

Health Letter

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"Neglected to Death": The Scandalous Condition of American Nursing Homes

About This Article

The basic material in this article was adapted from a series entitled "Neglected to Death," which ran in the St. Louis Post Dispatch in October 2002. The series was later reprinted as a special report that filled two broadsheet sections totaling 28 pages and containing 15 major articles and additional supporting data. According to the newspaper's promotion department, actual copies of the special report are no longer available, but the entire series is available on the Web at <http://www.stltoday.com/nursinghomes>.

In a nation beset by scandals as outrageous as Enron and as trivial as Martha Stewart's agony, one of the biggest and most shameful scandals of all has been largely overlooked: the unspeakable treatment of our helpless elderly in what are mistakenly called "nursing" homes. In a vast number, possibly a majority, of instances, the 700-year-old warning from Dante's *Inferno*—"All hope abandon, ye who enter here"—might appropriately be displayed over the entrances to these charnel houses.

There has been a general, localized awareness that things are not as they should be in the places where old folks go to spend their last months or years, but it took a recent major effort by a large midwestern newspaper, the *St. Louis Post-Dispatch*, to bring the national picture into focus and "tell it like it is" for all to read in horror. If one of the journalistic prizes that bear the name of this newspaper's founder, Joseph Pulitzer, does not go next year to the team that compiled this truly great piece of reportage, it will

be a surprise to those of us at Public Citizen.

Consider the basic fact about our nation's treatment of its elderly: Of all the Federal money allocated to fighting abuse and neglect (\$7.4 billion), less than 2 percent (\$153 million) goes for abuse of the elderly. Domestic abuse (men beating up on their wives and vice versa) gets over three times this much (\$520 million) and child abuse gets the rest (\$6.7 billion, or 93 percent). The best that can be said about this nation's treat-

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ment of the aged is "benign neglect"—but not much of it is benign.

This is the message of the *Post-Dispatch* series, aptly entitled "Neglected to Death." An introductory paragraph is worth reprinting here in full:

"Thousands of our nation's parents and grandparents are being killed by neglect each year because their nursing homes fail to provide them with basic care. Nine out of 10 homes don't have enough nurses and aides to provide the residents with sufficient food and liquid or to prevent bedsores. The *Post-Dispatch*, after a yearlong investigation, documents how these deaths happen. The series also examines why most law-enforcement officers, medical examiners and prosecutors refuse to get involved and why regulators and legislators have been unable to achieve reform."

In this land of ours, where "all men are created equal [and] ... are endowed by their creator with certain unalienable rights," George Orwell's comment that "some [people] are more equal than others" constantly comes to mind. It is especially true in the case of the aged and infirm. While thousands of aged residents of poorly supervised nursing homes all over the country were lying virtually unattended in their own filth, suffering from bedsores that often exposed their bare bones, and gradually dying from dehydration and inadequate nourishment, Senator Strom Thurmond of South Carolina (already the oldest legislator in congressional

history) was sweating out the coming of his 100th birthday on December 5, 2002, while receiving royal-quality government-funded nursing care at the Army's Walter Reed Hospital in Washington, at the same time playing the role of a real-life legislator with his own corps of sitters constantly close at hand.

But one doesn't have to go to extremes to understand the injustice, bordering on inhumanity, that confronts Americans "of a certain age." Millionaires have nothing to worry about; they can buy end-of-life treatment almost as good as centenarian senators get, or can even die at home with first-class, round-the-clock attention. Less fortunate people who have built up smaller nest eggs (and haven't lost them in the dot.com or other recent financial collapses), or who have bought long-term-care insurance policies that really deliver in time of need, or have property or other assets that will supplement their Medicare benefits can still avoid "death by neglect" if they are lucky. But the poor—even the so-called "working poor"—who must depend on Medicaid, are most likely to fall into the hands of neglectful or even felonious custodians in the last years of their lives.

Even people a cut above the poor can end their days in a climate of neglect. As people spend down their assets to one or two thousand dollars or so, Medicaid kicks in, supposedly to provide minimal standards of care for the remaining months or years of the recipient's life.

But what is minimal care, and who decides? A box accompanying one of the *Post-Dispatch* articles states that "[m]ost researchers and experts have agreed that it takes 4.5 hours of nursing care each day to properly care for a nursing home patient. Alaska is the only state in the country to exceed that total, with 4.8 hours." An accompanying chart shows Illinois (3.0 hours) and South Dakota and Iowa (3.1 hours each) lag far behind even the acceptable minimum.

And the hours-per-patient criterion says nothing about quality. And when a patient dies—as eventually all of us must do—in most cases there is no clear answer to the question of cause. "Cardiac arrest" is a common entry on death certificates. Big deal; all cardiac arrest means is that the heart has stopped beating: a universal cause of death, one might observe.

The things that really kill people in nursing homes rarely show up on death certificates, which are often signed by doctors who have not autopsied—or even seen in real life—the people they are signing off on. And when negligence or outright cruelty (which also occurs in many nursing homes) is involved, police and prosecutors usually look the other way. Sometimes the reason for this official disinterest is workload: the cops and the D.A.s are already too busy, and often there just isn't money in the budget to handle all the questionable cases that come out of nursing homes.

The budget crunch is a big item all
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through the nursing home picture. States are strapped for money to finance their share of Medicaid, localities have limited resources for monitoring the operation of nursing homes, proprietors watch their dwindling bottom lines with anxiety and try to shave every expense item to the bone, and the unemployed people seeking jobs often are not, as the *Post-Dispatch* puts it, "...willing to accept a position that requires long hours at odd times of the day or night for an average salary of about \$35,000 a year."

Thirty-five thousand, it might be noted, works out to about \$17 an hour, based on a 40-hour week with two weeks' vacation—hardly enough in these days to base a career on—especially when the chance to advance from dirty, disheartening work (although otherwise rewarding to many "saints" in these jobs) is minimal to say the least.

So neglect happens and people die. What then? In Missouri, for example, the paper notes, "[e]ven when fines are assessed in cases of death, the penalty can be negligible." It cites a nursing home where, in 1995, "more than a dozen residents [were found to be suffering] from improperly treated bedsores. Two women later died. A jury in 1998 found the nursing home and the administrator guilty of two counts each of felony neglect."

The penalties? A \$250 fine per death levied against the nursing home, and \$500 per death against the administrator. Two corpses; total assessment, \$1,500. Some people get away with homicide real cheap.

Not only negligence and customary levels of governmental inefficiency play roles in the Death by Neglect scandal that is sweeping this country; greed, graft and deception are deeply involved as well. Lobbyists thrive, especially at the statehouse level, and officials with their hands out are far from unknown. It is, one might say, "the same old same-old." But why do those the least able to speak and act for themselves suffer

the most?

The question almost answers itself—with another question: Who watches the watchmen? People at the top of the pyramid have agendas of their own, admittedly not always selfish in nature. A regulator, faced with outrageous conduct on the part of a nursing home operator that would justify shutting the place down, might well decide instead on a slap on the wrist, such as a modest fine, on grounds that closing the badly run home would impose an unbearable burden on other homes in the area already filled to capacity.

"Regulators are losing the fight against neglect," the paper says. In Illinois, "some ... inspectors say they feel under assault by nursing home owners and their own bosses.... Several accuse department heads of ordering them to ignore violations they find in some nursing homes. Those who refuse are disciplined.... [Inspectors] end up being disciplined for something they haven't done."

This happens not only in Illinois; apparently it is national in scope. This from California, in the words of the series: "Something needs to be done that is effective and will result in improvement of quality of care," said Candace Heisler, who served as an assistant district attorney in San Francisco for 25 years. "Look at the history of regulatory agencies going into nursing homes. When a home is brought up on violations, was the issue resolved quickly and effectively? Sadly, the answer is no."

Lest the situation seem uniformly hopeless, there are some bright lights, the *Post-Dispatch* acknowledges. One nursing home that might serve as a model for other budget-strapped institutions was the subject of a special report in the series. Thanks to the work of an imaginative operator in a non-metropolitan setting, the Crestview nursing home in rural northern Missouri operates "on the lowest Medicaid rate in the state—\$85 per resident per day. Yet Crestview is winning national acclaim and consistently posts near-perfect scores on state inspectors'

tests."

The article quotes the home's operator, Eric Haider, as saying, "If I can do it at this price, how come the home a half-mile away from here—at \$99 a day—can't?"

As described by reporter Virginia Young, Crestview sounds like the kind of place anyone would settle for in his or her declining years: "... [r]esidents use their own furniture. They get up when they choose. They eat when they want. They have pets and bird feeders and gardens. They go shopping and bowling and fishing and even Ferris wheel riding."

In short, Haider gives back to residents what they hated most to lose: "their privacy and ... control over their lives."

Unlike many administratively top-heavy nursing homes, Haider cuts out higher-salaried middle-managers and gives the working staff more authority than people at this level normally get. The entire article about Crestview, worthy of the attention of anyone interested in something that's being done right, can be found on the website mentioned in the accompanying box. When the index for the special report comes up, go to "Day 6" and click on the item, "Innovative home lets people take control of their lives."

Clearly, there are not enough Eric Haiders around to clean up the mess that has historically plagued what used to be called "old folks homes" (or sometimes "poor houses"). Twenty years ago a veteran champion of the elderly, Sen. Claude Pepper (D-Fla.), asked his colleagues, "What have the elderly in this country done to make their government and their neighbors so willing to have them starved, neglected and uncared for?" Twenty years before that, Sen. Frank Moss (D-Utah) had released a voluminous report based on committee hearings and entitled "Nursing Home Care in the United States: Failure of Public Policy."

Decades later, in a new century and a new millennium, an old French saying comes to mind: "The
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Product Recalls

November 12—December 11, 2002

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.

Class I Recall

Name of Drug or Supplement; Class of Recall; Problem

Lunelle Monthly Contraceptive Injection (medroxyprogesterone acetate 25mg and estradiol cypionate 5mg) Injectable Suspension, Single Use 0.5 mL syringe and physician samples, For Intramuscular Use Only, Rx only; Subpotency of the active ingredients

Lot #: Quantity and Distribution; Manufacturer

All lots distributed in 2002; 800,000 units distributed nationwide; Pharmacia Corporation, Kalamazoo, Michigan

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more things change, the more they stay the same." And nothing—but talk, perhaps—is happening today. In Congress, as Rep. Henry Waxman (D-Calif.) told the *Post-Dispatch*, "There hasn't been a hearing in the House [of Representatives] since 1995 on problems in nursing homes. That's an outrage."

What about the "senior lobby," supposedly so powerful on Capitol Hill? "Not when it comes to nursing homes," an attorney for the Center for Medicare Advocacy told the paper. "Most of the groups supporting reform are small, underfunded and almost powerless. The larger,

more powerful organizations like [AARP] don't see nursing homes as a major issue. At the national level, nursing homes are not on their radar screen. Their attention is directed toward elderly who are healthy and who want to go on cruises rather than nursing homes."

Which validates, again, George Orwell's comment that "some [people] are more equal than others."

What of the future? Will a compassionately conservative administration in Washington, its attention fixed on terrorism and the supposed menace of Saddam Hussein, be depended on to rescue the distressed elderly in mismanaged nursing homes any time

soon? Don't bet on it. The *Post-Dispatch* reports:

"Last November, the Centers for Medicare and Medicaid Services, formerly called the Health Care Financing Administration, released a plan that would comply with a desire by the Bush White House to cut regulation of the nursing home industry. It called for reducing annual government inspections of nursing homes from once a year to once every three years."

Obviously, if anyone is wondering where the fox is, he's out watching the henhouse. Don't expect any sudden changes in the status quo.

Name of Drug or Supplement; Class of Recall; Problem

Etodolac Extended-Release Tablets, 500 mg, 100 count bottles, Rx only; Class II; Tablet mixup – a bottle labeled to contain Etodolac Extended-Release tablets was found to contain both Etodolac Extended-Release tablets and one tablet of Tramadol HCl 50 mg

Liqui-Char (activated charcoal), in an Aqueous Base, and in a Sorbitol Base, various size tubes; Class III; Stability – lack of assurance product potency will be maintained through labeled expiration date

Member's Mark Acetaminophen Caplets, 500 mg, Non Aspirin, Extra Strength, 500 caplets per bottle; Class III; Misbranding – product contains undeclared cherry flavoring

Novolin 70/30 InnoLet, 70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection (rDNA origin), 100 units/mL, 3mL Prefilled Insulin Syringes, Novo Nordisk; Class II; Defective container – delivery system may dispense less than the expected amount of insulin

Premarin Tablets (conjugated estrogens tablets) 1.25 mg, 100, 1000 and 5000 count bottles, Rx, only; Class III; Failure to meet dissolution specifications

PRO-RED Syrup Antitussive, Nasal Decongestant, Antihistamine, Alcohol Free, (Hydrocodone bitartrate 2mg, Phenylephrine hydrochloride 5mg, Pyrilamine maleate 8.33mg) 4 fl oz (118 mL) and 16 fl oz (473 mL) bottles, Rx Only; Class II; Yeast contamination (*saccharomyces cerevisiae*) causing bottles to swell

Pyrethrin Lice Treatment (Piperonyl Butoxide 4% and Pyrethrum Extract (equivalent to 0.33% Pyrethrins), Kinray Preferred Plus brand, A Creme Rinse Application, 2 fl oz (59 mL) bottles, single and twin packs; Class III; Mislabeling; one active ingredient is incorrectly declared on the bottle label as Permethrin rather than correctly as Pyrethrin

Rhinocort Nasal Inhaler (budesonide) 7g, 200 Metered Doses, For Nasal Inhalation with Rhinocort Adaptor Only, Rx only; Class III; Defective container – inhaler may not consistently deliver acceptable spray after the initial spray

Robinul Forte Tablets (glycopyrrolate tablets) 2mg, physician sample cartons of 8 tablets, Rx only; Class II; Product contains glass particles

R-Tanna S Pediatric Suspension (Chlorpheniramine Tannate 4.5mg and Phenylephrine tannate 5 mg) 4fl oz (118mL) bottles, and CP-Tannic Suspension (Chlorpheniramine tannate 4.5mg and Phenylephrine tannate 75mg) 4fl oz (118mL) and 16fl oz (473mL) bottles, Rx only; Class III; Subpotent for phenylephrine tannate (3 month stability) and chlorpheniramine tannate (1 month stability)

Lot #: Quantity and Distribution; Manufacturer

Lot number 502044 exp. 2/04; 4,084 bottles distributed nationwide; Teva Pharmaceuticals USA Inc., North Wales, Pennsylvania

Numerous codes; 28,014 units distributed nationwide, England and Canada; Jones Pharma, Inc., St. Louis, Missouri

Lot #s 1CB0498, 1CB1311 and 1HA1970; 14,570,437 caplets distributed nationwide; Leiner Health Products, Carson, California

Lot # MS 60812 Exp. 6/2004; 83,789 units distributed nationwide and Puerto Rico; Novo Nordisk Pharmaceuticals, Princeton, New Jersey

Lot 9981205, Exp. 3/02, Lots 9981348 and 9981207 Exp. 3/03; 4,801 bottles distributed nationwide; Wyeth Pharmaceuticals, Richmond, Virginia

Lot# 01092 Exp 06/2004; 4,228 bottles distributed in Missouri, Iowa and Illinois; Great Southern Laboratories, Houston, Texas

Lots 2F15A, exp. June 2004, 2G02A, and 2G25D, exp. July 2004; 1,251 units quarantined at distributor awaiting return to Qualis; Qualis, Inc., Des Moines, Iowa

Lot CH300, Exp. Date: February 28, 2003; 90,540 units distributed nationwide; Astra Zeneca, Wilmington, Delaware

Lot Number H020572; 386 cartons distributed nationwide; Mikart, Inc., Pharmaceutical Manufacturers, Atlanta, Georgia

Lots GB024, GA984, GA986, GB005, GB033 and GB036; 18,280 bottles distributed in Ohio and Mississippi; Kiel Laboratories, Inc., Gainesville, Georgia

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M E D I C A L D E V I C E S

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 1-800-FDA-1088. The FDA web site is <http://www.fda.gov>.

Class I Recall

Name of Device; Class of Recall; Problem

Oral Swabs in Mouth care kits under the Centurion Healthcare Products brand; Sponge may become dislodged from the oral swab and present a choking hazard

Lot #: Quantity and Distribution; Manufacturer

92,330 kits distributed nationwide; Tri-State Hospital Supply Corp., Howell, Michigan

Name of Device; Class of Recall; Problem

Blood Glucose Test Strips – Genuine One Touch and Lifescan; Class II; Products not approved for sale in USA & Canada, and may give inaccurate readings when used with readers from US & Canada

Lot #: Quantity and Distribution; Manufacturer

All lots; Unknown quantity distributed in Ohio, Utah, Michigan and New York; Payless Wholesale Inc., Glendale, New York

Glucose Test Strips; Class II; Stability failure

Lot numbers 200250700833, 200250700825, 200250700798 and 80120700790; 17,298 distributed nationwide; LXN Corporation, San Diego, California

Little Soothers Cold Pack; Class II; Product contains ethylene glycol instead of propylene glycol

Style # FSC: F68115-1; 1,129 units distributed nationwide; Avon Products, Inc., New York, New York

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 1-800-638-2772. The CPSC web site is www.cpsc.gov.

Name of Product; Problem

Chain Saws; Fuel can leak out of the chain saw's tank, causing a fire or injury hazard

Lot #: Quantity and Distribution; Manufacturer

MS 170 and MS 180 C with serial numbers 255120848 through 255122797 and 255739074 through 255741150; 3,000 sold nationwide from July through October 2002; Stihl Inc., Virginia Beach, Virginia (800) 610-6677 www.stihlusa.com

Compound Bows; Limbs can break during use, causing impact injuries

Junior sized, sold under the names Warrior and Buckmaster/Warrior; 2,250 sold nationwide from September through October 2002; Bear Archery LLC, Gainesville, Florida (800) 342-4751 www.beargoldeneagle.com

Flashlights and Batteries; "AA" batteries provided with flashlight can leak, which could cause irritation to the skin. When disassembled, flashlights also have small parts that can pose a choking hazard

Multicolored translucent plastic; 9,500 distributed as a premium in kids meals at Halo Burger stores in Genesee and Saginaw Counties in Michigan from October through November 2002; Halo Burger, Flint, Michigan (810) 238-1839

Infant Girls' Garments and Sandals; Small, decorative items on garments can detach, posing a choking hazard

Three different garments; 52,000 sold nationwide from January through April 2002; Good Lad Apparel Philadelphia, Pennsylvania (877) 599-5530

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Phyllis McCarthy Annual Public Interest Award

Phyllis McCarthy, who devoted 24 years to Public Citizen, primarily as the detail-oriented managing editor of all of the Health Research Group's publications and office manager for the group, died in November 2002. She began her career at Public Citizen in 1978 as a typist in the Health Research Group, having asked to work here so she could spend the rest of her career doing public interest work. She was key in the development and preparation of all of our health publications, including the books *Pills That Don't*

Work, Over the Counter Pills That Don't Work, Worst Pills, Best Pills and *Questionable Doctors* and more than 1,000 other reports, medical journal articles and petitions to governmental health and safety agencies such as the FDA and OSHA. As managing editor of the newsletters, *Health Letter* and *Worst Pills, Best Pills News*, Phyllis ensured the publications were error-free and on time. She was always ready with a peppery quip, always willing to pitch in and do what was needed. Phyllis was intensely loyal to Public Citizen and

was someone without whom the organization would not have thrived.

We are establishing the annual **Phyllis McCarthy Public Interest Award** to be given to a person who has worked long and hard in a public interest group, performing critical functions, as did Phyllis, but who has not received public credit commensurate with their contributions. Donations can be sent to: Phyllis McCarthy Public Interest Award, 1600 20th Street NW, Washington, DC 20009.

CONSUMER PRODUCTS cont.

Name of Product; Problem

Infant Swings; Screw on support arm can loosen or detach, causing the seat to separate and drop to one side, presenting a fall hazard to infants

Kidz Club flashlights, sold under Energizer brand; Flashlights can overheat and cause batteries to leak, posing a risk of burns

Men's Sweatshirts; Fleece fabric on the inside of these sweatshirts fails to meet federal mandatory standards of fabric flammability

Plush Dolls; Hair has ponytail holders that could detach, posing a choking hazard

Power Equipment Engines; Misrouted fuel line in the engine can become damaged, allowing gasoline to leak out, posing a fire hazard

School Supply Sets; Sets contain razor knives, which pose a laceration hazard

Scuba Regulators; Extreme vibration can occur within these CDX regulators, which can cause an air leakage underwater. Divers could run out of air

Toy Attachments on Baby Walkers; Flower toys on tray can detach from stems, exposing sharp edges and posing a laceration hazard

Lot #: Quantity and Distribution; Manufacturer

Trend Swing; 15,000 sold at Toys R Us stores nationwide from November 2001 through September 2002; Baby Trend Inc., Ontario, California (800) 328-7363 www.babytrend.com

Multicolored flashlights; 24,000 sold April through October 2002; Eveready Battery Co. Inc., St. Louis, Missouri (800) 669-6394

Heather-gray, hooded with full-zippered front and "P87" embroidered on left chest; 6,000 sold at Target stores nationwide from August through September 2002; Target Corp., Minneapolis, Minnesota (800) 440-0680 www.target.com

12-inch doll Sulley with Boo; 14,500 sold at The Disney Store nationwide; The Disney Store, Inc., Glendale, California (800) 566-3161 www.disneystore.com

Model numbers HMSK 80 through 110 and HM 80 through 100; 25,000 sold June through November 2002; Tecumseh Products Co., Tecumseh, Michigan (888) 271-4048 www.tecumsehpower.com

10-piece kits sold in 8-inch plastic cases; 26,000 sold in California, Texas, Washington, and Maryland from June through October 2002; Damo Plus Corp., Vernon, California (323) 583-8484

Oceanic CDX; 24,700 sold worldwide from May 1999 through October 2002; Oceanic USA, San Leandro, California (866) 723-2642 www.OceanicWorldWide.com

Tot Rider and Carter's brands, various models; 410,000 sold nationwide from January 2000 through July 2002; Kolcraft Enterprises, Inc., Chicago, Illinois (888) 695-9988 www.kolcraft.com

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Health Letter Cumulative Alphabetical Index

(through 1/02)

Topics are listed alphabetically. Following each topic, the volume and issue number of the Health Letter containing the article is listed. For example, an article on the topic of Accutane can be found in volume 4 number 5 (V4#5) of the Health Letter. Volumes are chronological (volume 1 was issued in 1985). Back issues are \$3.00 each. Indicate issues wanted and send check made to Public Citizen, 1600 20th Street, NW, Washington, DC 20009.

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for each adverse reaction report submitted by a resident to the agency, a far preferable, public health-derived way of funding residents activities than the "free lunches" from drug companies now so much a way of life.

Also omitted is a discussion of the inadequate feedback to the reporting physicians or pharmacists. The FDA would surely engender better will and increase the likelihood of future additional reports from the small

fraction of physicians who do take the time to report adverse drug reactions if the agency would inform the reporters about other similar adverse reactions submitted for the drug and after a more thorough review of the problem of action taken by the agency.

Processing Risk Information by the FDA: Pre And Post Approval

The author cites 11 recent examples of drugs withdrawn because of safety reasons, actions "stimulated by

adverse drug reaction (ADR) reports." That the withdrawals were at least precipitated by the postmarketing ADR reports received by the FDA is not in dispute; however, what is unstated is that for at least four of the drugs, bromfenac (Duract), mibefradil (Posicor), troglitazone (Rezulin), and alosetron (Lotronex), clear evidence of danger existed before approval. This evidence was of the same kind that eventually led to the withdrawal, but it was not

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adequately heeded. For an additional 5 of these drugs, terfenadine (Seldane), astemizole (Hismanal), cisapride (Propulsid), and phenylpropanolamine (PPA), there was also clear evidence of serious adverse effects long before eventual market withdrawal, similarly not acted upon until much later.

The concept of generating a signal from ADRs is useful only if the signal is taken seriously and the action taken is prompt and proportional to the strength of the signal. This is especially important when the signal confirms earlier, preapproval evidence of dangers seen in randomized controlled trials, as in the four drugs cited above. There has been an historic split and an imbalance of power between FDA drug review divisions and the postmarket surveillance (Office of Drug Safety) division. In too many instances, serious postmarketing safety problems identified by the Office of Drug Safety have not been acted upon because of resistance from FDA management and from the review division that originally approved the drug.

Who Owns the FDA

A recent cover story in the *British Medical Journal*, underneath a photograph of the Parklawn Building in Rockville, Maryland, where much of the FDA is located, carried the caption "Who Owns the FDA?" In several articles in that issue, the planned re-entry onto the market

of Lotronex, Glaxo's previously withdrawn dangerous drug for irritable bowel syndrome, illustrates the pernicious new relationship between the FDA and the drug industry, related in part to the 1992 Prescription

In too many instances, serious postmarketing safety problems identified by the Office of Drug Safety have not been acted upon because of resistance from FDA management and from the review division that originally approved the drug.

Drug User Fee Act (PDUFA). That Act required companies to pay fees directly to the FDA for drug regulation. Richard Horton, editor of *The Lancet* wrote, also referring to alosetron, "This story reveals not only dangerous failings in a single drug's

approval and review process but also the extent to which the FDA, its Center for Drug Evaluation and Research (CDER) in particular, has become the servant of industry.

One of the reasons the morale in the Center for Drug Evaluation and Research (CDER) appears to be lower than in 30 years has to do with what CDER Director Dr. Woodcock has aptly described as the "sweat shop environment" created in the wake of PDUFA. In a survey by the FDA of CDER personnel in 2001, intended to find out the reasons for the high rate of staff turnover, the problems found included the following: "About one third of respondents did not feel comfortable expressing their differing scientific opinions...over one third felt that decisions such as holds, refuse-to-file actions, and non-approvals are stigmatized in the agency. Over one third felt that their work has more impact on a product's labeling and marketability than it does on public health. A number of reviewers added comments stating that decisions should be based more on science and less on corporate wishes." One of the 13 recommendations in the report is to "Encourage freedom of expression of scientific opinion." Unless this occurs, along with healthy debates, the FDA will not be able to attract and keep its best staff. Debate, attention to dissident views, and freedom of expression are not only the hallmarks of good science: they are also the essence of democratic governance.

Remedies Needed to Address the Pathology in Reporting Adverse Reactions and Food and Drug Administration Use of Reports

The following editorial by Health Letter editor Dr. Sidney Wolfe appears in the January, 2003 issue of the Journal of General Internal Medicine and is reproduced with the permission of the Society of General Internal Medicine.

The articles in this issue concerning adverse events and errors provide an overview of the anatomy and physiology of the process of soliciting and analyzing adverse drug reaction reports at the Food and Drug Administration (FDA) and a useful taxonomy of the ways of measuring errors and adverse events more

generally in health care. Both fall short, however, of addressing the most serious pathology and proposing adequate remedies.

Increasing Adverse Drug Reaction Reporting

It is clear that if the reporting of adverse drug reactions to the FDA rose from the current estimated 10% of all that occur to 20%, it would take half as long to accumulate the number of reports of deaths or injuries necessary for a postapproval decision to ban or put a boxed warning on a drug, thus sparing the lives and health of many patients harmed during the interval. Despite success-

ful experiments by the FDA and others that have shown that such increases are possible, this concept has never been nationalized or even regionalized on an ongoing basis. In Rhode Island for example, an FDA-funded project in the 1980s resulted in a 17-fold increase in adverse reaction reports submitted annually from Rhode Island to the FDA compared with the yearly average before the project. Similar increases were not experienced nationally. Without the continuation of the intervention, the reporting rate dropped back down. In the 1960s, the FDA paid residency programs a modest fee (\$25 dollars)

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