological Substances Causing Adverse Effects in Therapeutic Use." More consistent use of codes for "Complications of Surgical and Medical Care" (ICD codes 960-979 and 996-999) might improve the recognition of the magnitude of their effect; currently, most deaths resulting from these underlying causes are likely to be coded according to the immediate cause of death (such as organ failure). The suggestions of the IOM document on mandatory reporting of adverse effects might improve reporting in hospital settings, but it is unlikely to affect underreporting of adverse events in noninstitutional settings. Only better record keeping, with documentation of all interventions and resulting health status (including symptoms and signs), is likely to improve the current ability to understand both the adverse and positive effects of health care.

(3) The relationships among income inequality, social disadvantage, and characteristics of health systems, including the relative contributions of primary care and specialty care. Recent studies using physician-to-population ratios (as a proxy for unavailable data on actual receipt of health services according to their type) have shown that the higher the primary care physician-to-population ratio in a state, the better most health outcomes are. The influence of specialty physician-to-population ratios and of specialist-to-primary care physician ratios has not been adequately studied, but preliminary and relatively superficial analyses suggest that the converse may be the case. Inclusion of income inequality variables in the analysis does not eliminate the positive effect of primary care. Furthermore, states that have more equitable distributions of income also are more likely to have better primary care resource availability, thus raising questions about the relationships among a host of social and health policy characteristics that determine what and how resources are available.

Recognition of the harmful effects of health care interventions, and the likely possibility that they account for a substantial proportion of the excess deaths in the United States compared with other comparably industrialized nations, sheds new light on imperatives for research and health policy. Alternative explanations for these realities deserve intensive exploration.
This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements and the Consumer Product Safety Commission (CPSC) recalls of consumer products.

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.

<table>
<thead>
<tr>
<th>Name of Drug or Supplement: Class of Recall: Problem</th>
<th>Lot #: Quantity and Distribution: Manufacturer</th>
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<tbody>
<tr>
<td><strong>Dexamethasone Tablets</strong>: 0.75 mg, 12 count, unit dose pack, under Qualitest and Vintage labels; Class II; Lack of data to support labeled expiration date</td>
<td>Lot Numbers: Qualitest 022D9A, 022D9B, 022D9C, 022D9D, 022D9E, 014E9A, 014E9C, 014E9D, 053F9A, 052L9B, 052L9C, 022D9F, 014E9B, 014E9E, 052L9A. Vintage 014E9B, 014E9E, 052L9A, 022D9F; 179,728 packages distributed nationwide and in Puerto Rico; Vintage Pharmaceuticals, Inc., Huntsville, Alabama</td>
</tr>
<tr>
<td><strong>Doxycycline Hyclate Capsules</strong>: 50 mg in bottles of 50, and 100 mg in bottles of 50 and 500; Class III; Product exceeds USP limit for water content</td>
<td>Lot Numbers P9H0299 EXP 8/01 and P9E0179 EXP 5/01; 38,683 bottles distributed nationwide and internationally; Danbury Pharmacal of Puerto Rico, Inc., subsidiary of Schein Pharmaceutical, Inc., Humacao, Puerto Rico</td>
</tr>
<tr>
<td><strong>Prednisone Tablets</strong>: Qualitest brand, 10 mg, in 21 and 48 count, unit dose pack; Class II; Lack of data to support labeled expiration date</td>
<td>Lot numbers 071F0A and 071F0B; 4,483 packages distributed nationwide; Vintage Pharmaceuticals, Inc., Huntsville, Alabama</td>
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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.

The Association of Home Appliance Manufacturers (AHAM) and its refrigerator/freezer manufacturing members have announced a voluntary recall initiative to prevent suffocation deaths to children who become trapped inside non-working chest freezers in homes. AHAM has set up a toll-free number (800) 267-3138 where consumers can receive detailed information on identifying the affected units and how to dispose of them or disable the latch. Even if consumers have working pre-1970 chest freezers, they should still call to get information on what to do when the freezer is no longer working. Consumers also can receive information at http://www.aham.org/freezer_safety.htm

The Window Covering Safety Council is announcing a recall to repair horizontal window blinds to prevent the risk of strangulation to young children. The recall involves millions of window blinds with pull cords and inner cords that can form a loop and cause strangulation. About 85 million window blinds are sold each year. Consumers who have window blinds with cords in their homes should call the Window Covering Safety Council toll-free (800) 506-4636 to receive a free repair kit for each set of blinds in the home. You can also visit their web site — www.windowcoverings.org — to get more information on checking your window covering.
**Name of Product:** Batteries (for notebook-style personal computers); Batteries can short circuit, even when the battery is not in use, causing them to become very hot, release smoke and possibly catch fire

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

Dell notebook computers: Latitude CPIA, CPIR, CPCR, CPRS, CPV, CPXH and CPXJ, and Inspiron 3700 and 3800; 27,000 sold June through mid-September 2000; Dell Computer Corp., Round Rock, Texas (877) 741-6420 http://support.dell.com/battery/

**Name of Product:** Battery Chargers; Metal clips inside the chargers could come loose and stick through the chargers' vents, possibly resulting in consumers receiving an electrical shock; used with DeWALT cordless tools

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

Model DW9116 date codes from 9927EM through 9952EM and 0001EM through 0031EM; 825,000 sold nationwide September 1999 through August 2000; DeWALT® Industrial Tool Co., Baltimore, Maryland (888) 368-3273

**Name of Product:** Bunk Beds; Side rail and guardrails can break, causing the bed to collapse

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

Stinson bunks in white or honey model numbers 3443082 or 3443090; 200 sold through Pottery Barn Furniture Outlets in Leesburg, Virginia, Memphis, Tennessee, Dawsonville, Georgia and Jeffersonville, Ohio and nationwide through the Pottery Barn Kids catalog from September 1999 through July 2000; Pottery Barn Kids Inc., San Francisco, California (800) 671-8312

**Name of Product:** Computer Battery Packs (for notebook computers); Packs can short circuit, causing them to overheat, release smoke and possibly catch fire

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

Armada E500 and V300 Date code TCGK with serial number from 00001 to 10500, 20001 to 21800, and 40001 to 83100, or Date code TCHK with a serial number from 40001 to 44700; 55,000 sold nationwide from June through July 2000; Compaq Computer Corp., Houston, Texas (800) 889-7613 http://www5.compaq.com/newsroom/pr/2000/pr2000102701.html

**Name of Product:** Crib Mobiles; Screws that connect the mobile’s arm assembly and crib clamp can become loose if overtightened. The arms can detach and fall into the crib, injuring the baby

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

“John Lennon” model with white wooden dowels that attach to cribs with white clamps, plays the song Imagine; 47,000 sold nationwide from June 1999 through August 2000; The Betesh Group, New York, New York (877) 810-4264

**Name of Product:** Fleece Sweatshirts (Ladies); Fail to meet the federal mandatory standards for fabric flammability

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

Long-sleeved, pullover, gray 90% cotton/10% polyester. Sewn-in label reads in part, “Route 66 Original Clothing”; 42,000 sold at K-mart stores nationwide from June 1999 through March 2000; Five-Y Clothing Inc., Miami, Florida (888) 343-4838

**Name of Product:** Front Suspension Bicycle Forks; Compression rods inside these forks can break, causing rider to lose control of the bicycle

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


**Name of Product:** Infant Car Seats/Carriers; When used as an infant carrier, the handle can break

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

All Century rear-facing infant car seats/carriers with one-piece handles manufactured from January 1991 through July 1997, molded, one-piece, one-color plastic handle colored white, gray, or tan; 4 million sold nationwide; Century Products (Century) Macedonia, Ohio (800) 865-1419 www.centuryproducts.com. Consumers can also call NHTSA's toll-free Auto Safety Hotline at (888) DASH-2-DOT (327-4236) or visit NHTSA's web site www.nhtsa.dot.gov. The NHTSA number to call in the Washington, DC area is (202) 366-0123

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Osteoporosis

An article published last September 26 in the Washington Post's Health Section provides a long-overdue examination of the issues surrounding osteoporosis in women. The diagnosis and treatment of this condition has evolved into a multi-billion-dollar industry based on a disease that was unknown to most people as recently as 15 years ago. It has led women (mainly, but men are the newly-added target) to get bone density scans and start taking drugs, which for most people are unnecessary and may even be harmful.

Because women are bombarded with scare stories and statistics produced by people with a vested interest in selling drugs, Sandra Boodman, the author of the Post article, has listed five myths along with the relevant facts to counter the misinformation.

Myth: "The more calcium, the better."  
Fact: "Calcium is necessary but not sufficient to protect bones. It's important to get the recommended daily intake at all ages, preferably from dietary sources as part of an overall approach to preventing osteoporosis and fractures. And it's important not to exceed recommended limits." (Amounts recommended by the National Academy of Sciences are 1300 mg (ages 9-18), 1000 mg (ages 19-50), and 1200 mg (ages 51 and older).)

Calcium intake is over-rated as a preventive of fractures. A Harvard School of Public Health researcher studied 70,000 American nurses and found that women with the highest calcium consumption from dairy products had more fractures than those who drank less milk. Furthermore, Asian women have lower fracture rates even though they derive little calcium from dairy products and are both small boned and thin (both accepted "risk factors" for osteoporosis).

Myth: "Getting a baseline bone density test at menopause is essential."  
Fact: "For most women, a bone density test at menopause is not useful because the majority of women under 65 have an insignificant risk of fracture. There is insufficient evidence that current bone density tests are a sufficiently reliable way to predict bone loss decades later."

The recent NIH panel and the U.S. Preventive Health Services Task Force (primary care physicians) decided against endorsing routine bone density screening for any age group because of questions about the test's accuracy and lack of evidence as to its usefulness.

The definition of osteoporosis for women depends on a comparison between one's current bone density and that of a healthy 35-year-old. The resultant "T-score" is the number of standard deviations (steps) below the 35-year-old norm, with a T-score of -2.5 qualifying as osteoporosis. However, it is possible that a particular woman always had a lower density than normal and hasn't changed much over time.

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<thead>
<tr>
<th>Name of Product/Problem</th>
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<tbody>
<tr>
<td><strong>Power Drills:</strong> Switches (manufactured by Eaton Corporation, Cleveland, Ohio) can stick. Tools can continue to operate after the trigger has been released, posing a risk of injury</td>
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<tr>
<td><strong>Power Mowers:</strong> Wiring on these mowers can short circuit, posing a fire hazard</td>
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<tr>
<td><strong>Toy Xylophones:</strong> Mallet sold with the toy xylophone can get lodged in the throats of young children, posing a choking hazard</td>
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Bosch-brand drills 1011VSR, 1012VSR, 1013VSR, 1014VSR, 1030VSR, 1031VSR, 1032VSR, 1033VSR, 1034VSR, 1035VSR.  
Makita-brand rotary hammers, drills and screwdrivers HR2410, HR2420, HP2040, HP1501K, 6407, 6408, 6408K, 6410, 6821.  
Milwaukee Electric Tool-brand band saws 6227, 6230, 6232-6, and 6234; 180,000 sold nationwide from January through September 2000.  
S-B Power Tool Co. Chicago, Illinois (800) 661-5398, Makita U.S.A. Inc. La Mirada, California (800) 462-5482, Milwaukee Electric Tool Corp. Brookfield, Wisconsin (800) 274-9804

Model 20045 Toro Key Start gasoline-powered, walk-behind mowers with a 21-inch cutting blade; 23,000 sold nationwide from February 1999 through September 2000; The Toro Co., Bloomington, Minnesota, (888) 877-8873

White, rectangular-shaped with green handle and multi-colored bars and displaying a yellow button shaped like the face of a cat; 113,000 sold at Dollar General stores nationwide from July 1998 through October 2000; Dollar General, Goodlettsville, Tennessee (800) 678-9258
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Furthermore, the relationship of bone mineral density to fracture is not clear: an analysis of 11 separate studies with more than 2,000 fractures concluded that bone mineral density “can predict fracture risk but cannot identify individuals who will have a fracture.” Bone mineral density is only one factor to be considered and may not be the most important one; bone quality—the internal architecture—and rate of bone loss are other important determinants.

Myth: “Half of white women over 50 will have a fracture in their lifetimes.”
Fact: “Lifetime risk numbers can be misleading because the risk of osteoporosis rises with age. For most women the chance of breaking a bone at 55 is remote, while the chance of a fracture at 85 is significant. Don’t let misleading lifetime risk numbers steer you into unnecessary treatment.”

According to Mark Helfand, director of the Evidence-Based Practice Center at Oregon Health Sciences University, “...if you live to be 90, there’s a high chance that when your mind goes you’ll fall down and break your hip.”

Myth: “Hip fracture equals nursing home equals death.”
Fact: It’s not the hip fracture that leads to death, it’s the fact that many women who are frail, demented or suffering from other serious health problems often fracture their hips. Women who get hip fractures and are relatively healthy rarely die from the fracture itself.

The National Osteoporosis Foundation likes to cite the statistic that 20 percent of women who break a hip will end up in a nursing home and be dead within a year. “That’s true, but at least half of them would have been dead within a year anyway,” according to Mayo Clinic epidemiologist L. Joseph Melton.

Myth: “Menopause is the most important cause of osteoporosis.”
Fact: “Menopause contributes to osteoporosis but is not the chief cause. For most women in their forties and fifties, drugs taken largely to prevent osteoporosis may carry more risks than benefits.”

The data from a definitive study of whether estrogen replacement actually prevents hip fractures will not be available for several years. Meanwhile, for those most concerned with fracture prevention, the advice of Dr. Susan Love, UCLA breast cancer surgeon, is to delay hormone replacement therapy (HRT) until 65 or 70 (to keep overall time on the drug low) so that one isn’t trading a fracture for breast cancer.

The new bone-building drugs have not only not been studied for longer than four years, but all have potentially serious side effects including esophageal ulcers and blood clots. A study published in October 1998 found that 12 percent of women (1 in 8) using alendronate (FOSAMAX) needed to receive medical attention for gastrointestinal effects; 14 percent of those required hospitalization.

Coupled with the risk of gastrointestinal adverse events is the minimally efficacious outcome with alendronate (FOSAMAX).

Examples

In women who already had a vertebral fracture: One would have to treat 37 women for three years to prevent one new vertebral fracture, i.e., 36 women would have to take the drug for three years with no benefit and with the risk of a gastrointestinal or other problem.

In women who had not had a fracture: One would have to treat 500 women for four years to prevent one hip fracture, i.e., 499 women would have to take FOSAMAX for four years with no benefit and only potential risks (plus the expense of the drug). They might, in fact, be at risk for both GI adverse events as well as a wrist or hip fracture, depending on their hip bone mineral density.

A National Institutes of Health (NIH) consensus panel that met last March emphasized exercise as a way to reduce risk. Exercise improves not only bone strength but cardiovascular fitness and mental health as well. Unless continued on page 8

| PM women with low bone mineral density and one or more vertebral fractures (treated for 3 years) |
|-----------------------------------------------|----------------|----------------|---------------|
| New vertebral fracture                       | 5.0%           | 2.3%           | -2.7%         | 37            |
| Hip fracture                                  | 2.2%           | 1.1%           | -1.1%         | 91            |
| Wrist fracture                                | 4.1%           | 2.2%           | -1.9%         | 53            |

| PM women with low bone mineral density and no previous fractures (treated for 4 years) |
|-----------------------------------------------|----------------|----------------|---------------|
| New vertebral fracture (All T scores)         | 4.3%           | 2.3%           | -2.0%         | 50            |
| Hip fracture (All T scores)                   | 1.1%           | 0.9%           | -0.2%         | 500           |
| Wrist fracture (All T scores)                 | 3.2%           | 3.7%           | +0.5%         | 200 (increased fracture rate) |
| Hip fracture (T score -1.6 to -2.5)           | 0.4%           | 0.8%           | +0.4%         | 250 (increased) |
| Wrist fracture (T score -1.6 to -2.0)         | 1.7%           | 3.3%           | +1.6%         | 63 (increased) |

PM: postmenopausal

T-score: the number of standard deviations (steps) below the average bone density of a 35-year-old woman; -2.5 qualifies, by definition, as osteoporosis but -2.0 does not.
A Better Quality Alternative
Single Payer National Health Reform

This article was published six years ago in the November 1994 issue of Health Letter. Unfortunately, with the growing number of uninsured—more than 40 million, it is just as vital today as it was then.

The following two statements were presented at a press conference announcing the publication of an article on quality improvement under a single payer national health insurance in the September 14, 1994 Journal of the American Medical Association.

Dr. Sidney Wolfe, Health Letter Editor and Director of Public Citizen's Health Research Group

The temporary collapse of all efforts to end one of our major national disgraces—the fact that for Americans, health care is not a right—is a proper time to look at the damage which has already been done to the quality of our health care system without any legislation to blame. The forces of greed—led by the health insurance industry—are fiercely pushing and shoving each other to grab as much as they can of the trillion dollar annual pot of health care gold. En route, they have already done much to destroy the doctor-patient relationship and worsen the quality of medical care.

The 10-point list of quality principles which the Physicians for a National Health Program (PNHP) study group is publishing clearly shows how a single payer plan, modeled on the Canadian system, will improve quality. This contrasts sharply with all of the other national health insurance proposals which, by virtue of strengthening the hand of the health insurance industry, will worsen quality even more than the not-so invisible hands of the market have already done.

The list of quality-improving principles is a blueprint for a national health program which would make our country a world leader instead of a shameful laggard. The implementation of this blueprint is inconsistent with the continued existence of the health insurance industry. The sooner we realize this, the better it will be not only for the 40 million who are uninsured but also for the other 210 million Americans whose health care quality has been dangerously eroded.

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one belongs to a family with a strong history of fractures, the best course appears to be to follow the usual advice for good health: get regular exercise, eat a healthy diet and avoid long-acting sedative-hypnotic agents, quit smoking, and treat impaired vision.

Conclusion

The use of these drugs should be sharply curtailed, limited to women clearly at very high risk of fractures: the rest of us should make an effort to follow a healthy lifestyle including regular exercise. We benefit both by building healthier bones and avoiding the possibility of suffering adverse events.

Physicians are taking courses for credit, courses that are taught by M.D.s financed by drug companies, the "lessons" being excerpts from company-sponsored lectures. The courses are available both on tapes that are mailed to physicians, and on the web. These propagandists espoused all the "myths" discussed in this article, scaring physicians and encouraging them to have their patients get bone density scans and, subsequently, start using drugs. The drug's benefits are exotiled and exaggerated while the likelihood of any adverse effects is not mentioned. Patients need to educate themselves to withstand this pressure.

Dr. Gordon Schiff, President of Physicians for a National Health Program, Senior Attending Physician at Cook County Hospital in Chicago and lead author of the article.

In the Congressional debate, "quality" has become a code word for maintaining the status quo in health care. We wrote this article to let the American people know what real quality would be in a health care system that took the patient and the patient's needs seriously.

As Dave Barry notes, commenting on the foolishness of the current Washington health reform debate, there are only two things that are agreed upon: 1) we have the best quality health care in the world; and 2) something must be done about it.

In fact, our health care system is plagued with a myriad of health care quality problems. Unfortunately what is being done about them is likely to worsen, not improve, health care quality.

America's health care system is being rapidly corporatized. Decisions previously made by physicians are now being made by corporate executives exclusively focused on the bottom line. Meanwhile quality problems smolder as Washington fiddles with incremental reforms that will only compound these problems rather than pursing the only approach likely to maintain and improve quality—a single payer universal financing system.

Over the past two years a task force which includes some of the nation's leading physician experts on health quality and access have been delineating key criterion for improving quality via health system reform. The Physicians for a National Health Program Quality of Care Working Group report which appeared in the September 14, 1994 issue of the Journal of the American Medical Association (JAMA) outlines 10 key principles that are needed to truly bring "highest quality" care to the people of the U.S.

The first criteria for quality must be
uncompromising support for universal access. What is the quality for the more than 10,000 uninsured patients on a waiting list to the clinic I direct, the General Medicine Clinic at Cook County Hospital? What is the quality of care for a diabetic patient we recently sent home from our hospital who had a leg amputated and a deep bed sore, for whom we could not provide home health or rehabilitation services because she was uninsured.

Multiple studies demonstrate how the quality of uninsured patients, even those who do receive health care suffers. An even larger number of people, who are insured, now report access problems, such as limitations on benefits and financial barriers, increasingly obstruct their care. Only the single payer plan provides for universal coverage in this century. It is the only Congressional plan that does not use financial barriers, such as co-pays and deductibles, to deter care and shift costs to the patients. Cost barriers, as a Rand Health Insurance Study has shown, deter necessary care just as often as care that is less needed.

While the reform debate focuses almost exclusively on how many people Congress will “write off,” Congress compromised on universality, compromised quality and the best route for quality improvement has been largely ignored.

The second quality principle: the need for a fair and unified system, where medical interventions are determined not on ability to pay, as is the case in our current system, but on medical necessity. We reject the notion that different people are entitled to different standards of quality. The highest quality health care system can only be achieved when rich and poor alike are guaranteed the same kind of care. The high standards of quality care can only be achieved when rich and poor alike are guaranteed the same kind of care.

The third, critical, and rapidly eroding, feature for quality health care is the continuity of care coupled with the ability of patients to freely choose their own providers. The days when physicians and hospitals attracted patients based on the quality of the care rendered, are over. Patients are assigned to a restricted panel of physicians in health plans selected by their employers who may change their insurance with little or no notice. Both patients and physicians face steep financial penalties if they seek to continue ongoing quality care relationships. Amazingly, even though this quality-imparing restrictiveness on patient choice is justified as a cost saving measure, in Canada where health costs are 40 percent less than the U.S., patients face no such restrictions. Others of the 10 key quality principles include:

Financial neutrality of medical decisionmaking: combining the uncertainties which pervade clinical medicine with financial inducements to order more, as under fee for service, or less as in various managed care arrangements, is a prescription for distorted judgment and suboptimal quality. It is difficult enough to decide whether a patient with metastatic breast cancer should be advised to undergo bone marrow transplantation. It is impossible to offer unbiased advice when the health plan offers thousands of dollars of bonus incentives for each such procedure denied as was the case in an $89 million lawsuit recently awarded in California. Co-author Dr. Andrew Bindman, Director of Primary Care Research at the University of California, points to a recent example where managed care physicians were threatened with $250 penalties each time they referred a patient to an out-of-network doctor. Financial neutrality is essential to preserve the physicians’ role as the patient’s advocate.

Automating clinical information: to both improve care efficiency, protect confidentiality and create a unified database to improve care. Every day we, at Cook County, see dozens of patients with problems such as abnormal lab test results, or patients with wounds but don’t know when they last had a tetanus immunization. Without a clinical database, it is often impossible to know details of past history and to practice optimal medicine.

Meanwhile, the public is spending hundreds of millions of dollars so that each managed care system and hospital develops and installs their own systems—systems whose unstandardized “proprietary data” cannot be communicated with each other. The data thus is unavailable to contribute to medical knowledge or improve patient care, bearing out the Institute of Medicine’s prediction of disastrous results if a standardized approach is not taken. Single payer equals a single unified database.

Enhanced public accountability: the 6,000 physicians in PNHP believe medicine needs more, not less accountability. There are really two malpractice crises in our country. We only hear about one from Congress—the one doctors face with malpractice suits. But the important malpractice crisis is the one the patients face and calls for increased public accountability. Prevention of malpractice is a far greater priority than protecting physicians addressing the causes and consequences of failed bad medicine. The narrow emphasis on antagonistic “all or none” approaches such as lawsuits or exiting one plan for another, constrains consumers from maximally exercising choices, sharing in decisionmaking and being genuinely involved in oversight and helping to prevent malpractice.

Health care will not be reformed by measures that fail to address the quality-imparing features of our current system. In each of our 10 critical measures a single payer approach moves us towards a higher quality system, whereas other approaches forfeit important opportunities to improve care. Congress started out with a lofty ideal, to reform and make America’s health system function better for everyone. But they have lost sight of this goal.

The massive show of public support, evidenced for example by the unprecedented volunteer-collected one million petition signatures for the California single payer referendum (Prop. 186) shows that rather than single payer being irrelevant to the reform debate, the debate is increasingly irrelevant to the public’s desires and needs. Single payer means much more than a particular financing structure—it is an expression of a commitment to access, fairness, efficiency, and we can now add, quality.
Medical Fluoroscopy: Radiation-induced Skin Injury

The following article was reprinted from the November 1994 issue of the Health Letter.

Today, most Americans would probably assume that risk of exposure to dangerous levels of x-rays in a hospital or doctor's office is too low to worry about. After all, the hazards associated with use of x-rays have been known by the medical community and the general public for decades. Increased mortality from leukemia and multiple myeloma (two forms of cancer) was reported by radiologists during the early years of use of medical x-ray equipment, and increased rates of thyroid cancer and leukemia have been reported in children treated with x-rays in the 1940s and 1950s for tinea capitis (ringworm of the scalp) and presumed thymus enlargement.

Complacent Americans may be wrong in downplaying the risks. According to Dr. Bruce Burlington, director of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health, his agency has received reports of occasional serious radiation-induced skin injuries to patients resulting from prolonged, fluoroscopically-guided invasive procedures. Fluoroscopy is an increasingly common procedure which uses x-rays in order to provide the doctor with a dynamic, or moving, visualization, rather than a snapshot. It is often performed by medical specialists who are not radiologists, and these doctors—such as cardiologists and gastroenterologists—may not be sufficiently aware of the radiation risks. Fluoroscopic procedures include radiofrequency cardiac catheter ablation and percutaneous transluminal angioplasty (PTCA), among others.

During a meeting of the National Electrical Manufacturers Association, Dr. Burlington stated that his agency has "become aware of significant problems, problems that we thought had been solved a couple decades ago with fluoroscopy standards, exposure standards, [and] limitations on time." He indicated that new and increasingly popular fluoroscopic procedures are requiring "long on-times" and "high image intensity with high radiation."

Some of the injuries reported to the FDA include inflammation of the skin, temporary and permanent hair loss, dry and moist desquamation (peeling of the skin), invasive fibrosis (formation of fibrous tissue), dermal atrophy (skin degeneration), telangiectasia (dilation of capillaries), dermal necrosis (irreversible skin damage), and secondary ulceration (lesions likely due to infection).

Furthermore, an assessment of whether or not an injury has occurred is complicated by the fact that effects are not immediately apparent. In fact, effects can take weeks to appear, which makes possible a dangerous doctor-patient combination: a caregiver who is unaware of the potential risks from prolonged exposure and a patient who, when eventual skin breakdown occurs, does not realize that there is a cause-and-effect relationship. To deal with this situation, the FDA has sent a letter to 11 medical specialty associations, and has prepared a public health advisory to send to risk managers and heads of radiology and cardiology departments in every U.S. hospital, addressing ways to prevent radiation-induced skin injuries. Five steps are recommended, with specific associated actions to be taken by the facility to avoid injuries without adversely affecting the clinical objectives of the procedure. The advisory states that "procedures of the type described here may also increase the risk for late effects such as radiation-induced cancers in other tissues and organs."

We applaud the agency's recognition of the problem, and the actions it is taking. However, you, the patient, must be diligent as well.

What You Can Do
- If you undergo any of the procedures listed in the accompanying box, tell your doctor beforehand of your concern about possible skin injury, especially if you are elderly or diabetic.
- Tell your doctor to chart information in your medical record, such as exposure time and radiation dose rate, which will allow for an estimation of the dose your skin absorbed during the procedure.
- If you notice any redness, inflammation or other indications of radiation-induced skin injury at the site of a prior fluoroscopic procedure, notify your doctor immediately.
- If you do sustain a skin injury after a fluoroscopic procedure, notify the FDA by phone at 1-800-FDA-1088.

<table>
<thead>
<tr>
<th>Procedures Typically Involving Extended Fluoroscopic Exposure Time</th>
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<tbody>
<tr>
<td>• Vascular embolization</td>
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<tr>
<td>• Endoscopic retrograde cholangiopancreatography</td>
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<tr>
<td>• Percutaneous nephrostomy, biliary drainage or urinary/ biliary stone removal</td>
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<tr>
<td>• Radiofrequency cardiac catheter ablation</td>
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<td>• Percutaneous transluminal angioplasty (coronary and other vessels)</td>
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<td>• Stent and filter placement</td>
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<td>• Thrombolytic and fibrinolytic procedures</td>
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<td>• Percutaneous transhepatic cholangiography</td>
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<tr>
<td>• Transjugular intrahepatic portosystemic shunt</td>
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(These procedures are related to problems with the heart, blood vessels, bladder, gallbladder and liver; your doctor can supply plain-English explanations of each.)
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Academic medicine was immediate. The corporate conglomerates running managed care companies had their eyes fixed resolutely on the bottom line and had no desire to subsidize medical education, even though well-trained physicians are essential to the delivery of quality medical care. This profit-only orientation combined with the forces preceding the advent of managed care to create an environment hostile to medical education: sicker patients admitted for shorter conferences. As Relman so aptly puts it: “A market-driven, price-competitive health care system has no incentive to support a common social good.”

Strapped for funds, academic medicine has turned to a source whose resources are rather less limited: multibillion-dollar pharmaceutical companies. Increasingly, medical research is funded by private industry, rather than the federal government, although important breakthroughs continue to emanate disproportionately from research conducted by the government or with federal funding. Drug companies often contract directly with universities to conduct research, an arrangement prone to conflict of interest as recent examples of drug company-squelched research attest.

But the effects of the increasing drug company presence in the halls of academe reach beyond the research arena into medical education itself. Here’s Relman again: “Sales representatives are now welcome at most teaching hospitals. They attend and support educational conferences, are present in the operating rooms to advise on the use of their companies’ new surgical devices, and they lavish free meals, free trips to medical meetings and all kinds of professional gifts on residents, students and staff in exchange for the opportunity to hawk their wares.”

A recent Public Citizen’s Health Research Group study is the first to systematically examine the growing phenomenon of Medical Education Services Suppliers (MESSs), private companies that assure educators that their intent is educational while seeking to modify physician prescribing behavior to favor a drug company’s product. As one MESS declared brazenly on its website, “Medical education is a powerful tool that can deliver your message to key audiences, and get those audiences to take action that benefits your product.”

The report, Medical Education Services Suppliers: A Threat to Physician Education (available at http://www.citizen.org/hrg/PUBLICATIONS/1530report.htm) demonstrates the extent and diversity of drug company involvement in medical education, at times without the knowledge of the educated. Based on only the one-third of MESSs surveyed who provided financial data, we calculated that the MESS industry had a 1999 income of $643 million. Of this sum, $289 million (45 percent) was earned through providing grand rounds ($115 million), symposia ($114 million) and publications-related activities ($60 million). An average of 76 percent of MESS clients were pharmaceutical companies.

Medical education is too important to be left to companies who stand to benefit from pseudo-educational activities that have more to do with marketing than education. The only practical solution that will preserve objective, evidence-based residency training is a prohibition on MESSs and pharmaceutical companies providing any “educational” activities whatsoever for resident physicians. This would require a ban on drug company or MESS-sponsored grand rounds presentations, noon conferences, and dinner meetings, as well as forbidding the distribution of textbooks, handbooks, pocket guides, reprints or any other publications by drug companies or MESSs to residents.
America's Ailing Medical Education System

Can medical education survive the onslaught of market medicine? This is the critical question raised by Kenneth M. Ludmerer in his book *Time to Heal: American Medical Education from the Turn of the Century to the Managed Care Era*, reviewed in a recent issue of *The New Republic* by Arnold Reiman, former editor in chief of *The New England Journal of Medicine*.

The book and Reiman's review, upon which this article is based, trace the development of the current medical education system. In the nineteenth century, medicine was primarily learned through an apprenticeship system, in which physicians-in-training accompanied practicing physicians while they worked. This was supplanted in the twentieth century by a system in which medical education became centralized in university-affiliated teaching hospitals. For the first time, carefully supervised residency programs in teaching hospitals, operating under standards created by national accrediting organizations, came to dominate medical education. Teaching was seen as an intrinsic part of the mission of these hospitals; strong educational and research programs were believed to lead to better quality medical care.

This system flourished, graduating more physicians, conducting more research and putting medicine more squarely on a scientific footing. But the system was based on a foundation that could not be sustained: because the medical schools were never able to fully cover the costs of medical education, they drew funds instead from federal research and training grants and from public and private reimbursements for clinical care. In the 1970s, federal policies on research grants became more restrictive, precluding their use for clinical teaching, and in the 1980s, the advent of more restrictive Medicare payment policies further limited funds available for medical education.

Academic medicine acted as if there was no noose around its neck, let alone one threatening to asphyxiate it. In 1984, Reiman warned that these fly-by-night funding arrangements would not continue. He called instead for increased public funding for medical education, to be justified by a renewed commitment by the schools to addressing the manifold health problems in the United States. Social commitment would be linked to social funding, he argued. His call went unheeded.

Enter managed care. The effect on continued on page 11