

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

JANUARY 2006 ♦ VOL. 22, NO. 1

Saving Money When Buying Prescription Drugs

Part III: Use Caution When Purchasing Drugs on the Internet

*The final section of this series about saving money when purchasing drugs deals with the newest way that many people have chosen to save money: the Internet. As we describe below, there are many concerns with this practice. The familiar adage applies here: Let the buyer beware. Public Citizen's Rule Five for Saving money when purchasing prescription drugs is therefore **Internet Purchase (with Caution) of Drugs and Importing Drugs from Canada.***

As is well known, the only reason that United States residents have increasingly turned to the Internet or to Canada as a source for drugs is that drug prices are out of control at home. Drug prices in foreign countries are often half of what they are for identical drugs in the United States. Unlike every other industrialized country, the United States refuses to negotiate drug prices or, as is done in Britain, negotiate a guaranteed profit margin for pharmaceuticals. In fact, we are in many respects going in the opposite direction; the recently passed Medicare prescription drug legislation actually prevents the Medicare program from using its massive purchasing power to negotiate lower drug prices.

Among its billions of pages, the Web contains a minigrowth industry in prescription drug sales. That much

of this industry has its sights trained on the United States should be no surprise: Americans use prescription drugs heavily and, thanks to the failure of the government to restrict prices or profits (as is done in most developed countries), we pay more for them.

Some consumers have responded to drug company pricing double standards by hopping a bus and heading north to Canada, but for most people in the United States, this will not be feasible. A trip to your computer terminal, however, puts you instantly in touch with dozens of drug-selling operations, all eager for your business. But can you trust them?

The General Accounting Office (GAO), an investigative branch of

Congress, recently conducted a study examining the practices of Internet pharmacy sales. The results should give pause to anyone contemplating succumbing to the allure of the less expensive products on offer on the Web.

The GAO identified 13 drugs of particular interest and filed orders with 90 different pharmacies around the world; in the end, 68 drugs were received. The top-selling drugs, including Celebrex, Lipitor, and (of course!) Viagra, were generally widely available, but drugs requiring patient monitoring to protect patient safety (Accutane, Clozaril) and narcotic pain relievers (OxyContin, Percocet) were tougher to find.

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All six pharmacies that accepted payments for the drug and then failed to fill the order were located outside of the United States or Canada. Not one of the 21 drugs obtained from outside the United States or Canada included a product label and only six contained warning information. Most improperly shipped drugs came from these countries as well: insulin that was not refrigerated, moisture-sensitive drugs that were not sealed, drugs hidden in compact disc cases, and drugs labeled as "dye and stain remover wax."

But the United States and Canadian sites were certainly not immune from problems. Sixteen of 18 Canadian drugs did not comply with U.S. regulations in that the packaging or labeling had not been approved by the FDA or the agency had not inspected the manufacturing plant. (These drugs may well have met the requirements of Canadian regulatory authorities, and Canadian labeling is quite similar to that in the United States.) However, all 29 U.S. and all 18 Canadian drugs proved to have the proper amount of the active ingredient, while four of the other foreign drugs did not.

Where the United States proved particularly inadequate was in requiring a prescription. Internet pharmacies are usually divided into three groups: (1) those to whom you have to mail a prescription; (2) those that have you fill out a questionnaire online and that, without ever examining you, dispense the drug; and (3) those that don't even maintain the pretense of a questionnaire and simply provide the drugs. Most states consider the latter two options to constitute an improper practice of medicine but have generally failed to discipline those physicians lending their names to such schemes. Only five of the 29 United States sites required a prescription, with the remainder requiring the online questionnaire. Three of the non-Canadian foreign sites required a questionnaire, but the remaining 18 simply mailed the drugs. In contrast, every Canadian pharmacy required a prescription from the patient's own physician, the most reputable option.

The United States government, at least, seems to suspect that illegal activity is rife in this industry. Fourteen of the 68 pharmacies (nine United States, one Canadian, and four from other foreign countries) were under investigation by either the United States FDA or the Drug Enforcement Administration for allegations including selling controlled substances without a prescription, lack of a doctor-patient relationship, selling adulterated or counterfeit drugs, smuggling, and mail fraud.

Given the way the drugs were obtained, it is difficult to make general statements about the reliability of different countries' Internet sites. The most reliable predictor of Web site quality appears to be whether or not it requires a prescription from your own doctor. Ironically, given the current focus on drug importation, the GAO data suggest that, on this measure at least (and assuming you are willing to accept Canadian regulatory standards as equivalent to those in the United States), if you're going to hop on a virtual Internet bus, it would be best if it were pointed North.

Importing Drugs from Canada

Spiraling drug prices have also driven desperate consumers to look to foreign countries, particularly Canada, to obtain prescription drugs at affordable prices. The FDA and the pharmaceutical industry have complained that such importation is unsafe, due to possible counterfeiting, poor quality manufacturing, and contamination. Counterfeits are a long-standing problem in United States health care, predating the importation debate by decades. The problem is not restricted to imports; domestically manufactured drugs are also all-too-frequently counterfeited or adulterated.

Yet, while the FDA continues to raise concern over counterfeiting, in part by producing misleading reports that exaggerate the problem or focus on the importation dimension of it alone, the agency is in fact part of the problem. A law that was designed to cut down on counterfeiting has, 17 years after it was passed, still not been implemented, thanks to industry-

inspired delays at the FDA.

The absurdity of the current situation can be appreciated by analogy. If a car develops a safety problem, the manufacturer has the ability to track down each car from, for example, that model-year to inform the current owner of the problem, no matter how many times the car has been resold. Incredibly, this is not possible for pharmaceuticals.

Historically, the path from a pharmaceutical manufacturer to a consumer was relatively simple: manufacturers sold to wholesalers who sold to hospitals or pharmacists who administered medications or filled prescriptions. Over the years, this path has become circuitous. Secondary wholesalers might obtain the drugs from one of the three major (primary) wholesalers and then sell it to hospitals or pharmacists. Sometimes primary wholesalers obtain drugs from the secondary wholesalers. Occasionally, secondary wholesalers procure the drugs from the manufacturers themselves. These circuitous roots to the patient provide the opportunity for counterfeiters and other fly-by-night operators to insert themselves into the process. In the process, quality assurances may be lost as drugs are not properly stored, for example.

A document could easily circulate with the batch of drugs with each resale, greatly reducing the possibility of counterfeiting or adulteration, because the perpetrator could be more easily identified. Such a document, called a pedigree, was mandated by Congress in the Prescription Drug Marketing Act (PDMA) of 1987. Even the pharmaceutical companies support it, presumably because it would protect their brands from being tarred by counterfeit knock-offs. In 1988, the FDA issued a guidance document that laid out its interpretation of the PDMA. However, the FDA did not even propose a regulation to implement the PDMA until 1994, and a final regulation was not completed until 1999. In fact, the final regulation was very similar to the 1988 guidance. It was only at that point that complaints from the drug wholesaling industry, which claimed that the paperwork would endanger their profitability, began in earnest.

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Recall Format Update

For many years, *Health Letter* has provided its readers with a list of the drugs, devices, and consumer products that have been recalled by the Food and Drug Administration. We will continue to provide this valuable information, but we have updated the format to allow more room for substantive articles.

Previously, each recall was broken into two sections and distributed into two columns. For drug and device recalls, the first column listed the item being recalled, the dose strengths of the items being recalled, whether the item was prescription or over-the-counter, the class of the recall, and the reason. The second column listed the lot numbers to which the recall applied, the number of pills being recalled and the areas in which they had been distributed, and the manufacturer of the drug and its location. Drug recalls were arranged alphabetically.

Drug and device recalls will now occupy only one column per recall.

The column will state the name of the drug and the strengths to which the recall applies, the reason for the recall, the lots to which the recall applies, and the manufacturer of the drug. Recalls will be divided into Class I and Class II recalls and alphabetized within each class. We will no longer provide information about Class III recalls. While Class I and II recalls indicate a problem which could potentially cause a serious health problem, Class III recalls are applied to drugs with minor manufacturing defects that will likely have little or no impact on the health or safety of the person using the product.

For recalls of products by the Consumer Product Safety Commission (CPSC), we have made similar alterations. In the past, the first column of the recall has listed the type of product being recalled and the reason; the second column listed the brand name, the number sold and the area and types of stores in which the items were distributed, the manufacturer and its

location, and contact information for the manufacturer. The new format will condense this information into a single column. The recall will include the type of item, the brand name and reason, and contact information for the manufacturer.

Consumers who would like more information about any particular recall can, as always, contact the issuing agency. For drugs and devices, the appropriate agency is the FDA. Consumers can call 1-888-INFO-FDA to get more information about recalls. For consumer products, consumers can reach CPSC at (800) 638-2772. The Web site <http://www.recalls.gov> also compiles information about recalls from all of the government agencies that issue them. Contact information for these agencies will, as always, be listed in each issue together with the recalls. ■

Product Recalls

November 30 — December 22, 2005

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. 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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

CLASS I Recalls

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

The Old Path "God's Herbal Blessing Tea Eye Food: God's Blessing to Mankind", 1 oz. bottles; Non-Sterility: The product was contaminated with multiple strains of bacteria and could cause eye infections and possible blindness. All lots recalled by The Old Path Natural Herbs, Inc.

CLASS II Recalls

*Indicates a problem that may cause temporary or reversible health effects;
unlikely to cause serious injury or death*

Name of Drug or Supplement; Problem; Recall Information

a) **Aspirin tablets**, 325 mg; b) **Ibuprofen tablets**, 200 mg; Microbial contamination of a non-sterile product. a) Lot numbers: 5JE0024 and 5JE0074; b) Lot number: 5HE0342 recalled by Perrigo Company.

GenTeal GelDrops Lubricant Eye Drops, Sterile 15 mL and 25 mL vials; Lack of assurance of sterility. Lot 51139 and Lot 51283 recalled by Novartis Pharmaceuticals Corporation.

Furosemide Tablets, USP, 20 mg; Adulterated; presence of foreign tablet (Labetolol Tablet 300 mg). Lot 136081 recalled by Ivax Pharmaceuticals, Inc.

Methotrexate Active Pharmaceutical Ingredient, Bulk Powder, 10kg, 10.5kg and 20kg drums; Methotrexate API contaminated with Ethylene Glycol during manufacture. Batch No. 1098057; 1097859; 1101822; 1098687 recalled by SST Corporation.

Cervical Amino Acid Cream (Urea, Methionine, Inositol, Cystine), Urea 8.34%, Methionine 0.83%, Inositol 0.83%, Cystine 0.35% Buffered to pH of 5.5 in a water-miscible cream base; Method validation deviations for finished product testing. Lot No. 40719-20, 41008 and 50609 recalled by Qualitest Pharmaceuticals, Inc.

Papain-Urea-Chlorophyllin Ointment, Contains Papain, USP (not less than 521,700 USP units per gram of ointment), Urea, USP 10% and Chlorophyllin Copper Complex Sodium, USP 0.5% in an ointment base; Method validation deviations for finished product testing. Lot no. 30314, 31216, and 40701 recalled by Cypress Pharmaceutical, Inc.

Children's Motrin Berry Suspension 4 oz. Ibuprofen 100 mg/5 ml; Presence of foreign matter: Product intended for destruction due to a lint free cloth found on an in-line screen was possibly diverted to retail stores. Lot number JFM179 recalled by McNeil Consumer & Specialty Pharmaceuticals.

Ciprofloxacin Ophthalmic Solution, USP, 0.3%; Degradation Products: Degradation level exceeds specification requirement of less than 0.2% impurities. Lot numbers GP1019, GP2332, GP2334 recalled by Apotex Corp.

Children's Motrin Grape Suspension 4 oz. Ibuprofen 100 mg/5 ml suspension; Product intended for destruction due to microbial contamination was possibly diverted to retail stores. Lot number JAM129 recalled by McNeil Consumer & Specialty Pharmaceuticals.

Pin-X Liquid, Pyrantel Pamoate (Pyrantel base 50mg/mL); USP Antimicrobial Effectiveness Failure (12 month stability). Lot # 048G04A recalled by Vintage Pharmaceuticals LLC.

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Ironically, it is among these very wholesalers that the counterfeiters lurk. Nonetheless, the FDA has "delayed" implementation of the rule five times, most recently through December 2006. Through these accumulating stalling tactics, the FDA has so far succeeded in frustrating the intent of Congress for 17 years.

This important public health issue has thus been in limbo since 1987, with the FDA never implementing its regulations but nonetheless assailing counterfeiters and importers who are

aided and abetted by the FDA's failure to regulate. Meanwhile, the secondary wholesalers practice business as usual—all at the cost of potentially exposing United States patients to counterfeit and adulterated drugs.

This leaves consumers in the lurch. On the one hand, they are besieged by rising drug prices; on the other they have been abandoned by the very agency that is supposed to protect them from counterfeiters. (The increasingly pro-industry FDA apparently is seeking to protect manufacturers' profits by preventing the importation of

less expensive drugs, an ironic stance for an administration that claims affinity to free-market principles.) For now, the best course is to write your congressperson and the FDA demanding that the congressionally mandated pedigree be implemented. If you live close to the Canadian border, a trip north to take advantage of the prices secured by a government that actually protects its residents from the profiteering of the pharmaceutical industry is probably reasonable. ■

DRUGS AND DIETARY SUPPLEMENTS

CLASS II Recalls *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

Potassium Acetate Injection, USP, Concentrated, 200 mEq (4mEq/mL); Exceeds specification for Aluminum content (12 month stability). Lot 141218, American Pharmaceutical Partners, Inc.

Zoloft (Sertraline HCl) 60 mL, oral concentrate, 20mg/mL; Presence of particulate matter: there is a potential that a small number of pouches containing the glass droppers used to dispense the medication may contain small fragments of glass. Lot numbers 0105082, 0105083 and 0105084 recalled by U.S. Pharmaceuticals Group, New York, NY.

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. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Manufacturer and Contact Information

ATVs. In **Honda Model Year 2005 and 2006 TRX400EX ATVs**, a safety defect could exist in the transmission that could allow the rider to downshift from 1st gear into reverse without operating the reverse assist (lockout) lever. The reverse lockout spring may not have been properly installed. Unintended engagement of reverse gear while moving forward could lock the rear wheels and cause the rider to lose control. American Honda Motor Corp. Inc., (866) 784-1870 or www.powersports.honda.com.

ATVs. In **Kawasaki 2005 model year Brute Force ATVs**, tie rod separation caused by either wear or severe impact can occur during operation, causing the front wheel to separate from the steering control. Separation of the tie rod can cause the rider to lose control of the ATV, resulting in a serious injury or death to the rider. Kawasaki Motors Corp., U.S.A., (866) 802-9381 or www.kawasaki.com.

Children's bicycles. The alloy frame used for **Novara Dirt Rider 20-inch 5-Speed and 6-Speed Bicycles** can be prone to fatigue failure. Frame failure results in the separation of the fork, head tube, and handlebar away from the rest of the bike causing a loss of control and crash, and posing a risk of serious injury to the rider. Recreational Equipment Inc. (REI), (800) 426-4840 or www.rei.com.

Children's books. For the **"Amazing Baby Look and Play" activity book**, the **"Amazing Baby Touch and Play" book**, and the **"Rattle, Rattle" activity book**, if the clear plastic container is removed from the book's back cover or breaks, young children can access the beads in it. This poses a choking hazard to young children. Advantage Publishers Group, (866) 748-3731 or www.advpubgrp.com.

Children's box toy. Small wooden pegs in the top corners of the **Little Tree Mini Learning Cube** can come loose posing a choking hazard to young children. Target, (800) 440-0680 or www.target.com.

Children's pajamas. The **Bobby Jack™ pajama set** fails to meet the federal mandatory standard for flammability of children's sleepwear under the Flammable Fabrics Act. This poses a risk of burn injuries to children. J & F Design, Inc., (800) 305-0510 or www.bobbyjackbrand.com.

Christmas tree topper. The **Spinning Star Christmas Tree Topper** can melt or smoke near the on/off switch, which could pose a fire hazard. Family Dollar Stores, (800) 547-0359 or www.familydollar.com.

Computer batteries. These batteries of **Dell Latitude™ D410, D505, D510, D600, D610, D800, D810; Inspiron™ 510M, 600M, 6000, 8600, 9200, 9300, XPS Gen 2; and Precision™ M20 and M70 mobile workstations** can overheat, which could pose a fire risk. Dell Inc., (866) 342-0011, www.dellbatteryprogram.com, or Dell Inc., Attn: Battery Program, 9701 Metric Blvd., Suite 200 Austin, Texas 78758.

Cribs. The screws on the wooden mattress support of **Aspen 3 in 1 Cribs**, sold under the Graco Trademark, can come loose, allowing a portion of the mattress to fall, posing a suffocation hazard to young children. Simplicity Inc., (800) 784-1982 or www.simplicityforchildren.com.

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Name of Product; Problem; Manufacturer and Contact Information

Doorway baby jumpers. The plastic clamp that attaches the **Bounce Bounce Baby! Door Jumpers** seat to a door frame can break, which can cause the unit and child to fall to the floor. This poses an injury hazard to young children. Kids II Inc., (877) 325-7056 or www.kidsii.com.

DVD Home Theater System. A problem in the circuit board of the **Toshiba 5-Disk DVD Home Theater System**, model number SD-C67HT could pose a fire hazard. Toshiba America Consumer Products LLC, (877) 290-6064 or www.tacp.toshiba.com.

DVD player batteries. The battery in **Polaroid-brand portable DVD players**, model numbers PDV-0700 and PDV-0800, can overheat and melt the plastic case while recharging, posing a fire and burn hazard to consumers. Petters Consumer Brands LLC, (866) 866-6292 or www.Polaroid.com.

Gas grills. The regulators on **Aussie™ Gas Grills**, the component that controls the amount of gas released to the burner, can leak propane when the propane cylinder is connected and open, and the grill is not in use. This poses a risk of fire and burn injuries. Meco Corp., (800) 251-7558, csr@meco.net, or www.meco.net.

Gas ranges. The **GE Monogram® 36-inch and 48-inch Professional Gas Ranges** were manufactured with a design flaw that can cause an electrical arc between the wiring and adjacent gas supply tubes at two locations in the control housing of the range, posing a fire hazard. GE Consumer & Industrial, (866) 696-7583 or <http://GEAppliances.com>.

Oil-filled heaters. Welds in the heating fins of the **Maxi-Heat™ Electric Oil-Filled Radiator Heater** can break, allowing oil to leak. This poses a burn and fall hazard to consumers. King of Fans Inc., (866) 443-1291 or www.kingoffans.com.

Pacifiers. The nipples of **Cachito Pacifiers** can detach from the base, posing a choking hazard to young children. Ideal Distributors Inc., (773) 889-2997 or rpena@fhbc.com.

Party favors and costume shield. The **Mystery Drawer and Dice Tunnel Magic Party Favors** and the dragon on the **Costume Shield** could break or crack, exposing sharp points that present a possible laceration hazard to children. Celebrate Express Inc., (888) 551-3995 <http://www.celebrateexpress.com>.

Propane heaters. There is a carbon monoxide hazard with **Legacy Propane Infrared Plaque Heaters**. A non-specification gasket around the heating plaques could allow heater carbon monoxide emissions to leak into the area in which the heater is being used. CFM Corporation, (866) 333-4833 or www.cfmcorp.com.

Ski boots. The plastic boot cuff on **Scarpa T2X Telemark Ski Boots** can crack when flexed open in an unbuckled, non-skiing position causing discomfort on the ankle or shin, making the problem evident prior to skiing and thus unsuitable for use. Black Diamond Equipment, (801) 278-5533 or e-mail scarpa@bde.com.

Whistles. The recalled **Chuck. E. Cheese plastic siren whistle's** internal pieces can detach from the toy, posing a choking hazard to children. Chuck E. Cheese's (CEC Entertainment), (888) 778-7193 or www.chuckecheese.com.

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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 Published Monthly by
 Public Citizen Health Research Group
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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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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is www.citizen.org/hrq.

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 government negotiated prices or price controls. Thus, the end of the story about the way it could have been and the beginning of the story of why tens of millions of Medicare recipients are so bewildered and confused by the market-based, competition-is-king

solution that they have not decided to participate.

Just as the ill-thought-out catastrophic coverage legislation for Medicare recipients was passed in 1988 and then repealed in 1989, as soon as enough people became aware of the dire consequences, this

Medicare Part D legislation should be promptly repealed and replaced with a real Medicare drug benefit with price controls that is both affordable and understandable. Then, like Part B of Medicare, the outpatient services benefit, almost everyone will join instead of most people staying out. ■

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The New Medicare (Part D) Drug "Benefit"

The Outrage of the Month, if not the year, is the flawed Part D Medicare Prescription Drug Benefit that goes into effect this month. Voting with their feet, the overwhelming majority of those Medicare enrollees with the option of signing up for the program had chosen not to join as of December 22, shortly before the program was to begin on January 1, 2006. As of then, only one million people had voluntarily signed up. This is in addition to the 10.6 million who were enrolled automatically by the federal government or by health maintenance organizations and 5.9 million retirees to whose drug benefit-providing employers Medicare will pay subsidies. This means that of the 25 million people not in these other programs and who are therefore able to choose whether they are in or out, only one million (4%) decided to join. Despite

this, the delusional Secretary of Health and Human Services, Michael O. Leavitt, said the data showed that "the new prescription drug benefit is off to a strong start."

After waiting more than 40 years for prescription drug coverage to be added to the other services provided by the program, the 42 million Medicare enrollees deserve something far better — simpler and less costly — than the complex and expensive disaster that characterizes this market-based program. It need not have been this way.

Approximately 10 million people on active duty in the military or covered by the Veterans' Administration receive low-cost, excellent, and relatively uncomplicated prescription drug benefits. This is possible because these government programs are run on the principle that there must be govern-

ment-negotiated prices with drug companies in order to be able to provide excellent drug coverage at an affordable price. Why were the 42 million Medicare beneficiaries not important enough for the government to provide the same kind of benefits for them?

The answer is simple: A corruption of the political process, aided and abetted by the largest and most powerful voice allegedly representing seniors, the American Association of Retired Persons (AARP), acquiescing to the drug industry's wishes and supporting the Part D benefit as it is now structured. With more than 800 lobbyists in Washington and with more than \$100 million in campaign contributions in 2003, the industry was able to insert language into the Part D legislation that essentially said there will be no

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