

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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Health Care: Beyond Markets

The following article by George Silver appeared in the November 11, 2004 issue of the Washington Post.

As the United States moves into the 21st century, nowhere are the long-term adverse consequences of its political choices during the previous century more in evidence than in health care. Today's dysfunctional health care system is a palpable example of the lessons that come from our national obsession with markets at all costs. In the face of explosive evidence regarding the toll our choices have taken on our ability to protect citizens from the cost of illness and promote the well-being of our most vulnerable populations, our political leaders cling to them. Americans deserve better. During more than 60 years of work in public health and health policy, I have reached some conclusions about how to achieve meaningful forward movement in our seemingly unending national health reform struggle.

Health care reform is hardly the first issue over which the federal government has confronted the need to introduce a level of discipline and control over the private market to protect the public's health and meet our desire for stability and reliability. Government has faced similar challenges in the areas of banking, industrial safety and transportation. Surely health care is as important to

society.

Today's approach to health insurance is a peculiar holdover from an earlier time, when medical care was far less valued and much less costly. As modern society moved to control and reduce more pressing public health risks, and as medical science and technology made almost inconceivable leaps, medicine's relative social worth skyrocketed. To spur the growth of the nation's modern medical industrial complex, Congress made a series of Faustian bargains, first through the guarantee of lucrative tax breaks and the promise of an unregulated market in the case of health insurers and, later, with the adoption of legal architecture in Medicare that was guaranteed to provide high profitability for hospitals and physicians. In 2003 this architecture of profitability was taken to new extremes through the

distressingly named Medicare Modernization Act, which prohibits the government from negotiating the price of covered prescription drugs.

This approach has produced a system in which Americans face a one-in-six chance of exclusion from insurance coverage. It is a system that rests on an increasingly shaky foundation of voluntary employer and individual contributions, along with tax breaks skewed to the wealthiest members of society. The most vulnerable have Medicaid, but an equally large number — overwhelmingly workers with modest incomes — get no help other than at health centers, health agencies and public hospitals struggling against terrible odds to provide basic care.

This approach has also produced a supplier market like no other. The private forces that underwrite, organ-

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ize and deliver care consist of a number of colossal private health insurers, as well as consolidated and entrepreneurial health care companies providing everything from specialty physician and laboratory services to nursing home care. These industrial giants, many of them publicly traded, have been enticed to the table by the promise of large profits and guarantees of total federal immunity from efforts to regulate their practices and businesses.

Our health care costs are astronomical compared with those of other nations. Our population health indicators rank poorly among industrialized democracies. And the cost of care means that our people get less of what they need. Millions go without coverage, and Medicare and Medicaid stagger under the weight of the system. Preventive investments are almost nonexistent.

The failed effort at national health care reform under President Bill Clinton taught us how difficult it is to try to address the crisis through a single federal approach. For this reason, I believe that the most important step we can take is enactment of legislation to give state leaders the resources and legal tools they need to begin addressing the crisis. Our

nation has relied on state innovation before: Social Security Old Age Benefits grew out of a 1911 Missouri pension program for widows, and federal labor laws evolved from state efforts to demand basic accountability of the market. Other nations have also followed this incremental route. The modern Canadian health system is an outgrowth of a Saskatchewan experiment to ensure health care for everyone.

From a historical standpoint, it's understandable that a large and heterogeneous country such as the United States — with a population 10 times as large as Canada's — should move cautiously into a national program. This nation has considerable variations in underlying health care costs and customs that must be allowed to evolve over time. Population demographics vary enormously. Furthermore, pluralism is an important characteristic of the American political scene. We may ultimately decide to go the Canadian way, but it will only be after clear-cut decision making based on public awareness of all the facts, benefits and deficiencies of various approaches.

Congress could take steps to restore the state capability for innovation and initiative through a program that appropriates funds and

asks for a few basic things in return: (1) universal coverage, (2) a single source of payment, (3) global budgeting, (4) quality-control measures and (5) guarantee of service. These ground rules, along with the power on the part of states to overcome federal preemption of their authority to meet these goals, would go far, in my view, toward giving us the models we need to move forward as a nation.

Taking this path will require concessions from all sides: professionals, patients and politicians. And it will require forsaking "sacred principles" on all sides. Wilbur Cohen, the onetime secretary of health, education and welfare, and a consummate politician, had an amusing and insightful response to arguments of procedure "on principle." He would say, "Sometimes we have to give up our principles and do what's right." ■

The writer is professor emeritus of public health at the Yale University School of Medicine. He was a deputy assistant secretary for health in the Johnson administration. Dr. Silver has written many articles for Health Letter in the past.

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Product Recalls

November 15—December 15, 2004

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. A Class I recall is a situation in which there is a probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is www.fda.gov.

DRUGS AND DIETARY SUPPLEMENTS *cont.*

<i>Name of Drug or Supplement; Class of Recall; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
Amnesteem (Isotretinoin), 40 mg capsules, packaged in 3 x 10 count blister packs within cardboard display box, Rx only, Class III. Dissolution Failure.	Lot No. RP044731P; Exp. 11/04; 19,280 boxes distributed nationwide; Bertek Pharm; Greenboro, NC
Ciprofloxacin Ophthalmic Solution USP 0.3%, Each ml contains 3.5 mg ciprofloxacin hydrochloride equivalent to ciprofloxacin base 3 mg, 10 mL plastic dropper bottles, Sterile, Rx only, For Topical Ophthalmic Use Only, Class II. Presence of Particulate Matter (stability).	Numerous lots. 142,459 bottles distributed nationwide; Bausch & Lomb, Inc., Tampa, FL
a) Lotrimin AF Antifungal (Clotrimazole cream 1%), 12 g tubes. Recall # D-055-5; b) Lotrimin AF Antifungal Jock Itch, (Clotrimazole cream 1%), 12g tubes. Recall # D-056-5; c) Clotrimazole Cream, USP, 1%, 15g and 30g tubes, Rx only; Class III. Impurities. Degradation Products	a) Lot No. 2-KPE-402, Exp. 02-05; b) Lot No. 2-KPE-102; Exp. 03-05; c) Lot Nos. 2-KPE-203, 2-KPE-401; Exp. 01-05; 463,356 tubes distributed nationwide; Schering Plough Corp.; Kenilworth, NJ
Premarin (conjugated estrogen tablets USP), 0.625 mg, 1,000 tablet bottles, Rx.; Class III. Dissolution failures (stability).	Lot no. A48207; Exp. 9/05; 15,230 bottles distributed in AR, VA and TN; Richmond Division of Wyeth Pharmaceuticals; Richmond, VA.
Xopenex (levalbuterol HCl) Inhalation Solution Concentrate, 1.25 mg/0.5 mL, 30 Sterile Unit Dose Vials, Dilution required, For Oral Inhalation Only, Rx only; Class III. Good Manufacturing Practice (GMP) deviation (process validation).	Lot nos. S4F162, S4F163, S4F164, S4F165, S4F166, S4G005, S4G006, S4G007, and S4G008, 669,000 vials distributed nationwide; Spracor, Inc.; Marlborough, MA

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs: Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call (800) FDA-1088. The FDA web site is www.fda.gov.

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M E D I C A L D E V I C E S *cont.*

Name of Device; Class of Recall; Problem

Oral-B CrossAction Power Toothbrush: Battery Operated and Rechargeable; and Oral-B CrossAction Power Brushhead Refills, Class II. Brushhead may unlatch from the power handle.

Lot #: Quantity and Distribution; Manufacturer

Numerous Lots; 22,304 million distributed nationwide; Gillette Research Institute; Needham, MA

C O N S U M E R P R O D U C T S

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is www.cpsc.gov.

Name of Product; Problem

AC Power Adapters. The adapters can overheat, posing a fire hazard to consumers.

Lot #: Quantity and Distribution; Manufacturer

AC Power Adapters for Psion Teklogix Notebook Computers; 682 sold nationwide between December 2003 and October 2004; Psion Teklogix Corp., a subsidiary of Psion Teklogix Inc., of Ontario, Canada; (800) 387-8898; www.psionteklogix.com

ATVs. ATVs were assembled with an incorrectly sized mounting bolt under the fuel tank. This could result in fuel leakage presenting a fire safety hazard and risk of injury or death.

2004-2005 Eiger and Vinson ATVs; about 27,000 sold by Suzuki motorcycle/ATV dealers from August 2, 2003 to August 26, 2004; American Suzuki Motor Corp.; Brea, CA; (800) 444-5077; www.suzukicycles.com

Basketball Hoops. The bolt attaching the arm to the vertical post can break, causing the backboard to fall and injure someone standing below.

First Team Attack, Force and Titan Basketball Hoops; about 7,600 sold nationwide from January 1996 through August 2004; First Team Inc.; Hutchinson, KS; (800) 649-3688

Children's Corduroy Overalls. The buttons on the front and side panels of the overalls can detach from the garment, posing a choking hazard to young children.

Children's Corduroy Overalls style number 27267; about 1,900 sold exclusively through Hanna Andersson's catalog and Web site from July 12, 2004 through October 15, 2004; Hanna Andersson; Portland, OR; (800) 222-0544

Children's Pajama Sets. The heat-sealed patches on the front of the garment can detach, posing a possible choking hazard to young children.

Okie Dokie Alligator Football Pajama Set; about 41,300 sold at J.C. Penney stores nationwide from June 2004 through September 2004; J.C. Penney Corporation; Plano, Texas; (888) 333-6063; www.jcpenney.com

Children's Snow Suits and Jackets. These snow suits and jackets have decorative compasses and corded zipper pull tags that can come off, posing a choking hazard to young children.

Falls-Creek(r). Children's Snow Suits and Jackets; about 14,400 sold to stores in Michigan, Ohio, Indiana, Kentucky and Illinois from August 2004 to October 2004; Meijer Distribution Inc., Grand Rapids, MI; (866) 280-8419; www.meijer.com

Cordless Electric Lawnmowers. In units containing the defective switch, when the handlebar is released, the motor continues to run which causes the blade to continue to spin. When this occurs, the potential for personal injury or property damage exists.

2004 Model Neuton Cordless Electric Lawnmowers; 25,000 sold nationwide from March 15, 2004 through November 12, 2004; Country Home Products, Inc., Vergennes, VT; (877) 405-7462; www.chp.com

Electric Heaters. Fire hazard if an electrical failure leads to overheating and melting of plastic parts.

Lakewood MPH-25 fan-forced mini-personal electric heater; about 18,000 sold nationwide from August 2001 through November 2004; Lakewood Engineering & Manufacturing Company; Chicago, IL; (888) 858-3506

Name of Product; Problem

Electric Pictures. These pictures have inadequate construction, incorrect wiring, and use flammable materials, all of which pose fire and electric shock hazards to consumers.

Fitness Machines. The seat pin on the Power Pro with "Lat Tower" and Ultimate models can break or become disengaged, allowing the seat to move suddenly. Also, the incline support bracket on the Power Pro without a "Lat Tower" can break, allowing the incline bench to move suddenly. Both hazards pose a fall risk to the user.

Fluorescent Light Bulbs. The bulbs can overheat and spark, posing a burn hazard to consumers.

Garden Carts. Over-inflation of the tires can break the metal tire rim, causing users and bystanders to be struck with pieces of metal.

Gas Cooktops. The recalled cooktops have switches located too close to the gas tubing leading to the grill burner. Electrical arcing can cause the tubing to leak gas and ignite, resulting in a fire hazard to consumers.

Gas Furnaces. These furnaces can overheat, causing heat-exchanger cracking, burn-through and, in extreme cases, furnace wrapper burn-through. This can lead to heating and possible burning of the drywall and other combustibles adjacent to the furnace, which poses a fire and smoke hazard to consumers.

Girls' Hooded Sweaters. Hooded sweaters have drawstrings, posing a strangulation hazard to children.

Lawn Tractors. These lawn tractors can develop abrasions on the fuel tank because of the fuel line clamp's location. This can result in a fuel tank leak, which could pose a fire hazard to consumers.

Off-Highway Motorcycles. On some units, the rear shock absorber may have been assembled with an incorrect o-ring, allowing fluid to leak from the shock. Fluid loss from the shock absorber can compromise the shock's damping characteristics, which can render the motorcycle unstable creating a potential for an injury or death.

Off-Road Motorcycles. The rear shock absorber may have been assembled with an incorrect o-ring, allowing fluid to leak from the shock absorber. Fluid loss from the shock absorber can compromise the shock's damping characteristics, which can render the motorcycle unstable creating a potential for injury or death.

Lot #: Quantity and Distribution; Manufacturer

Framed electric pictures that utilize electric lights and sound and feature moving background scenes, including waterfalls, snow, beach scenes, city skylines, and religious figures; 55,600 sold nationwide from October 2001 through April 2004; Chicago Imports Inc.; Chicago, IL; (800) 656-0000

Bowflex Power Pro and Bowflex Ultimate Fitness Machines; 680,000 Power Pro units and 102,000 Ultimate units sold nationwide from January 1995 through April 2004; The Nautilus Group; Vancouver, WA; (800) 820-8604; www.bowflex.com

Commercial Electric and DuraBright 3-way compact fluorescent light bulbs; about 158,000 sold nationwide from April 2004 through November 2004; Technical Consumer Products Inc.; Aurora, OH; (800) 397-2647

GardenPlus Industrial Garden Carts, item number 128483; 196,788 sold at Lowe's retail establishments nationwide from March 2003 through October 2004; LG Sourcing, Inc.; North Wilkesboro, NC; Lowe's Home Centers, Inc., North Wilkesboro, NC; and Lowe's HIW, Inc. of Washington, DC; (800) 444-6742; www.lowes.com

Jenn-Air Downdraft Gas Cooktops; about 1,170 sold nationwide from January 2004 through September 2004; Maytag Corp.; Newton, IA; (888) 330-3810; www.maytag.com

Coleman, Coleman Evcon and Red T brand furnaces; about 226,000 sold nationwide between 1995 and 2000; The Unitary Products Group (UPG) of York International Corp.; York, PA; (888) 665-4640; www.dgatprogram.com

Energie Brand Hooded Sweaters; about 157,300 sold nationwide from July 2004 through November 2004; Norton McNaughton; Squire, Inc., New York, NY; (800) 258-5663; www.nortonmcnaughton.com

Husqvarna Lawn Tractors models LTH18542A and LTH18542B; 5,280 sold nationwide from November 2003 through July 2004; Electrolux Home Products Inc.; Orangeburg, SC; (800) 448-7543; www.usa.husqvarna.com

2005 Kawasaki model KLX110-A4 off-highway motorcycles; about 1,500 sold from July 2004 to present; Kawasaki Motors Enterprise (Thailand) Co., Ltd. of Thailand; (866) 802-9381; www.kawasaki.com

Suzuki 2005 model year DR-Z110K5 Off-Road Motorcycles; about 1,500 sold nationwide between July 2004 and early November 2004; Kawasaki Motors Enterprise (Thailand) Co., Ltd. Of Thailand; (800) 444-5077; www.suzukicycles.com

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Name of Product; Problem

Riding Lawn Mowers. Due to the location of the fuel line on the Lazer Z EFI riding mowers a hole can develop resulting in a fuel leak that could present a fire hazard.

Riding Lawn Tractors. Fuel can leak out of the carburetor, posing a risk of fire and burn injuries.

Riding Mowers. The fuel tanks can crack and leak fuel presenting a potential for fire or burn injuries.

Sandals. The sole of the sandal can become slippery, causing the consumer to fall and receive bodily injury.

SCUBA manifolds. Undersized o-rings installed on the cross bar can cause a loss of breathing air from the SCUBA cylinder, presenting a risk of drowning.

Snowmobiles. The fuel connections between the fuel line and the fuel pump and fuel filter can leak. Failure of the fuel connection can result in leaking fuel and a possible fire, which can result in severe injury or death. In addition, the drive shaft may have been incorrectly heat treated resulting in brittle drive shafts that could fail at lower loads than the shafts were originally designed to meet.

Stools. The legs of the stool can bend and the stools may collapse when used on smooth hard floor surfaces.

Table Saws. The blade drive mechanism may loosen or the motor can separate from the tool. Loosening of the blade drive mechanism can result in kickback of the item being sawed, resulting in possible laceration. Motor unit separation can cause the coasting saw blade to damage the saw wiring resulting in possible electric shock, or the separated motor could strike the user and cause injury.

Table Soccer Games. The lighting structures may spark if the tube lights are not properly installed, posing a fire hazard.

Utility Vehicles. The front hood of the RTV900 utility vehicle can come off during operation, striking the driver or passenger and causing serious personal injury.

Vacuum Cleaners. In some cases, when the vacuum cleaner is left in the "on" position, the rotor can lock up and cause the unit to over-heat. This poses a smoke and fire hazard.

Lot #: Quantity and Distribution; Manufacturer

Lazer Z EFI Zero Turn Radius Riding Lawn Mowers; 1,215 sold nationwide from July 2003 to September 2004; Exmark Manufacturing; Beatrice, Nebraska; (800) 479-8379; www.Exmark.com

Scag Tiger Cub Riding Lawn Tractors; about 16,000 sold nationwide from November 1999 through July 2003; Scag Power Equipment; Mayville, WI; (866) 821-9208

John Deere GX85 and SX85 Riding Lawn Mowers; about 4,400 sold at Authorized John Deere dealers in the United States and Canada from November 2003 through July 2003; Deere & Company; Moline, IL; (800) 537-8233

Mossimo Beaded Sandals; 1.2 million sold at Target Stores nationwide from January 2004 through August 2004; Target Corporation, Minneapolis, MN; (800) 821-8684; www.target.com

Rotating Cross Bar SCUBA Manifold; about 140 sold at dive stores nationwide from December 2003 through September 2004; Ocean Management Systems, Inc.; Middletown, NY; (845) 692-3600; kim@omsdive.com

Polaris "900 Fusion" and "900 RMK 151" snowmobiles; about 2,850 sold nationwide from June 30, 2004 to October 7, 2004; Polaris Industries, Inc.; Medina, MN; (800) 765-2747; www.polarisindustries.com

The TriLite Stool; about 7,800 shipped between February 19, 2004 and June 16, 2004; The Byer Manufacturing Company; Orono, ME; (800) 338-0580; www.byerofmaine.com/recall.pdf

Skil(r) Table Saw Model 3400; 120,000 sold nationwide from July 2002 through October 2004; Robert Bosch Tool Corporation; Mount Prospect, IL; (800) 351-5788; www.skil.com

Classic Sport Underlit Table Soccer game, models X0725, X0743 and X0761; about 1,470 sold nationwide between August 2004 and October 2004; Classic Sport Companies, Inc., Broomfield, CO; (800) 225-5712; www.classicsport.com

Kubota RTV900 Utility Vehicle; about 16,000 sold nationwide from January 2004 through October 2004; Kubota Tractor Corporation; Torrance, CA; (888) 458-2682, Ext. 990; www.kubota.com

Sweep+Vac by Swiffer Vacuum Cleaner; about 175,000 sold nationwide from September 2004 through November 2004; Procter & Gamble Company (P&G); Cincinnati, OH; (800) 487-5915; www.swiffersweepandvac.com

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(through 10/04)

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- AARP: V5#6,7;V7#6,8;V8#1,3,4,8;V9#2,5,12;V10#2,9;V20#2
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B

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 - Breakthroughs, Medical: *see Medical Breakthroughs*
 - Breast Cancer: V1#3;V3#6;V7#6;V10#8;V16#3 (and HRT) 10 (and Health Food Store Recommendations) V17#7 (and HRT);V18#1;V20#1 (and mammography) *see also DES, Silicone Gel Implants, Tamoxifen*
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health care system. Among older Americans, falls are the leading cause of hospital admissions for trauma. Nearly 40% of all nursing home admissions are in some way related to falls. A study of people aged 72 and older found that the average cost of a fall injury (not including physician services) was \$19,440. The total cost for all fall injuries in older Americans was \$27.3 billion in 1994, and is expected to reach \$43.8 billion by 2020.

This case-control study, published by researchers at the CDC, Group Health Cooperative, and the University of Washington in the September 2004 issue of *Journal of the American Geriatrics Society*, monitored 1,371 adults, aged 65 and older, over a two-year period. 327 fall cases were compared with 327 controls. Wearing athletic or canvas shoes was consistently associated with lowest risk of falling, whereas going shoeless was associated with highest risk. Wearing shoe styles other than athletic/canvas shoes was associated with more

modest, but significantly, elevated risk of falling (30% to 50% increased risk relative to athletic/canvas shoes). These associations held up across several multivariate analyses that controlled for age, sex, gait abnormality, grip strength, and activity. Another analysis of the same study by the same authors found that shoe characteristics associated with a greater risk of falls included greater heel height and smaller shoe contact area (compared with the size of the foot).

We look to your leadership now to

Attention Seniors:

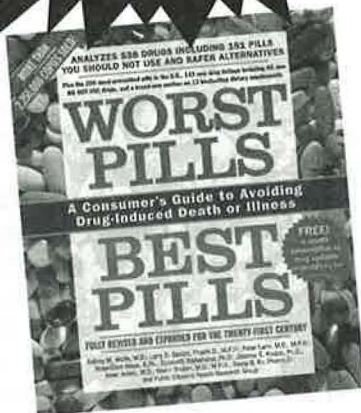
Falls are the leading cause of both nonfatal and fatal injury in older Americans. A recent study has shown that not wearing shoes dramatically INCREASES risk of falls. Persons wearing athletic or canvas shoes have up to an 11 times LOWER risk of falling than those not wearing shoes. Protect yourself from serious injury and potentially devastating medical bills by:

- Not walking barefoot or in stockings or slippers
- Wearing shoes both outdoors and in your home
- Wearing athletic or canvas shoes instead of high heels, sandals, boots, or other shoe styles
- Replacing old or ill-fitting shoes

ensure that elderly Americans are properly informed about this life-saving new information. When such a simple act as putting on a pair of sneakers can reduce the risk of a crippling or fatal injury by as much as 1100%, we have a duty to our elderly population to make these findings common knowledge.

Sincerely,

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HHS Fails to Warn about Preventing Falls in Older Adults

The following letter was recently sent by the Public Citizen's Health Research Group to Health and Human Services (HHS) Secretary Tommy Thompson.

Dear Secretary Thompson,

An important study of urgent importance to America's seniors was recently published on the effect of footwear on the risk of falls in older adults. The study found that people not wearing shoes (i.e. barefoot or in stockings) had an 8- to 11-fold greater risk of falling than those wearing athletic or canvas shoes. This study was funded by two parts of HHS, the National Institute on Aging and the Centers for Disease

Control and Prevention. Although the public health implications of this study are enormous and they demand high-level attention by HHS, we are not aware that that you or the Surgeon General have issued any alert despite the fact that this study was published almost four months ago.

We strongly urge you to immediately warn senior citizens about this highly preventable increased risk of falls. A warning, similar to that enclosed, should be included along with the Social Security checks mailed out to over 47 million seniors. In addition, an announcement from yourself and Surgeon General Carmona will emphasize the importance of this crucial safety message to everyone in this country.

As you know, falls are the leading cause of nonfatal and fatal injury in older Americans. More than 11,000 Americans aged 65 and older die from fall-related injuries each year, and that number is steadily rising as our population ages. One in three Americans over the age of 65 falls each year, and 20% to 30% of those who fall suffer serious injury such as hip fractures or head traumas, severely affecting quality of life and risk of premature death. 250,000 elderly Americans suffer hip-fractures every year, 87% of which are due to falls. Falls also diminish mobility and quality of life due to fears of falling again.

Beyond the devastating impact on the individual, falls are costly to our

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