

Health Letter

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Prescriptions And Profit

The following is the transcript of the 60 Minutes Program on March 14, 2004: Concerning Prescription Drug Prices.

It may come as no surprise that the pharmaceutical industry is the most profitable business in the country. Americans pay far more for their prescription drugs than citizens of any place on Earth.

It will also come as no surprise that as a political issue, the high price of drugs has united both Republicans and Democrats. More than a million Americans now buy their medications in Canada.

And it's no longer just older people taking buses across the border. Mayors and governors from Minnesota to Alabama are helping Americans get Canadian drugs by mail.

Such purchases are technically illegal. So far, the government has declined to prosecute individual customers or the cities and states involved. But the FDA — The Food and Drug Administration — has raised the specter of safety.

For more than a year, the FDA Commissioner, Dr. Mark McClellan, has been waging a campaign against Canadian importation. The FDA has also issued a serious warning that using Canadian drugs could be unsafe. Correspondent Morley Safer reports.

How unsafe? How common are the problems for drugs that people

are buying in Canada?

"Well, that's the problem. We don't know," says Dr. McClellan. "Because we don't have the authority to tell where these drugs have come from, or to monitor closely how they're getting into the United States. And to make sure that the drugs that come in are safe, it could be a widespread problem."

"That's a lot of hooey. There is no reason that buying drugs in Canada is any less safe than buying them in the United States," says Dr. Marcia Angell, who was executive editor of *The New England Journal of Medicine* for 11 years. She's currently writing a book on the secrets of the drug industry.

"The people who say you have to

worry about the safety of drugs from Canada are imagining the way it was in the old days. That there's a moat around the United States, that drugs that are sold in the United States are made by only American companies. And made in this country," says Angell.

"It's not that way anymore. Pfizer, for example, has 60 manufacturing sites in 32 countries. So the drugs are made all over the world. They're sold all over the world."

Most of Pfizer's anti-cholesterol drug Lipitor is made in Ireland. The same Lipitor that's sold in both U.S. and Canadian pharmacies. Other familiar drugs like Zocor, Nexium, and Prevacid are the same as the

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ones sold in Canada. They're much cheaper there because the drug companies must abide by Canadian government price controls.

Do the drug companies still make a profit?

"Oh, sure. Why else would they sell them in Canada? They're not charities. Of course they make a profit," says Angell.

The United States is the only industrialized country without some form of control on the prices of drugs. The U.S. also accounts for more than half of the industry's profits.

In order to keep those profits up, the drug companies have joined the FDA in trying to shut down imports from Canada, and Canadian pharmacies are feeling the pressure. In one pharmacy just over the border, Americans account for 30 percent of its business. They were nervous about having *60 Minutes* mention the actual name of the pharmacy.

"We've had several letters from the big multi-nationals, certainly threatening to cut off the drug supply very explicitly if you are supplying medications to U.S. patients," says the pharmacist.

This pharmacy supplies drugs to municipal workers in the city of Springfield, Mass., through a program set up by former Springfield Mayor Michael Albano.

"Major pharmaceutical companies are saying, 'We're going to limit our supply.' What does that tell you? It

tells you that they want to keep the artificially high prices in America," says Albano. "How brazen is that? It just boggles my mind that they can get away with this."

When Albano was faced with a budget crunch last year, he had to lay off firefighters, police officers, and teachers. By arranging for 3,000 city employees, retirees, and family members to buy Canadian drugs, the city can make substantial savings.

"We can save anywhere from \$4 to \$9 million on an annual basis if I get everybody enrolled and everybody goes to Canada. And that's a huge amount of money right now," says Albano. "If I can save \$9 million for my city and put it back, redirect it back into police and fire and to public education, it'll make a world of difference. So it's a huge savings."

Does he do it himself?

"I do it for my family's use. My son Mikey is diabetic. And we get his insulin and related products for diabetes from Canada," says Albano, who says that saves his family \$250 a year because there is no co-payment. "And it'll save the taxpayers who front 76 percent of the payment about \$850 a year. So it's a rather substantial savings for my family and for the taxpayers of Springfield."

The FDA says importing drugs from Canada or buying drugs from Canada is unsafe. Does Albano agree?

"The American public is not buying that safety issue. The fact is that it is getting insulting for the FDA to say that. I view myself as a responsible father," says Albano. "And I

could tell you that I would not let my son inject insulin into his body three times a day if I thought there was a safety factor here."

Mayor Albano concedes that casually buying drugs on the Internet could be risky, but says it was quite simple for him to check out his Canadian supplier, and challenges the FDA to do the same thing.

"The FDA has become a pawn of the pharmaceutical industry, that they are protecting those high profit margins. If the FDA wanted to put a plan together similar to what we're doing in Springfield, that would be good for all Americans, they can do it in 15 minutes, relative to safety," says Albano.

"We get all our medications from certified, regulated pharmacies in Canada. It's no different than going to your neighborhood pharmacy. And it's the exact same medication."

So why can't the FDA insure the safety of products from Canadian pharmaceutical exporters — and make sure that it's as safe as any product leaving an American company?

"Under current law, we don't have the authority to insure the safety of foreign produced, foreign distributed drugs," says McClellan.

So what would motivate the FDA, which is not in the business of profiting from drugs, to put out an alarm about Canadian drugs?

"The influence of the pharmaceutical industry on our government is huge. And the FDA is a part of the

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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Publicity about Recent Studies on the Cholesterol-lowering Statin Drugs: Misinterpretations

There has been an extraordinary amount of news attention focused on recent studies concerning statins and heart disease, presented at the American College of Cardiology meetings in March and, in

one case, published in the April 8, 2004 *New England Journal of Medicine*.

Without disparaging the importance of the studies themselves, we believe that spin-doctors and a scien-

tifically uncritical news media have interpreted and stretched the findings in ways that go far beyond the actual data from the studies. A few examples will illustrate this:

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executive branch of the government. And this is just the propaganda that's put out to do the drug company's bidding, to make sure that Americans don't have access to cheaper drugs," says Angell.

"Because then they'll come to know what's going on. And what's going on is that these drugs, while they're made by global companies all over the world, are sold in this country for about double what they're sold for everywhere else. And that they wanna keep secret."

"Our interest is in protecting and promoting the health of the public," says McClellan.

Of course, the whole controversy over Canadian drugs would be moot if Republican Congressman Dan Burton of Indiana had his way. During the recent debate over the Medicare bill, he co-sponsored a provision that would have legalized bringing in Canadian drugs with safeguards.

But Burton says he ran into two brick walls: the drug industry and the U.S. government: "This is a perfect example, in my opinion, of where a special interest, the pharmaceutical industry, has been able to manipulate the Congress and the government of the United States to their benefit, and to the detriment of the American taxpayer and the American people."

Since 1999, the drug industry has given more than 45 million dollars in political contributions, and it's spent hundreds of millions more on an army of more than 600 lobbyists to work its will on Capitol Hill.

Congressman Burton says the new Medicare act makes it clear the industry got its money's worth. He says billions of dollars are in it for drug companies in this new Medicare Prescription Drug Benefit.

"In the new Medicare Act, the federal government is specifically prohibited from negotiating prices with drug companies," says Safer.

"That is unconscionable. The government of the United States negotiates prices in the Defense Department, in every area of government," says Burton. "And here we are, going to spend billions and billions and billions and probably trillions of dollars on pharmaceutical products. And we cannot negotiate the prices with the pharmaceutical industry. That's just not right."

In December, surrounded by members of Congress, President Bush signed the new Medicare Act. Since 1999, these legislators have accepted more than a million and a half dollars in campaign contributions from people working in the pharmaceutical industry. President Bush alone has received more than half a million dollars.

But now, the new Medicare prescription drug benefit is being billed as a big victory for America's seniors.

"You gotta be kidding me," says Burton. "Seniors, when they find out what's in that bill, are gonna be very angry. The problem is, they're not gonna find out about it until after this next election."

The plan doesn't start until 2006. Does Burton think that will reduce the attraction of importing drugs from

Canada?

"Oh, I don't think so," says Burton. "Because even when you talk about the discount cards and the other things, you're gonna find that seniors are gonna be paying, in many cases, more than they are paying for Canadian imports right now."

60 Minutes contacted Bristol-Myers Squibb, Pfizer, Merck, Wyeth, Glaxo SmithKline, and Eli Lilly. None of them would agree to be interviewed. Safer asked Dr. Angell about the case the industry invariably makes to justify drug prices.

"This is a kind of blackmail. What they're saying is, 'Don't mess with us. Let us charge whatever we want for our drugs. Otherwise, you won't get the miracles,'" says Angell. "And the truth is that they spend less in R&D than they make in profits. And far less than they spend on marketing. And they don't make that many miracles in the first place ... The problem is, is that we're no longer getting our money's worth."

Adds Albano: "The pharmaceutical industry is gouging the American consumer. There's no other conclusion one can draw. And why should we, in this country, have to pay the highest prices in the world? Why isn't the president doing something? Why isn't Congress doing something? Someone has to wage this battle. So we're prepared to do it here."

Political pressure is building. Congress now plans to reconsider legislation that would legalize Canadian drugs. As for Dr. Mark McClellan, he is leaving the FDA and becoming President Bush's new head of Medicare and Medicaid.

Misinterpretation #1

Statins will prevent heart disease even in people who have not yet had a heart attack, stroke, angina or other kinds of cardiovascular disease if they have elevated cholesterol levels.

These recent studies are so-called **secondary prevention** studies. That is, the drugs were given to people who, in the case of one study, had been hospitalized with an “acute coronary syndrome,” meaning either a heart attack or high risk unstable angina. Although there are some earlier studies involving people without previous evidence of cardiovascular disease (angina, heart attacks, bypass surgery, angioplasty or strokes), the evidence for treatment of these people, especially with cholesterol-lowering drugs, is weaker and is known as **primary prevention**. This is especially so for those people who do not have more than one of the risk factors listed below.

These risk factors include hypertension, diabetes, smoking, obesity, or a close family history of premature heart attacks or strokes. Other predisposing risk factors include a sedentary life style and a high-fat diet. It is likely that millions of people being given cholesterol-lowering drugs such as statins for primary prevention do not have more than one of these risk factors and are only being treated because of their total cholesterol or LDL cholesterol levels.

Thus, it is extremely important to look at the global risk of cardiovascular disease rather than focusing on just the blood pressure or just the cholesterol level. For primary prevention, it is usually most prudent to attempt to improve your cardiovascular risk through sensible programs of diet and exercise.

A case example of primary prevention involving someone who will, unfortunately, more times than

not be recommended to start statins follows:

Ben is a 55-year-old man with a total cholesterol of 240 and an HDL of 50. However, his blood pressure is a normal 120/90 and he is neither a diabetic nor does he smoke. Ben turns out to have a 5-year risk of having a cardiovascular event (heart attack, stroke, etc) of only 5.1%, about one-half of the 5-year risk of over 10% that might merit drug treatment. It would be a good idea for Ben — or most people, for that matter — to adopt the non-drug approaches to lowering his cholesterol discussed above, but since his global risk is as low as it is, drug treatment is not indicated even if his total cholesterol and HDL cholesterol stay the same.

In summary, these new studies did not even examine the role of statins in primary prevention. There are many people who have had heart attacks and strokes with elevated cholesterol levels who are not being aggressively enough encouraged and helped to lower their subsequent risk with diet, exercise or statins, the very kinds of secondary prevention the studies did address.

Misinterpretation #2

The study showed that atorvastatin (LIPITOR) prevents heart attacks.

The study published in the *New England Journal of Medicine* was designed primarily to see if the subsequent occurrence of a **combination** of adverse cardiovascular events was different in those taking a high or “intense” dose of atorvastatin (LIPITOR) versus those using the “standard” dose of pravastatin (PRAVACHOL). The combination included death from any cause, a heart attack, unstable angina (chest pain) requiring hospitalization,

bypass surgery or angioplasty, or a stroke.

It is correct that the study showed that those taking atorvastatin were significantly (16%) less likely than those taking pravastatin to have any of the above events — and this is an important finding. However, there was not a significant reduction in heart attacks alone, death alone, or in the combination of death and heart attacks. The most significant reduction in the Lipitor group was in the subsequent occurrence of unstable angina requiring hospitalization.

Misinterpretation #3

The studies prove that atorvastatin (LIPITOR) is superior to pravastatin (PRAVACHOL).

As mentioned above, the purpose of the study was to see how intensive statin therapy (80 milligrams daily of atorvastatin) compared to standard therapy (40 milligrams of pravastatin) in people who had already had a cardiovascular event. There is reason to believe that the most important variable may be the intensity of the treatment rather than characteristics of the individual drugs.

Ideally, the study should have explored both the different drugs and different doses — standard or intense — of each.

Cholesterol-lowering Drugs For People 70 or Older

Aside from these recent papers, there is still some misinformation about the evidence for treating — in the form of primary prevention — elevated cholesterol levels in people over 70 years of age.

It is clear that the relationship between moderately elevated cholesterol levels and increased risk of heart disease is not as clear as people get older. As geriatricians Fran Kaiser and John Morely have written: “Given the uncertainty of the effects of cholesterol manipulation in older individuals, what should be the

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Product Recalls

February 18 — March 17, 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.

Name of Drug or Supplement; Class of Recall; Problem

BOCA PHARMACAL, INC FE C Tab Plus, (Carbonyl Iron 100 mg, Vitamin C (Ascorbic Acid) 250 mg, Vitamin B-12 (Cyanocobalamin) 25 mcg, Folic Acid 1 mg), Rx only; Class III; Mislabeling: Tablets lack the identifying debossment (ID# "G-3") on one side.

Lot #: Quantity and Distribution; Manufacturer

Lot No. 18317, Exp.10/2005; 5,000 bottles distributed nationwide; Gemini Pharmaceuticals, Inc.; Commack, NY

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CHOLESTEROL-LOWERING DRUGS, *from page 4*

approach of the prudent geriatrician to hypercholesterolemia [elevated blood cholesterol levels]? In persons over 70 years of age, lifelong dietary habits are often difficult to change and overzealous dietary manipulation may lead to failure to eat and subsequent malnutrition. Thus in this group minor dietary manipulations such as the addition of some oatmeal [or other sources of oat bran or soluble fiber] and beans and modest increases in the amount of fish eaten, may represent a rational approach. Recommending a modest increase in exercise would also seem appropriate. Beyond this, it would seem best

to remember that the geriatrician's dictum is to use no drug for which there is not a clear indication."

The use of cholesterol-lowering drugs in people 70 or older should be limited to patients with very high cholesterol levels (greater than 300 milligrams) and those who manifest cardiovascular disease (previous history of heart attack or angina, stroke). More recent reviews of this topic have reached similar conclusions: In one review, it was concluded that "unanswered questions include cholesterol treatment for primary prevention in the elderly, gender effect, and benefit of treatment in persons older than 70." There are even questions as to

whether elderly people who are hypertensive should have their cholesterol lowered by drugs. One review concluded that "Further trials are required before routinely suggesting that it is advantageous to lower cholesterol in an elderly hypertensive who does not have pre-existing evidence of coronary heart disease."

What You Can Do

If your doctor recommends a cholesterol-lowering drug, especially for primary prevention, ask on what basis this is being done. This is especially true if you either are over age 70 or have no more than one risk factor.

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

a) CombiPatch Transdermal System, (estradiol/norethindrone acetate transdermal system), 0.05/0.14 mg per day, 3 patient packs of 8 systems, 8 systems per patient pack (inner carton), and physician samples (4 x 2's) and (1 x 2's); **b) CombiPatch Transdermal System**, (estradiol/norethindrone acetate transdermal system) 0.05/0.25 mg per day, 3 patient packs of 8 systems, 8 systems per patient pack (inner carton), and physician samples (4 x 2's) and (1 x 2's), Rx Only; **c) Vivelle-dot** (estradiol transdermal system), 0.0375 mg/day, cartons of 3 patient packs of 8 systems, 8 systems per patient pack (inner carton), Rx Only; **d) Vivelle-dot** (estradiol transdermal system), 0.05 mg/day, 3 patient packs of 8 systems, 8 systems per patient pack (inner carton), 5 patient packs of 2 systems, Individual patient packs of 2, Rx Only; **e) Vivelle-Dot** (estradiol transdermal system), 0.1mg/day, 3 patient packs of 8 systems, 8 systems per patient pack (inner carton), Rx Only; Class II; OOS for estradiol and norethindrone acetate potency and impurities due to packaging components. (Stability failure).

Darvon Compound USP 32 (Propoxyphene hydrochloride 32 mg, aspirin 389 mg and caffeine 32.4 mg), 100 Pulvules, Rx only; Class III; Dissolution Failure: Aspirin and Propoxyphene hydrochloride (6 month stability).

Mysoline (primidone) Tablets, 50 mg tablets, 500 count bottles. Rx Only; Class III; Tablet hardness failure.

Paremyd Ophthalmic Solution (hydroxyamphetamine hydrobromide/tropicamide ophthalmic solution), 1%/0.25%, Sterile, in 15mL low density polyethylene bottle, Rx only; Class II; Product's degradation level exceeds specification (6 month stability).

Premarin (conjugated estrogens tablets, USP), 0.625 mg, 100 count bottles, RX only; Class III; Dissolution Failure.

Lot #: Quantity and Distribution; Manufacturer

Numerous lots; 723,639 distributed nationwide; Novartis Pharmaceuticals, Corp.; Suffern, NY

Lot Nos. 03082B, 03083B and 03084B; 4,328 distributed nationwide; Aaipharma; Wilmington, NC

Lot Number: J0300071; 3,728 bottles distributed nationwide; Xcel Pharmaceuticals, Inc.; San Diego, CA

Lot No. 3C19A, Exp. 02/05; Lot No. 3C28A, Exp. 02/05; Lot No. 2L86A, Exp. 10/04; 26,439 units distributed nationwide; Akorn Inc., Buffalo Grove, IL

Lot No. A30811; Exp. 03/05; 114,187 distributed nationwide; Richmond Division of Wyeth; Richmond, VA

CONSUMER PRODUCTS

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

Name of Product; Problem

Candleholders. The candleholders can tip over, posing a fire and burn hazard to consumers.

Childrens' Rings. The rings contain high levels of lead, posing a risk of lead poisoning to young children.

Lot #: Quantity and Distribution; Manufacturer

Tree shaped candleholders, gold metal; 300 sold nationwide by Bloomingdale's By Mail from September 2003 through December 2003; Bloomingdale's By Mail; New York, NY; (800) 472-0788

Silver with shapes including hearts and stars, with slashes of colored paint; one million sold nationwide from December 2002 through August 2003; Brand Imports LLC, Scottsdale, AZ; (800) 967-3048

C O N S U M E R P R O D U C T S *cont.*

Name of Product; Problem

Cribs. The slats on the drop side rail can loosen and detach. When this happens, the space created by the gaps can allow a baby to become entangled, strangle or fall.

Drill Charger Bases. A defective battery can cause the charger base to overheat, causing the base to melt and possibly burn nearby objects.

Fire Engine Pull-along Toys. Small parts can detach from the toy, posing a choking hazard to small children.

Gas Grills. If moisture gets inside the temperature gauge, the glass cover on the gauge can break, posing a risk of injury to people nearby.

Gas Grills. If moisture gets inside the temperature gauge, the glass cover on the gauge can break, posing a risk of injury to people nearby.

Hair Dryers. These hair dryers do not have an immersion protection device or ground fault circuit interrupter (GFCI) on the power cord, which poses a serious electrocution hazard if dropped in water.

Hair Dryers. These hair dryers do not have an immersion protection device or ground fault circuit interrupter (GFCI) on the power cord, which poses a serious electrocution hazard if dropped in water.

Industrial Cord Reels. Electric shock or fire possible because the internal grounding conductor may not be properly secured to the receptacle.

Lighters. These novelty lighters were imported without first being tested to show compliance with CPSC requirements that the lighters be child-resistant. They pose fire and burn hazards to young children.

Music Radio Boxes. A wooden turning knob and antenna top can break off, posing a choking hazard to young children and exposing a sharp point.

Snow Throwers. The blade may not stop when the blade brake control is applied, resulting in continued blade movement. The potential for injury exists if consumers make contact with the rotary blade.

Lot #: Quantity and Distribution; Manufacturer

Legacy Cribs, model numbers 16741, 21021, 23111 and 28721; 3,500 sold nationwide from March 2002 through January 2004; Child Craft Industries; Salem, IN; (888) 844-2674; www.childcraftindustries.com

Wagner cordless drill charger base including 9.6-volt, 10.8-volt, 12-volt, 14.4-volt and 18-volt; 180,000 sold nationwide from January 1996 through December 2003; Wagner Spray Tech Corp., Plymouth, MN; (800) 214-0585; www.wagnerspraytech.com

Toys are red with yellow ladder and made of wood, come with six toy fireman; 323 sold in FAO Schwarz stores nationwide from September 2002 through January 2004; FAO Schwarz Inc.; King of Prussia, PA; (888) 889-5437

Bakers & Chefs(r), Members Mark(r) and Kenmore models Gas Barbecue Grills; 162,000 sold nationwide from April 2001 through December 2002; Grand Hall Enterprise Co. Ltd.; Taiwan; (888) 735- 5709; www.grandhall.com

Char-Broil(r) Gas Grills; Commercial, Professional and Stainless Steel series; 108,000 sold from January 2002 through November 2003; Char-Broil; Columbus, GA; (866) 239-6769

Electric hand-held hair dryers, units Turbo 1650 and Turbo 2650; 500 sold in Florida from March 2003 through November 2003; Light Distribution Inc.; Miami, FL; (877) 418-1881

Electric hand-held hair dryers units Formula 2000, Energy Turbo, and Rapid 1085; 600 sold in New York from March 2003 through December 2003; Lado Co. of America; Flushing, NY; (800) 368-1130

Heavy Duty Portable Industrial Cord Reels are yellow, with carrying handle, extendable/retractable extension cord and 6 electrical outlets/plugs; 9,390 sold on Harbor Freight Tools catalogs and website from January 2000 through February 2004; Harbor Freight Tools; Camarillo, CA; (800) 444-3353; www.harborfreight.com

Nibo Space 5 (model 12679) and Nibo Space 19 (model 13919) Novelty Lighters; 313 sold nationwide from April 2003 through September 2003; Quality Fresh Cigars; Troy, MI; (800) 978-1908

"Picture Radio" song boxes; 15,600 sold nationwide from September 2003 through January 2004; Schylling Associates Inc.; Rowley, MS; (800) 767-8697; www.schylling.com

Ariens 13-Horsepower Sno-Throw(tm), Model 924506; 571 sold at Home Depot stores in U.S. and Canada from October 7, 2003 through October 24, 2003; Ariens Co.; Brillion, WI; (888) 927-4367; www.ariens.com/safety_recall

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Direct-to-Consumer Advertising: Bad News for Most Patients and Doctors

A recent study of patients and doctors has found that most people in both groups have very negative views about the impact of prescription drug direct-to-consumer (DTC) advertising campaigns, now costing the public — which ultimately pays for the campaigns — about \$3 billion a year. The study, published in the *Archives of Internal Medicine* in February, examined the attitudes of 784 doctors, in Colorado and nationally, and 500 Colorado households about many issues concerning DTC advertising.

At the most general level, 71% of public respondents did not think that DTC advertising is a positive trend in health care. For physicians, an even higher proportion, 90.2%, did not think so. Whereas 42.9 % of physicians, fewer than one-half, thought that DTC advertising made patients better informed about their medical problems, only 28.6% of the public respondents thought it made them better informed.

Only 10.5 % of the public thought that DTC advertising motivated them to seek medical care; 64.4% of physicians thought so. The authors pointed out, however, that unlike an indi-

vidual patient's experience, a physician's experience involves a large number of patients and if any of them would have demonstrably sought health care because of DTC advertising, that doctor would have had the view that the ads encourage the seeking of medical care. Similarly, although only 11.3% of public respondents thought that DTC advertising would change their expectations of their doctors' prescribing practices, 67% of doctors thought so. Only 13.3% of patients thought that DTC advertising led them to request specific information while 80.7% of doctors thought so.

The answers to more detailed questions were equally interesting. Only 45.2% of doctors and 51.6% of public respondents thought that DTC advertising did a good job of informing about adverse effects. Only 5.1% of doctors and 15.1% of public respondents thought that the ads provided enough information on other treatments. Only 1.3% of physicians and 5.4% of public respondents thought that DTC advertising provided enough information on the costs of the medications and only 3.5% of doctors and 3.2% of public respondents thought that DTC advertising

leads to a decrease in cost of medications. Fifty-three percent of public respondents (doctors were not asked this question) thought that it increases the cost of medical care. (see article in this issue entitled "Prescription Drug Ads and High Drug Prices: A Relationship?").

There were other questions that were asked only of physicians. Whereas only a minority of physicians (23.5%) acknowledged that DTC advertising changes their prescribing practices, if this is true, that translates into an enormous impact on the prescribing of new drugs, very few of which are actually superior or as good as older drugs and most of which are much more expensive than older drugs. Sixty-one percent of physicians also thought that DTC advertising increases overall drug consumption. Consistent with recent data on drastically decreased enforcement by the FDA over prescription drug advertising (an 85% decrease from 1998 through the end of 2003), 68.8% of physicians thought that DTC advertising needs better regulation. As we have said previously, largely unregulated prescription drug ads that all

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CONSUMER PRODUCTS cont.

Name of Product; Problem

Space Heaters. The power cord connection can overheat and cause the cord to separate from the space heater. This poses a fire, burn and shock hazard.

Spider Baby Toys. The round stuffed feet on the spider can detach, posing a choking hazard to young children.

Steam Cleaners. Hot water and steam can escape from the steam cleaner's handle and inner hose, posing a burn hazard to consumers.

Lot #: Quantity and Distribution; Manufacturer

Lasko space heaters, models 5500 and 5700; 186,000 sold nationwide from July 2001 through December 2003; Lasko Products Inc.; West Chester, PA; (800) 233-6373; www.laskoproducts.com/recall_heaters.html

"Webster" Activity Spider Toys, plush bug-shaped activity toys, which also can be hung from a crib, carriage or other object; 10,000 distributed nationwide from January 2002 through September 2003; Mary Meyer Corporation; Townshend, VT; (800) 451-4387

Steam Buggy Deluxe; 5,000 sold on the Home Shopping Network from June 2002 through September 2002; Tristar Products Inc.; Fairfield, NJ; (800) 649-2297; help@productsontv.tv

Comments of a Canadian Doctor

After 10 years, has anything really changed for the better?

The following article was written ten years ago and originally published in the February, 1994 issue of the Health Letter. If anything, the situation in the United States is far worse now than then, with several million more people uninsured, mainly working people, and health costs bursting through the roof. Despite \$1.6 trillion being spent on health in 2003, upwards of 45 million Americans are now uninsured. The arguments for a single payer system, freeing up hundreds of billions of dollars of administrative waste and profiteering each year continue to escalate.

Comments of a Canadian Doctor

We Americans have been living with our health care "system" (so-called) for so long that we take it for granted, warts and all, and indeed tend to overlook the warts even when complaining about them. How does this system appear to an alien — not

an alien from another galaxy, but one from next door? A Canadian physician, temporarily pursuing studies in Baltimore, MD and currently working with Public Citizen's Health Research Group, has provided this alien's eye view that may help put our own thinking about health care into sharper focus.

I just don't get it. Health care in America and the present debate regarding its reform don't make any sense to me — no way. Having grown up in Canada and gone to medical school and practiced there, I got my first exposure to U.S. medicine in 1992 when I crossed the border to study public health. Even now, with a year's stateside experience under my belt, I am still utterly baffled by what seems to be incompatibility between apparent fundamentals of the U.S. health care system and it's professed goal of improving American health.

My reaction is by no means

unique; several other Canadian physicians alongside whom I am studying are equally puzzled. Many Americans have tried diligently and patiently to explain their system to us but we are still perplexed. And to compound perplexity, even while we were struggling to understand the *American* system of health care delivery, we were challenged from every side to defend the *Canadian* one. This was not totally unexpected, but the overload of misinformation among Americans about Canadian health care definitely was. Let me explain several reasons why U.S. health care is so confusing to Canadians and try to correct some of the most common falsehoods regarding our system.

First, the U.S.

There seems to be a compulsion to link *health care* and *employment*; why? What does being employed have to do with need for health care?

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too often overstate the benefits and understate the risks can lead to inappropriate prescriptions that could arguably cause serious injury or even death to patients who would otherwise have gotten a safer and more effective drug.

The World Health Organization, referring, in part, to the expensive and powerful drug promotion campaigns by the pharmaceutical industry, has stated that there is "an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers to select and use drugs in the most rational way."

The shift toward much more DTC

advertising coincides with a tripling of the national spending on pharmaceuticals in the past 10 years. This increased use of DTC advertising comes at a time when, for understandable reasons, patients are demanding a larger and more active role in health care. This role can only be meaningful and actually helpful to the patient if the information that enables more active participation is accurate and unbiased. To place the concept of prescription drug advertising and accurate and unbiased information in the same sentence is a contradiction, and DTC advertising is an exploitation of the notion of empowerment of patients. It is a contradiction that brings to mind the words of Canadian economist Stephen Leacock in his 1924

book on advertising, *The Garden of Folly*: He defined advertising as "the science of arresting the human intelligence long enough to get money from it."

What You Can Do

The most important thing for patients or potential patients to do is to pay as little attention to DTC advertising (none would be the healthiest) as possible. We have repeatedly offered the same advice to physicians with the additional advice of not looking at **any** prescription drug advertising, including that directed only at physicians, nor wasting time meeting with drug salespeople.

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Don't the jobless also get sick? It seems to me that if you are so unlucky as to become ill enough to require health care, this may limit your opportunities for current or future employment. Those who need health care the most (for example, the chronically ill) are less likely than healthy people to be employed. President Clinton, for all his work on reform, is insistent on retaining this aspect of the status quo. Would someone else please explain, in clear and simple terms, how this linkage tends to improve Americans' health?

This leads to a second point: Why are there separate health programs for different groups: gold-plated plans for the affluent, more meager plans for the less well-off, Medicaid for the poor (some of the poor, to be strictly accurate), Medicare for the elderly and disabled? After all, people fall victim to different ailments according to age, sex, and economic status but all are susceptible to getting sick and needing care. With different programs that are at best tenuously coordinated, many people can and do fall through the cracks. Fragmenting health plans does nothing that I can see about "insuring" the public's health.

The most perplexing thing to me about American health care is this: why don't Americans demand that adequate health care be defined as a universal human right? America has led the world in establishing "rights" to many things, notable in the 1776 declaration of "life, liberty, and the pursuit of happiness," even though the right to liberty was formally abridged for a substantial part of its population for more than a century. Is it not time for a "right" to adequate health care, extended to and enjoyed by all?

And Now Canada

If America is to have a real debate about health care reform, the discussion cannot afford to be muddled up by misperceptions propagated by any side. Canada's system has

become a hot topic of debate, which has caught most Canadians off guard. This attention to our much smaller society may be flattering, but the inaccuracies involved are disturbing. When Americans begin to talk with me about health care in Canada I find myself asking: Is this my country they're talking about? It serves to

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only confuse Americans (and incidentally Canadians who watch American TV) to allow those untruths to persist. Let me clarify some of the most flagrant errors.

I have often heard it said that "*Canadians can't choose their own doctor.*" Balderdash! Canadians have the opportunity to see the doctor of their choice, not only in their own province but anywhere in the country. If a patient doesn't like the care a family doctor is providing, he or she can simply walk across the street and patronize another practitioner. Government insurance picks up the tab no matter what.

Another preposterous statement is that "*Canadians hate their system.*" Nothing could be further from the truth. Canadian politicians often refer to the system as a "sacred trust"; by broad consensus it is the most popular government program ever intro-

duced in Canada. Parenthetically, Canadians don't suffer government ministrations gladly — it is as hard for a program to gain widespread popularity in Canada as in the U.S. Canadians' contentment with their system was confirmed by a 1990 study in which 10 industrialized nations were ranked according to popular satisfaction with health care; Canada led the list, and the United States was tail-end Charlie.

Next in the litany of falsehoods is that "*doctors are government employees.*" Not so; Canadian doctors are very much independent practitioners; they can decide where they want to work, if they want to associate with a hospital, what hours they will keep, which patients they will see. Governments do not make these choices for them. However, instead of sending claims to a multitude of different insurers, they send them only to one, the provincial government. Payment rates for the varying services are set by negotiation between the governments and medical associations of the various Canadian provinces.

Canadians "*wait in line for everything*": wrong again. For the vast majority of services required by Canadians there are at most minimal waits. Most cities have an abundant supply of primary care physicians (with available lab and x-ray equipment) to take care of urgent problems and provide preventive care. Surgical waiting lists have received the most attention. What is given little notice, however, is the fact that surgery is prioritized by its urgency. For instance, Canadians have no fear that if they require an emergency appendectomy or a C-section they will get it in a timely fashion. However, they also realize that if they want a bunion removed (which they may have had for several years) they will likely wait for several months. It is a tradeoff that only a few have trouble making.

These are only a few very obvious examples of the mythology about Canada's health care system; there

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are many more. It is not my intention to instruct America on how to change its health care system: that's up to Americans to decide. What is unfair — and unfair to Americans in particular — is that they are not getting the straight facts on which to

make judgments about what the most important components of their health care system should be. Many Canadians feel relieved that Canada, unlike the U.S., has a system that provides equal access to all. Although many Canadians are tempted to gloat, Canada is being driven to

consider many health care reforms of its own mainly because Canada is much poorer than the U.S. But, when push comes to shove, if I become unfortunate enough to need serious medical attention, I would high-tail it as fast as I could back home to Canada.

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the kind of tests necessary for the FDA to accurately and comprehensively evaluate the device do not have to be done because of the much more lenient testing criteria for 510(k), substantially equivalent devices.

The understanding of medical problems and the treatment of children can not be derived simply by assuming that they are some appropriate fraction of an adult and all you need to know about them can be derived from the knowledge about what happens to an adult. Similarly, the assumption that the safety and performance of a small, miniaturized ventilator, modeled in part, after much larger ones, can be understood and predicted primarily by the testing and understanding that has been derived from the larger model may be dangerously wrong. Those tests actually done by the company on the miniaturized devices may not have been adequate to predict the problems that have occurred.

One of the more troubling and consistent problems with the Pulmonetic portable, miniaturized ventilator, according to the *Newsday* report, has been the failure to sound an alarm when the device is not functioning properly and to warn caregivers that the patient's breathing supply could be in danger. "At least 10 reports refer to incidents in which the breathing system and the alarm apparently failed simultaneously." The company's first recall of these devices, on April 4, 2000, identified 2,415 ventilators that the company said might experience alarm failures.

In its defense, Pulmonetics told *Newsday* that "We know of no incident, current or past, where a death has been conclusively attributed solely to a ventilator malfunction."

What You Can Do

Beware of using the miniaturized ventilators described above. Urge

your elected representatives to introduce legislation to significantly tighten the 510(k) loophole in the devices law that allows such devices to be approved without an adequate burden on the company to prove safety before the FDA allows them to be marketed.

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Serious Concerns about a Portable Ventilator (respirator)

A recent investigative report has highlighted serious problems with the manufacture and the FDA's regulation of a life-saving medical device, a miniaturized portable ventilator. According to an article published in the February 10th issue of New York's *Newsday* by reporter Kathleen Kerr, since 1998, when it was first approved by the FDA, there were "close to 1000 adverse event reports.... including 18 reports of deaths of people" using the lap-top sized Pulmonetic Systems portable ventilator.

The article further stated that "despite the fact that Pulmonetic has pulled back 11,458 ventilators in six recalls between 2000 and 2002 — twice because of life-threatening risks — the machine remains on the market, used by more than 20,000 people since its initial approval,

"At least 10 reports refer to incidents in which the breathing system and the alarm apparently failed simultaneously."

including children who find the smaller machine easier to use."

We believe that the origin of the problem may lie, in part, in a dangerous loophole in the FDA's regulation of medical devices. For a prescription

drug, if as little as one atom of a large molecule of a drug previously approved is changed in order for a new patent to be granted, the company seeking FDA approval for the new drug must go back to the drawing board and perform new animal and human studies to establish that the new drug is safe and effective. Quite the opposite is the case for medical devices. Under a provision in FDA's regulatory authority over devices known as 510(k), as long as a new device is "substantially equivalent" to products already on the market, the company does not have to subject the device to the rigorous testing for safety and effectiveness anywhere near as much as it would have to if it were a brand new device. Unfortunately, this can all too easily become a Catch-22. That is,

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