PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR FEBRUARY 2002 ◆ VOL. 18, NO. 2

The Destruction of Medicine by Market Forces: Teaching Acquiescence or Resistance and Change?

The following article by Dr. Sidney Wolfe is reprinted from Academic Medicine, *Vol. 77, No. 1, January 2002.*

Medical schools have too often taught—actively, or passively by example—acquiescence to the increasing trends toward medicine as a business rather than teaching resistance to those trends in a manner consistent with medicine as a profession. A rapidly growing amount of research has documented the deleterious effects of this business model on doctors and/or patients. But except in rare instances, medical curricula for students or residents neither include in-depth discussions of such research nor map out strategies for resisting and reversing these dangerous trends, including encouraging more research in these areas. As we approach the 100th anniversary of the 1910 Flexner Report, which revolutionized and rationalized medical education, we must heed his admonition to apply the scientific method to all dimensions of medicine, including elucidating evidence for the destruction of medicine and medical education by market forces. Ironically, the revolution in medical education occasioned by that report included the evidence-based elimination of a large number of poor quality medical schools being run on a for-profit basis. The new model that evolved emphasized a non-commercial ethic of professionalism and service, but this model is now in jeopardy.

Health Services and Medical Education

Among developed countries, the United States is unique in having a substantial proportion of health services delivered by for-profit businesses. Research has documented that the quality of care is worse in for-profit HMOs, kidney dialysis centers, nursing homes, and hospitals than in nonprofits, just as Flexner documented poor quality education in for-profit medical schools. We are also the only country in the world in which the predominant mode of health care delivery is for-profit managed care companies, squeezing doctors and patients into shorter visits and less care, in too many instances simply to pay CEOs and stockholders more. The managed care industry has driven teaching hospitals into an entrepreneurial response that undermines the critical missions of teaching as well as professionalism and service.

Resistance to these dangerous directions is needed to diminish the incursions of for-profit medical care. Research and teaching concerning the poorer quality of for-profit care would

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add to the atmosphere and strength of resistance.

But there are two concomitant and similarly unique aspects of this market-driven system, now caused and controlled by private insurance companies with an increasing amount of for-profit care. First is the failure to provide health care as a right to all citizens, leaving one seventh of our population, about 40 million people, without health insurance. Second is the failure of our government to provide low cost medical education to all who are qualified to enter medical school because of the lack of an overall national policy to pay for medical education.

Medical schools should end the general silence on the absolute necessity for a single payer, government-financed health insurance plan by teaching students its unique advantages. In addition, a coalition of medical students and faculty should be leading a national effort for government subsidy of a much larger part of medical education so that socioeconomic-class-based discrimination does not continue to pose barriers for many to attend medical school and so that medical teaching institutions and their faculties are on firmer financial footing, less dependent on commercial ventures. Another important advantage of a single government payer for all medical services would be to overcome the perpetual private health insurance industry's resistance to such a subsidy.

The Pharmaceutical Industry and Medical Schools

Another important area in which medical educators need to be offering much more resistance involves the pharmaceutical industry. Medical journal articles that distort the actual results of clinical trials concerning drugs or other medical products, ghost-written articles, delayed articles and publication bias as a result of industry pressure have led to guidelines endorsed by editors of 13 leading international medical journals. The cause was succinctly stated in the prologue to the guidelines. "As CROs (contract research organizations) and academic medical centers compete head to head for the opportunity to enroll patients in clinical trials, corporate sponsors have been able to dictate the terms of participation in the trial—terms that are not always in the best interests of academic investigators, the study participants, or the advancement of science generally."

But the publication step is at the end of the research process, and much damage can be done by then, especially because many of the most alarming findings of drug-company-sponsored research are not published. Medical schools should prohibit equity interest in drug companies by academic researchers who are doing clinical trials. The broader issue is that drug companies should fund clinical trials but have no control over their design and implementation, the interpretation of data, or publication. More than merely a change in journal publication policy is needed for this to occur, and medical schools need to be at the forefront of advocating such a change.

There has been an increase in deals between medical schools and pharmaceutical or medical device manufacturers to develop products under exclusive arrangements that will generate income for the medical schools and faculty members. The formation of small companies involving faculty to develop products is, at the least, a drain on teaching and other non-commercializable research efforts.

There is good evidence that money from drug companies or contacts with them can influence faculty decisions regarding hospital formulary additions. There is also widespread drug company funding of hospital rounds, and contact with drug reps is allowed in many academic medical teaching centers. Attendance at free drug-company-sponsored dinners, sports events, and thinly disguised marketing efforts labeled as research are often viewed as an acceptable norm. Contrary to a recent statement by former AMA President Alan Nelson, MD, that "Ongoing interaction and strong communication between physicians and [the pharmaceutical] industry is vital for good patient care," many of the best physicians have little if any contact with this industry.

The need for resistance to these influences has been articulated by the eminent medical historian and ethicist, David Rothman: "Medical training should not include acquiring a sense of entitlement to the largesse of drug companies.... Medical schools should... prohibit all gifts from drug companies to students.... Teaching hospitals should proscribe drug company sponsorship of lunches, conferences, and travel for residents."

An extensive collection of references and slides of published articles refuting the notion that there can be, in the context of the relationship between drug companies and physicians, a truly free lunch, is available on the Internet and is frequently updated. Bob Goodman, of Columbia University College of Physicians and Surgeons, the founder of the No Free Lunch web site, *www.nofreelunch.org*, is currently developing, with several colleagues, a curriculum for use with medical students and residents to review this evidence and teach resistance to the "free lunch" concept.

Other educational efforts to counter drug industry influences on prescribing practices could include teaching students and residents a process for the evaluation of newly emerging or older prescription drugs that utilizes publicly available information from the FDA web site, *www.fda.gov*, or other information available from the FDA through the Freedom of Information Act.

The Center for Drug Evaluation and Research (CDER) Freedom of Information web page is located at *www.fda.gov/cder/foi/index.htm*. The link can then be made to New Drug Approval Packages. These documents are the reviews by FDA scientists of the data submitted by a manufacturer to support the approval of a new drug and include reviews of clinical trials. A direct link can be made to the new-drug approval packages at *www.fda.gov/cder/foi/nda/index.htm*.

FDA scientific reviews are also available for drugs not yet approved that go before public advisory committees. These reviews are known as briefing information. In general, briefing information is not as complete as approval packages and focuses mainly on efficacy and safety. Briefing information is

organized by the year and by the name of the advisory committee undertaking the review. This information can be accessed at *www.fda.gov/ohrms/dockets/ac/acmenu.htm*. It will also be necessary to know the date of the advisory committee meeting.

This site also allows a link to the transcripts of advisory committee meetings, which are organized in the same manner as the briefing information.

Reports made to the FDA's adverse drug reaction reporting system (MedWatch) can be purchased from the U.S. Department of Commerce's National Technical Information Service (NTIS) on CD ROM. Data are available back to 1969. The NTIS's web site is located at *www.ntis.gov/*. A direct link to descriptions of this information is *http://neptune.fedworld.gov/cgi-bin/waisgate*.

These sources often provide data concerning safety and efficacy unfavorable to the drug's approval, data that are often never published or are published in ways that distort the results.

Medical schools are mainly silent on the need for drug company price controls or negotiated prices, having bought into the misleading arguments that unless Americans pay about twice as much for pharmaceuticals as do citizens of other developed countries, the industry—the most profitable among major American industries—will not have enough money to do important research and develop new pharmaceuticals. A recent report by Public Citizen's Congress Watch casts serious doubt on the validity of these industry claims (*http://dev.citizen.org/documents/ACFDC.PDF*). There is a need for medical schools to advocate government price controls or negotiated prices as the only way prescription drug benefits—for Medicare or for everyone—would be affordable. Medical school ties with drug companies are probably another deterrent to advocacy for these price controls.

Medical School Courses In Research-based Activism

In many ways, the public is more educated about the evils and dangers of market medicine than is the medical profession. In order for a joint effort of doctors, working with patients, to succeed in supplanting the current market-based system and restoring professionalism to medicine and to the doctor patient relationship, there needs to be a radical shift in medical education to include such information.

We in the Public Citizen Health Research Group have been involved in helping to start several medical school courses in research-based activism that provide students with examples of evidence about such problems with our health care system. In some courses, students are taught to design protocols or even execute research projects that would add information and presumably help to cause changes in these areas. Information about one of the first such courses, at Case Western Reserve University School of Medicine, is available on a web site that is being expanded to include information about other such courses at Johns Hopkins, NYU, and other schools, *www.citizen.org/hrg/activistcourses*.

Over the 30 years since the Health Research Group was begun, 20 medical students and 11 residents in preventive medicine have done rotations with us, lasting from two months to a year. In addition, we have collaborated with 35 post-residency physicians since 1996 on research-based activism projects. Many of the projects they worked on have resulted in bans or warnings on prescription drugs and restrictions in the amounts of dangerous chemicals workers are exposed to. The results of some of these projects have been published, and our web site, *www.citizen.org/hrg*, includes the full details of many of the most recent efforts at research-based change.

Conclusion

As long as the predominant vision of medical educators is acquiescence to market forces instead of resistance and constructive change, market medicine will thrive, to the detriment of doctors and patients alike, and medicine, as a profession, will suffer, along with the simultaneous erosion of the doctor patient relationship.

Flexner taught evidence-based-resistance and change. The lesson of the elimination of for-profit medical schools must not be lost, and a concerted effort by medical educators and our students and residents as well as patients to eliminate all for-profit health services and to reduce medical school dependence on commercial activities must be undertaken.

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

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Good Business Suggestions

Once again, some radical ideas from an unexpected business source: With the title, *How to Control Drug Costs, Simply*, an editorial in the December 10th, 2001 issue of *Business Week* tackled this serious problem with keen analyses and an interesting, if not completely right, list of what needs to be done.

Under the banner of "Get Smart," *Business Week* points out that "for every dollar the country spends on drugs, it wastes another dollar fixing medical problems caused by those same drugs. Doctors and hospitals are prescribing the wrong drugs to many and too many drugs to others."

The editorial goes on to say that the extraordinary rise in drug spending is not primarily due to cancer and AIDS drugs, used by a small fraction of the population, "but by cholesterol-lowering heart medications, psychiatric medications, and painkillers used by tens of millions of people. Exercise and a good diet can help reduce heart disease, diabetes, anxiety and some pain."

"Get Tough" introduces their accurate accusation that the drug industry is "gaming the patent system to stymie competition." Under current law, the Food and Drug Administration is compelled to "freeze generic versions of drugs for 30 months if a drug company complains that the generic infringes on its patent. Two and a half years is a ridiculous wait; it should be shortened to three months."

"Get Honest" attacks drug advertising by stating that TV pharmaceutical advertising "promotes high-priced new drugs with marginal [if any] improvements over cheaper generic versions. The FDA should crack down harder on misleading ads."

Although we agree with all of the above, we would add that there needs to be government-negotiated prices or price controls, as currently exist in every other industrialized country in the world. For now, this would benefit Medicare recipients for whom a drug benefit is unlikely without such controls, which now benefit those in the military and Veterans' Administration programs that purchase pharmaceuticals at deep discounts. But otherwise, not bad, *Business Week*.

Product Recalls

December 6, 2001—January 10, 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 & DIETARY SUPPLEMENTS

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

Class I Recalls

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
T3 Pro-Thyroid Technology, 90 capsules, tiratricol, 1000 mcg; Unapproved new drug	All codes are recalled; 8,253 bottles distributed in Texas; Golden Desert Manufacturing, Phoenix, Arizona. Recalled by Global Enterprises, College Station, Texas
BIOPHARM T-Cuts Capsules, trycan 100 mgs (pharmaceutical grade tiratricol), 90 count bottles; Unapproved new drug	Lot #2276 EXP 6/03; 400 units distributed in California, Virginia, West Virginia, New Mexico, Indiana, South Carolina, Washington, North Carolina, Louisiana and Canada; Golden Desert Manufacturing, Phoenix, Arizona. Recalled by ATF Fitness Products, Inc., Oakmont, Pennsylvania

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Class I Recalls *continued*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Prostatin Formula #103, 500 mg capsules, 30 & 90 capsule bottles; Product contains aristolochic acid, a potent carcinogen and nephrotoxin	All lots and codes; 5/30 capsule and 2/90 capsule bottles distributed in Arizona, Kentucky, Pennsylvania and the Philippines; Sheng Chang Pharmaceutical Co Ltd., Taipei Hsein, Taiwan. Recalled by Herbal Doctor Remedies, Monterey Park, California
Vital Nutrients Joint Ease Capsules 60 and 120 count and **Verified Quality Brand Joint Comfort Complex Capsules** 60 and 120 count; Products contain aristolochic acid, a potent carcinogen and nephrotoxin	All lots; 692 bottles distributed nationwide; VITAL Nutrients, Middletown, Connecticut
Cortisporin Ointment (neomycin and polymyxin B sulfates, bactracin zinc, and hydrocortisone ointment), Rx, 1/2-ounce tube; Class II; Subpotent for Polymycin B Sulfate component (Stability 28-month test point)	Lot MK10/8899, EXP 12/04; 38,481 units distributed nationwide; King Pharmaceuticals, Inc., Bristol, Tennessee
Equate Allergy Medication Decongestant Caplets, 24 caplet blister cartons; Class II; Misbranding. Directions for use may lead to a doubling of the dosage	Lots 1GB0825, 1GB1041, 1GB1042; 45,504 24-caplet cartons distributed nationwide; Recalled by Leiner Health Products, Inc., Carson, California
Pangestyme Capsules (Ethex brand); Class II; Subpotency (Stability)	Numerous lots; 46,256 bottles distributed nationwide; KV Pharmaceutical Co., St. Louis, Missouri. Recalled by ETHEX Corporation, St. Louis, Missouri
Rescriptor 200 mg tablets (delavirdine mesylate tablets), bottles of 180 tablets; Class II; Lowered therapeutic effectiveness	Lot 17DSJ EXP 11/01; 1,949 bottles distributed nationwide; Pharmacai & UpJohn Barceloneta, Puerto Rico. Recalled by Pfizer Inc., New York, New York

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

Name of Device; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Sterile Dressings, labeled in part: "SURGIPAD" Combine Dressing DRESSING 8 in x 7.5 in.; Class II; Seal integrity—possibly non-sterile device	Code 2144, Lot Numbers 2001 07 1 01, 2001 07 2 01, 2001 07 3 01, 2001 08 1 01, 2001 08 2 01, 2001 08 3 01; 751,680 distributed nationwide; Johnson & Johnson Medical, Div. of Ethicon, Inc., Sherman, Texas
Wheelchairs, powered; Class II; While in operating mode, an unanticipated stop can occur	Quickie brand Model P-222, Serial Range: P22-8516 to P22-9181; 652 distributed nationwide and worldwide; Sunrise Medical, Fresno, California
Wheelchairs, powered; Class II; The dual-post clamping armrest receiver can collapse from the wheelchair	Quickie brand G-424, S-525, S-626, V-521, Model # Serial Number Range: G-424 G42-6010 to G42-12531 S-525 S52-10060 to S52-17155 S-626 S62-5801 to S62-11281 V-521 V52-10786 to V52-12221; 12,322 distributed nationwide and worldwide; Sunrise Medical Quickie Designs, Inc., Fresno, California

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at 1-800-638-2772. The CPSC web site is *http://www.cpsc.gov.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
All-Terrain Vehicles (ATVs); Pressure switch in braking system leaks fluid, which can cause brakes to fail	13 different models of manual and automatic transmissions; 15,500 sold nationwide from July through December 2001; Arctic Cat Inc., Thief River Falls, Minnesota (800) 279-9419 www.artic-cat.com
Candles; Glitter on the candles can ignite, posing a fire hazard	Candele Glitter Candles, 3 and 6 inch high pillars coated with glitter; 50,500 sold at Walgreens stores nationwide from August through December 2001; Walgreen Co., Deerfield, Illinois (866) 241-0105 www.walgreens.com
Candles; Candles can collapse, causing the flame to spread	Pine Tree shape; 12,000 sold at Dillard's stores nationwide from October through December 2001. 620 sold at Neiman Marcus stores nationwide and Bergdorf Goodman stores in New York from early Fall through December 21, 2001; Dillard's, Inc., Little Rock, Arkansas (800) 235-9660 www.dillards.com. The Neiman Marcus Group Inc., Dallas, Texas (800) 634-6267
Christmas Lights; Wires can be easily pulled out of the plugs and light sockets, posing electrocution and electric shock hazards	Rice lights, 22-feet long with 8 lighting effects; 7,500 strings sold at specialty garden stores nationwide from June through December 2001; Flora-Lite Co., Clearwater, Florida (800) 411-7381
Christmas Lights; Lights have undersized wire and could present electric shock or fire hazards	Marked "Rice Light," 21-feet long with 140 mini bulbs; 100,000 strings sold nationwide from June 1998 through November 2001; NBG International Inc., Houston, Texas (877) 532-8949 email to nbgjf@worldnet.att.net
Christmas Lights; Lights have undersized wiring and lack over-current protection, posing electrocution, electric shock and fire hazards	Miniature multi-color lights, 100 per string; 9,000 sold at discount and dollar stores in New York and New Jersey from October 2000 through November 2001; Winstar International Inc., Brooklyn, New York (718) 768-5172
Climbing Sticks and Tree Steps; Buckles can fail, posing a risk of serious injury to hunters	Gorilla Ultralite Climbing Sticks, model number 3163, serial numbers 040501, 050501, and 060801. Strap-on Tree Steps, model numbers 3152 and 3153, serial number 2899; 25,000 sold nationwide from February 1999 through September 2001; Game Tracker Inc., Flushing, Michigan (800) 241-4833 www.thegametracker.com
Cribs; Cut-outs in the end panels may allow young children to get their heads entrapped. Cribs fail to meet CPSC's standards	"Molly" and "Betsy" style wooden cribs in natural wood, antique green and white; 400 sold nationwide from May 2000 through September 2001; LaJobi Industries Inc., Edison, New Jersey (888) 266-2848 www.bonavita-cribs.com
Dressers (children's), In-home repair; Dresser can tip over during use, posing a serious injury hazard	Model 26224, production date 09-01 or older, light brown or off-white with heart-shaped handles; 8,200 sold nationwide from July 1999 through November 2001; Sandberg Manufacturer Co., Los Angeles, California (800) 498-2979
Garden Tractors; Rear wheel can loosen and spin free on its axle, resulting in a loss of power to the wheel and brake, which poses the risk of injury	Model Cub Cadet 3184 44-inch cutting deck, 18 or 20 horsepower engine; 6,000 sold nationwide from October 1999 through November 2001; Cub Cadet Corp., Cleveland, Ohio (888) 848-6038 www.cubcadet.com

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Girls' Jackets and Vests; Zipper pull and metal ring on these garments can detach, posing a choking hazard to young children	Baby Cool and Kid Cool polyester fleece, pink or violet; 5,100 sold nationwide from September through October 2001; Kid Cool LLC, New York, New York (800) 315-2376 www.sears.com
Lanterns; Lanterns can crack or catch fire due to excessive heat from the tealight candles	Votive Snowman Holiday Porcelain Lanterns; 33,000 sold through LTD Commodities mail-order catalogs from September through November 2001; LTD Commodities Inc., Bannockburn, Illinois (866) 736-3654
Mini-bicycles; Front fork assembly can loosen or break	Midget Racer, 31-inches long, 23-inches high; 28,000 sold in New Jersey, New York, Rhode Island, Minnesota and Massachusetts from October through November 2001; Kent International Inc., Parsippany, New Jersey (800) 451-5368
Outdoor Lighting Timers; Timers have reversed polarity in the wiring, potentially allowing a current to flow through a consumer's body, posing a shock hazard	Model HOT100; 50,000 sold at Menards stores nationwide from October 2000 through October 2001; Homemaster Inc., Eatontown, New Jersey (800) 443-0224 www.home-master.net
Portable Generators; A small hole in the generator's fuel tank, where it mounts to the frame, can leak fuel and pose a fire hazard	Porter-Cable model BSI550-W, date code 09-10-01; 600 sold nationwide from September through October 2001; DeVilbiss Air Power Co., Jackson, Tennessee (866) 422-4282 www.devap.com
Power Mowers; Stress cracks can develop in the mower's fuel tank, allowing gasoline to leak and posing a risk of fire and burn injuries	SilverPro and GoldPro Series walk-behind, 21- inch mowers powered by 2-cycle Duraforce engines; 90,000 sold nationwide from December 2000 through November 2001; Lawn-Boy Inc., Bloomington, Minnesota (800) 444-8676 www.lawnboy.com
Scuba Diving Devices; Overpressure valves can stick in the open position, posing a drowning hazard to divers	Used with Buoyancy Control Systems, all overpressure valves with red pulls are included in recall; 3,500 sold nationwide from November 1997 through November 2001; Diving Unlimited International (DUI) Inc., San Diego, California (800) 325-8439 www.DUI-Online.com
Shower Doors; Hinges can fail, causing the shower door to fall	Kohler Helios and Sterling Freestyle models made from January 1997 through September 2001; 41,000 sold nationwide from January 1997 through October 2001; Kohler Co., Kohler, Wisconsin (866) 782-6329 www.kohler.com/doorrecall
Spa Heaters; Heaters have an internal electrical connection that can overheat and ignite the heater and spa, posing a fire hazard	No-Fault 6000 model spa heaters sold with Hot Spring and Tiger River spas; 142,000 sold nationwide from January 1997 through January 2001; TruHeat Corp., Allegan, Michigan (800) 858-2122
Toys; Tips on the links that snap together like a chain can break off, posing a choking hazard to young children	Pop Links model 883, variety of colors and shapes; 20,000 sold nationwide from June through November 2001; Kids II Inc., Alpharetta, Georgia (877) 325-7056 www.kidsii.com
Toys; Button covers on the toy can come off, posing a choking hazard to young children	Round plastic baby toy with a face on the front, a red and blue "teethable ear" on each side; 8,800 sold nationwide from June through September 2001; Baby Buzz'r International, Sandy, Utah (866) 222-9289 www.babybuzzr.com

Health Research Group Asks New Mexico to Sanction Doctor

On November 2, 2001, Dr. Sidney Wolfe wrote the following letter to John Romine, MD, President, of the New Mexico State Board of Medical Examiners.

* * *

I have learned from several sources that Dr. Fred Pintz, the Chief Medical Officer of the State of New Mexico, has flagrantly violated a principle implicit in the New Mexico Medical Practice Act by providing authorization for the acquisition and provision of the drugs to be used by the New Mexico Department of Corrections in the execution by lethal injection of Terry Clark, scheduled for next Tuesday, November 6th. Unless Dr. Pintz is willing to immediately revoke his order for providing these drugs and ensure that the drugs are returned to the pharmacy in the State Department of Health, I urge that there be an emergency suspension of his license to practice medicine with the plan to permanently revoke it.

In 1992, the American Medical Association (AMA) articulated a position condemning the participation of physicians in state executions. A 1994 joint statement by the AMA, the American College of Physicians, the American Nurses Association and the American Public Health Association, *Health Care Professional Participation in Capital Punishment: Statement from Professional Societies Regarding Disciplinary Action*, recommended that "state professional licensure and discipline boards treat participation in executions as grounds for active disciplinary proceedings, including license revocation." The New Mexico Medical Practice Act has been interpreted to defer to the AMA's position on this issue, and thus, Dr. Pintz's participation in this planned execution clearly violates the ethical and legal principles governing the Board of Medical Examiners.

Since the Medical Officer of the Department of Corrections left New Mexico several months ago and because the company contracted by the state to provide prison health services refused to be involved in the execution of Terry Clark, the Governor asked the Secretary of Health, Alex Valdez, to facilitate the provision of the drugs for the lethal injection. Valdez asked a state pharmacist to obtain the drugs but the pharmacist allegedly refused unless so ordered by a physician. Thus, Dr. Pintz, the Chief Medical Officer of New Mexico, was asked to facilitate the acquisition of the drugs so they could be provided to the Department of Corrections.

In 1992, the American Medical Association (AMA) articulated a position condemning the participation of physicians in state executions

There have been 739 executions in the United States since 1976, including 574 by lethal injection. In most, if not all cases, physicians have been involved in one or more of the activities proscribed in the 1994 Joint Statement which include: …."Prescribing, preparing, administering or supervising injection drugs….prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure….monitoring vital signs….determining the point at which the individual has actually died…."

Such participation unequivocally contravenes the Oath of Hippocrates as well as the AMA Code of Ethics. Unless these important codes are acted upon, adherence to them will be dangerously low. The only way to accomplish this is to revoke the license of any physician who so participates in any way in the execution of a person. Dr. Pintz is the first such physician whose identity has come to my attention. Unless the New Mexico Board takes immediate action to suspend and revoke his license if he refuses to reverse the violent course of action which he has facilitated, the Board will have failed in its responsibility to uphold the legal and ethical principles under which it must operate.

* * *

Epilogue:

The NM Board decided to call Dr. Pintz and warn him that unless he reversed his decision to participate in the lethal injection by facilitating the acquisition of the necessary drugs, the Board might take an action against his license. Dr. Pintz recanted and the drugs which had been obtained with his permission were returned. Unfortunately for the person on death row, the drugs were nevertheless obtained without the involvement of Dr. Pintz and the execution was carried out. An important precedent was set, however, wherein a state medical board has successfully threatened a doctor-licensee against participation in an execution because the board correctly sees this as a violation of the state medical practice act as discussed in the above letter by Dr. Wolfe.

New Study Shows Low Income Minority Seniors Restrict Use of Prescription Drugs

A study of a large, nationally representative sample of older Americans, published in the December 4, 2001 issue of the *Journal of General Internal Medicine*, has found that 43 percent of those people without prescription drug coverage who are of minority ethnicity, have annual incomes of less than $10,000 and have out-of-pocket prescription drug costs of more than $100 per month reported restricting their use of prescribed medicines.

The study was conducted by researchers from the University of California, San Francisco, Department of Medicine, who collected information from a random sample of almost 5,000 Americans, 70 or older, with and without drug coverage, who regularly used prescription medicines. Even one of three risk factors—ethnicity, income and out-of-pocket drug costs of more than $100 a month—made it significantly more likely that people without prescription drug coverage would be forced to restrict their use of medications due to cost.

In the study, 20.9 percent of minority subjects, 15.6 percent of those with annual incomes under $10,000 and 13.4 percent of those with out-of-pocket prescription drug costs of more than $100 per month experienced medication restriction due to cost. Looked at from a different perspective, low-income study participants lacking prescription drug insurance were about 15 times more likely to limit their use of prescription drugs than low-income participants with full coverage.

Thus, in the absence of a prescription drug benefit, some of the country's most vulnerable seniors are most likely to go without the medicines they may need to maintain their health. The study's authors note that previous studies have shown that "policies designed to limit medication use may have serious consequences for patients' health, resulting in increased emergency department visits, nursing home admissions, [and] use of emergency mental health services."

"These findings bring to the fore the idea that when you judge societies by how they treat their most vulnerable members, the United States ranks very low," said Dr. Sidney M. Wolfe, director of Public Citizen's Health Research Group reacting to the study. "Our country fails to provide health insurance for about one-seventh of our population and fails to provide prescription drug coverage for millions of Medicare-covered older Americans who cannot afford to purchase drug coverage on their own."

The results of the study are consistent with a November 20, 2001 Harris Poll of a random sample of 1,010 adult Americans that found 39 percent of people with annual incomes of less than $15,000 a year had not filled a prescription for medicine in the previous 12 months.

Dr. Michael Steinman, the lead author of the study, works in the Department of Medicine, San Francisco Veterans Affairs Medical Center and at the University of California, San Francisco.

A copy of the Harris poll is available at: *http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2001Vol1_iss32.pdf*

What Ails the Mass. Board Of Medicine?

The following article is reprinted from the Boston Globe *and was written by Arnold S. Relman, MD, professor emeritus in the Departments of Medicine and Social Medicine at Harvard Medical School and former editor in chief of the* New England Journal of Medicine.

The front page of the Globe on January 1 had a story about the failure of the state's Board of Medicine to discipline an orthopedic surgeon with a long history of malpractice. Similar stories appear from time to time. Is the board as ineffectual in its disciplining of incompetent doctors as these stories would have you believe? And if the charge is even partly true, why is that? Having recently retired after six years on the board, I can offer some answers.

First, while not nearly as feckless as the news reports imply, the board is not providing the kind of protection against substandard practitioners that the public has a right to expect. Massachusetts is not different from many other states in this respect, but that doesn't justify its poor performance. So the answer to the first question is a qualified yes.

There are too many substandard practitioners in this state who may never even be identified, let alone reeducated or disciplined, including some who endanger their patients and ought to be removed from practice. There are many explanations, the most obvious and indisputable of which are the failure of state government to provide adequate financial support and its habit of allowing cronyism and patronage to influence appointments, policies, and operations.

Almost all of the board's budget is offset by medical licensure fees collected by the state, so the state makes essentially no contribution. The board is left underfunded, understaffed, and unable to meet all of its responsibilities. The five physicians and two "public" members on the board are overworked and vastly underpaid (they get $35 for each day they work). In addition, its professional quality and independence are often compromised by political interference that goes beyond the legitimate claims of accountability.

At least as great an impediment to the board's effectiveness are the restrictions of its actions by lawyers and some ill-conceived provisions of the law. Hospitals hire lawyers and administrators to protect them from being sued. They call it "risk management."

When the focus is on patient safety and prevention of medical mishaps, "risk management" is fine, but too often it simply becomes a legally managed cover-up of the facts. Board investigations of alleged malpractice or substandard care are often frustrated by the reluctance of hospitals to cooperate "on advice of counsel."

Such cover-up gains support from a 1987 ruling of the state's Supreme Judicial Court that the proceedings of hospital peer review committees are protected from disclosure.

Another legal obstruction to effective disciplinary action is the widely held conception that medical licensure, once granted, is the private property of the licensee and therefore can be limited or revoked only through a full legal process. Board hearings are conducted as if they were courtroom trials, with lawyers doing most or all of the talking for their physician clients. Often, testimony submitted by both sides is evaluated in separate hearings by administrative magistrates.

Contested decisions are reviewed by the courts.

But a medical license is more a privilege than a property right. It is granted and renewed by the state only after the applicant has satisfied requirements established by professionals who, while acting under state authority, are following standards that can only be established and interpreted by the profession. The application of legal procedures to medical disciplinary proceedings always delays and often stymies the process, and it risks producing a result that is medically unsound. By making licensure a property right and relying on legal process rather than on the medical judgment of the board and its consultants, the state is in effect placing the business interests of physicians ahead of the welfare of patients.

Last but not least, the Massachusetts board, like state boards generally, has to contend with the suspicion and timidity of most practicing physicians, who understandably are reluctant to become involved in an investigation of a colleague's alleged misbehavior. The board is often frustrated by its failure to gain testimony from an accused physician's colleagues and by the unwillingness of even its own expert witnesses to make judgments about the competence of a physician.

Practitioners who are whistle-blowers have little to gain from what is often a major investment of time and effort while they risk the ostracism of colleagues and possible countersuits by the accused. At the least they ought to be protected against such legal reprisals.

Given all these difficulties, the Massachusetts board does well to accomplish what it has, but under present constraints it cannot do a really good job of protecting the public interest. A good way to start improving things would be to give the board adequate financial support and greater independence and authority. Most of all, it needs some relief from the paralyzing notion that medical licensure is primarily a property right that takes precedence over public safety.

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The problems with the Massachusetts Medical Board, described by former Board member Dr. Arnold Relman, apply to a large proportion of medical boards in the United States. In our rankings of state medical boards, based on the rate of serious disciplinary actions 1000 physicians, Massachusetts has consistently been among the poorest performing boards in the country. For serious disciplinary actions it took in 2000, the state was 45th in the country and between 1991 and 2000 its rank was never higher than 37th and was as low as 48th.

FDA Action on Red Cross Long Overdue

A year ago, Public Citizen requested the U.S. Food and Drug Administration (FDA) to ask that the American Red Cross (ARC) be held in contempt of court because of longstanding, dangerous practices that are jeopardizing the safety of the U.S. blood supply. On December 13, 2001, the FDA finally made that request.

While we are pleased the government took action, it is long overdue, and we urge the court to act swiftly. Records indicate that the Red Cross has not come into compliance with a 1993 consent decree or with U.S. laws and regulations concerning blood and blood products.

The importance of having a safe blood supply cannot be overstated. The American public relies heavily on the Red Cross blood supply, and patients should know that when they receive blood, it will not be tainted. Records indicate that the ARC has improperly released blood products containing cytomegalovirus, a virus that can cause blindness in newborns. Also, FDA inspectors found that blood donors had incorrect histories and that Red Cross staff failed to follow test kit instructions for HIV.

Although the FDA insists the blood supply is safe, these findings cause grave concern. If proper procedures are not followed, it is only a matter of time before someone is seriously harmed. That would be inexcusable, particularly given the fact that the government has known about the Red Cross' violations for well over a decade. Even the ARC's former president, Dr. Bernadine Healy, said in an August 14, 2000, meeting that she found the FDA's findings "alarming" and that the severity of the situation held the potential for "grave impact" to patients, court records show.

We strongly support the efforts to hold the Red Cross in contempt of the consent decree. Unfortunately, given the lengthy history of this case, the fines that would accompany a contempt of court citation appear to be the only way the Red Cross will respond.

Canadians Begin Recall of Dangerous Drug Supplement Ephedra

On January 9, 2002, Canadian regulatory authorities announced the initiation of a voluntary recall of certain products containing the drug supplement Ephedra and one of its pure chemical constituents, ephedrine. Ephedra and ephedrine are mostly found in dietary supplements promoted for weight loss and energy enhancement. If voluntary compliance with the recall is not achieved, the option for stronger regulatory action, including the seizure of violative products, was left open.

Public Citizen's Health Research Group has already filed a petition to the Food and Drug Administration to ban all ephedrine-containing dietary supplements. You can access the petition at *www.citizen.org/publications/release.cfm?ID=7053* or by writing to us for a copy at Health Research Group, 1600 20th Street, NW, Washington, DC 20009.

The Canadian decision was reached after a risk assessment concluded that these products pose a serious health risk. Adverse events including stroke, heart attacks, heart rate irregularities, seizures, psychoses and deaths have been reported in association with the use of some products containing Ephedra or ephedrine.

This recall deals with the following types of Ephedra or ephedrine products:

1. Products having a dose of more than 8 milligrams of ephedrine or with a label recommending more than 8 milligrams per dose or 32 milligrams per day and/or are labeled or implied for use exceeding seven days.

You should not use Ephedra or ephedrine-containing drugs

2. All combination products containing Ephedra or ephedrine together with another stimulant such as caffeine and other ingredients which might increase the effect of Ephedra or ephedrine in the body.

3. Products with labeled or implied claims for appetite suppression, weight loss promotion, metabolic enhancement, increased exercise tolerance, body-building effects, increased energy or wakefulness, or other stimulant effects.

This action by the Canadian authorities is a rational regulatory policy to protect their citizens from dangerous drug supplements. In this country, the public must face alone the irrationality of an unregulated market for drug supplements because of the Dietary Supplement Health and Education Act enacted in 1994.

What You Can Do

You should not use Ephedra or ephedrine-containing drugs. They are dangerous and without a legitimate medical use.

The AMA Does It Again

The American Medical Association (AMA) has added another chapter to the seemingly endless succession of extremely poor, dangerous choices for executive vice president of the organization. The announcement that the new AMA chief executive, Dr. Michael Maves, is the former president of Consumer Healthcare Products Association (CHPA), the trade association representing the herbal, dietary supplement and over-the-counter drug (OTC) industries (presumably with the approval of the AMA's Board of Trustees), threatens to bring this troubled and dying organization from the early part of the 21st century back to the 19th century. In that earlier era, before medicines had to be proven safe and effective before being sold, patent medicines, some of which were referred to as snake oils, ruled the roost.

To the extent that CHPA now represents the herbal/dietary supplement drug companies, and to the extent that a large proportion of these products lack evidence of safety and efficacy, this appears to be another deadly embrace for the AMA.

Even in the realm of OTC drugs, CHPA funded and signed off on the design of a Yale study on the decongestant and weight reduction drug, PPA (phenylpropanolamine). But when the study showed a significant increase in hemorrhagic strokes in people using products containing the drug, CHPA—under the leadership of Dr. Maves—denounced the study. In the 1980s, the predecessor to CHPA, the Non-Prescription Drug Manufacturers Association, was instrumental in delaying the addition of warning labels on aspirin concerning the increased risk of Reye's Syndrome in children with flu or chicken pox who took aspirin. As a result of the delay, hundreds more children died or sustained brain damage.

We urge all physicians who still cling to their AMA membership—despite its embrace of the Sunbeam scandal (an uncritical proposed endorsement of products under the leadership of Dr. John Seward), the real estate scandal (under the leadership of Dr. James Sammons) and the recent predictably poor leadership of Dr. E. Ratcliffe Anderson—to resign from this dying organization, which once represented more than two-thirds of American doctors but soon will represent less than one-third. The hundreds of dollars of patients' money, which goes to pay for annual dues, could be better spent. Subscriptions to excellent medical journals such as the *Journal of the American Medical Association* are available to non-members as well as members.

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