PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JUNE 2010 – VOL. 26, No. 6

FDA-Sanctioned International Diabetes Drug Trial Is Unethical and Dangerous, Must Be Stopped

The Food and Drug Administration (FDA) should immediately halt an international trial designed to assess the cardiovascular risks associated with the diabetes drug Avandia because enough research has been done to show that the drug is more dangerous than a similar drug, Actos, Public Citizen and a leading scientific expert in Canada said in a joint statement.

In a letter sent to the FDA May 11, 2010, Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, and Dr. David Juurlink, a Toronto researcher who led a large study in 2009 that found Avandia to be more dangerous than Actos, said that continuing the Thiazolidinedione Intervention in Vitamin D Evaluation (TIDE) trial is unethical and should be stopped.

The trial, which GlaxoSmithKline started in May 2009 at the request of the FDA, involves 137 sites in 14 countries, including 19 sites in the U.S. and 34 in Canada. During April 2010, many new sites were added in developing countries, including Chile, Mexico, Colombia, Latvia, Pakistan and India, presumably to compensate for poor enrollment elsewhere. Eighty-three sites are already recruiting subjects for the trial, which has an anticipated sample size of 16,000 subjects and a targeted completion date in 2015.

A major objective of the trial is to compare the safety risks of Avandia (generic name: rosiglitazone) with those of Actos (generic name: pioglitazone). But that question has been studied in several jurisdictions using different methodologies, and the results are in: Evidence has steadily accumulated showing the increased dangers of Avandia compared to Actos, and both drugs are more dangerous than older diabetes drugs, Wolfe and Juurlink said.

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Both drugs have been associated with a host of side effects, including macular edema, anemia, edema, congestive heart failure, myocardial infarction, bony fractures and acute liver injury, some cases of which have been fatal. Strong evidence suggests that both drugs cause edema and congestive heart failure.

However, a large body of research has shown Avandia to be more dangerous than Actos. It is more likely to cause heart failure; even FDA scientists estimate that the risk of heart failure with Avandia is roughly 50 percent higher than with Actos. Avandia also is associated with a higher risk of death than Actos.

In 2008, the American Diabetes Association and the European Association for the Study of Diabetes advised against using Avandia, and the Saudi Arabian drug regulatory agency has recently removed Avandia from the market. The FDA has ordered a black box warning to be placed on Avandia (but not Actos) because of concerns about heart attacks.

"It really does not make sense that this trial should continue," Juurlink said. "Given the gathering cloud of data regarding the risk of rosiglitazone as compared to pioglitazone, what really is the 'big picture' purpose of this trial? To see if the previous studies are right, and that rosiglitazone — which has no advantage over pioglitazone — really is more dangerous than pioglitazone? The need for certainty is not a reason to do a trial. These are patients, not guinea pigs."

Juurlink led a study, published in 2009, comparing adverse effects in 39,000 people who started using either Avandia or Actos between 2002 and 2008. Juurlink and colleagues found a significantly higher risk of congestive heart failure and death from any cause in patients taking Avandia. The authors estimated that one additional hospitalization for heart failure would occur annually for every 120 patients prescribed Avandia rather than Actos, and that one additional death would occur each year for every 269 patients treated with Avandia rather than Actos.

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Editor
Sidney M. Wolfe, MD

Managing Editor
Kate Resnevic

Contributor
Sidney M. Wolfe, MD

Graphic Designer
James A. Decker

Public Citizen President
Robert Weissman

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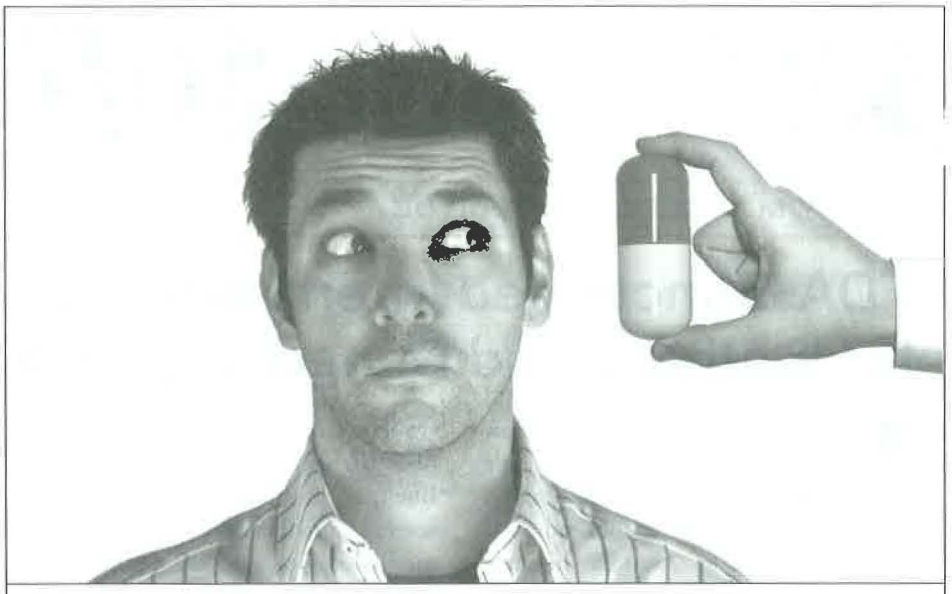

Are your medicines SAFE?

Many drugs that come to market have risks that outweigh their benefits. Others, found to have risks only after they are approved, are left on the market for dangerously long periods of time. Find out which drugs are safe — and which you should avoid — with Public Citizen's WorstPills.org and *Worst Pills, Best Pills News.*

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"Surely no patient would willingly participate in a trial in which they have a substantial likelihood of taking a drug that, in the opinion of a large group of experts, has no role in present-day therapeutics because of its risks," Wolfe said. "The trial shouldn't continue because the question has been answered. If the trial continues, the health of thousands of patients will be jeopardized. It is unethical to continue this trial. As unethical as it is in developed countries such as the U.S. and Canada, it is even more unconscionable to subject people in developing countries such as Chile, Mexico, Colombia, Latvia, Pakistan and India to a drug known to be more dangerous than the drugs it is being compared to."✦

Severely Mentally Ill More Likely to Be in Jails Than Hospitals, Report Shows

The report mentioned in the following press release can be found on the website of the Treatment Advocacy Center (TAC; www.treatmentadvocacycenter.org), a national nonprofit organization dedicated to eliminating barriers to the timely and effective treatment of severe mental illnesses. TAC promotes laws, policies and practices for the delivery of psychiatric care and supports the development of innovative treatments for and research into the causes of severe and persistent psychiatric illnesses, such as schizophrenia and bipolar disorder.

TAC takes no money from pharmaceutical companies. The American Psychiatric Association awarded TAC its 2006 presidential commendation for "sustained extraordinary advocacy on behalf of the most vulnerable mentally ill patients who lack the insight to seek and continue effective care and benefit from assisted outpatient treatment."

E. Fuller Torrey, M.D., author of the study described below, has been a long-term colleague of Public Citizen. He and Sidney Wolfe, M.D., editor of this publication, co-authored the 1990 study "Care of the Seriously Mentally Ill: A Rating of State Programs," as well as the 1991 report, "Criminalizing the Seriously Mentally Ill."

Americans with severe mental illnesses are three times more likely to be in jail or prison than in a psychiatric hospital, according to "More Mentally Ill Persons Are in Jails and Prisons Than Hospitals: A Survey of the States," a new report by the Treatment Advocacy Center and the National Sheriffs Association.

"America's jails and prisons have once again become our mental hospitals," said James Pavle, executive director of the Treatment Advocacy Center, a nonprofit dedicated to removing barriers to timely and effective treatment of severe mental illnesses. "With minimal exception, incarceration has replaced hospitalization for thousands of individuals in every single state."

> **"If societies are judged by how they treat their most disabled members, our society will be judged harshly indeed."**
> **— E. Fuller Torrey, M.D.**

The odds of a seriously mentally ill individual being imprisoned rather than hospitalized are 3.2 to 1, state data show. The report compares statistics from the U.S. Department of Health and Human Services and the Bureau of Justice Statistics collected during 2004 and 2005, respectively. The report also found a very strong correlation between those states that have more mentally ill persons in jails and prisons and those states that are spending less money on mental health services.

Severely mentally ill individuals suffering from diseases of the brain, such as schizophrenia and bipolar disorder, often do not receive the treatment they need in a hospital or outpatient setting. The consequences can be devastating — homelessness, victimization, incarceration, repeated hospitalization and death.

"The present situation, whereby individuals with serious mental illnesses are being put into jails and prisons rather than into hospitals, is a disgrace to American medicine and to common decency and fairness," said study author E. Fuller Torrey, M.D., a research psychiatrist and founder of the center. "If societies are judged by how they treat their most disabled members, our society will be judged harshly indeed."

Recent studies suggest that at least 16 percent of inmates in jails and prisons have a serious mental illness. According to author and National Sheriffs Association Executive Director Aaron Kennard, "Jails and prisons are not designed for treating patients, and law enforcement officials are not trained to be mental health professionals."

Ratios of imprisonment versus hospitalization vary from state to state, as the report indicates. On the low end, North Dakota has an equal number of mentally ill inmates in hospitals as in jails or prisons. By contrast, Arizona and Nevada have 10 times as many mentally ill inmates in prisons and jails than in hospitals.

Among the study's recommended solutions are for states to adopt effective assisted outpatient treatment laws to keep individuals with untreated brain disorders out of the criminal justice system and in treatment. Assisted outpatient treatment is a viable alternative to inpatient hospitalization because it allows courts to order certain individuals with brain disorders to comply with treatment while living in the community. Studies show assisted outpatient treatment drastically reduces hospitalization, homelessness, arrest and incarceration among people with severe psychiatric disorders, while increasing adherence to treatment and overall quality of life.

Data on prisoners for "More Mentally Ill Persons in Jails and Prisons Than Hospitals," were obtained from the Bureau of Justice Statistics' "Prison and Jail Inmates at Midyear 2005." Data on the number of inpatients in public psychiatric hospitals, private psychiatric hospitals` and the psychiatric units of general hospitals were obtained from the 2004 Inventory of Mental Health Organizations, carried out by the Substance Abuse and Mental Health Services Administration under the U.S. Department of Health and Human Services. ✦

Product Recalls
April 15, 2010 - May 11, 2010

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.

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Bromodrol Tablets, Bromodrol Growth Complex, [Green Tea (Polyphenols), Hoelene, Bergamottin, Bupleurum, 6 Bromo 3, 17 di-oxoetioallochalane, Nettle Root, Chrysin, Saw Palmetto, Schizandra Berry, Wild Yam, Safed Musli] 531 mg, 60-count foil packed in a box, UPC 6 75941 00250 7. Volume of Product in Commerce: Unknown. Marketed Without An NDA/ANDA: product contains undeclared steroids or steroid-like substances, making them unapproved new drugs. All lots, CU32. Innovative Health Products, Inc.

Dual Action Grow Tabs Capsules, Proprietary Testopen Blend, (Kudzu root, Green Tea, zinc aspartate, Pygeum africanum extract, Stinging nettle leaf extract, 17 alpha methyl 17 beta hydroxyl 5 alpha androst 2 ene, 4 Androstene 4 chloro 17 alpha methyl 3 beta 17 beta diol, Urtica Dioca, Tongkat Ali (Malaysian Eurycoma Longifolia Jack), Dodder Seed) 250 mg, Bergamottin 50 mg, Bupleurum 50 mg, Hoelen 50 mg, 60-count foil packed 582 mg capsules in a box, UPC 6 75941 00252 1. Volume of Product in Commerce: Unknown. Marketed Without An NDA/ANDA: product contains undeclared steroids or steroid-like substances, making them unapproved new drugs. All lots, CW-68, DA-90. Innovative Health Products, Inc.

Mass Tabs Capsules, Proprietary Mass Tabs Blend, (Kudzo Extract 40%, Trifolium Pratense Extract 8%, Fenugreek Seed Powder, Tibulus Terrestris Extract 40%, MethylSten (17-beta-hydroxy-2-alpha, 17-dimethyl-5-alpha-androstan-3-one azine), Avena Sativa Extract 10:1, Pygeum africanum Bark Extract 4:1, Milk Thistle, Maca Powder Extract .6%, Epidmedium Leaf, Bacopa Monniera Extract 4:1, Rhodiola Rosea 3%, Nettle Leaf Powder) 87,000 mcg, 30-count bottles and 60-count bottles; UPC 6 75941 00149 4. Volume of Product in Commerce: Unknown. Marketed Without An NDA/ANDA: product contains undeclared steroids or steroid-like substances, making them unapproved new drugs. All lots purchased during or after 04/2009, Lot #s: 1022, 0205 and 81509.

Pai You Guo, 10 g tea packs individually packaged in a pouch, 18-count pouches per box, Produce: A Medicine Industry Group Company. Volume of Product in Commerce: Unknown. Marketed Without An Approved NDA/ANDA: The recall was initiated because PAI YOU GUO, a weight loss dietary supplement, sold and marketed by the firm was found to contains undeclared drug ingredients. All products shipped between 04/01/2009-09/30/2009. GMP Herbal Products, Inc.

Pai You Guo Slim Capsule, 30-count box, Produce: A Medicine Industry Group Company. Volume of Product in Commerce: Unknown. Marketed Without An Approved NDA/ANDA: The recall was initiated because PAI YOU GUO, a weight loss dietary supplement, sold and marketed by the firm was found to contains undeclared drug ingredients. All products shipped between 04/01/2009-09/30/2009. GMP Herbal Products, Inc.

Ripped Tabs TR Capsules, Anabolic Amplifier Proprietary Blend, (Hoenelen, Buplurium, Bergamottin) 300 mg, Energy XT Proprietary Blend (Green Tea, Caffeine USP, Mateine) 500 mg, anabolic Cutter Blend (1,3,7-trimethyl-1H-purine-2,6(3H,7H) dione, 19 Norandrosta 4, 9 diene 3, 17 dione, Juniper Berry, Cornsilk Stylus, Bulgarian Tribulus Terrestria (Standardized at a 25% saponin content), Fenugreek seed, Theine, Acetyl-L Carnitine, Zinc (as zinc aspartate), Stinging nettle leaf, Maca Root, Eurycoma Longifolia, Couchgrass Rhizome) 257 mg, 60-count bottle, UPC 675941001623. Volume of Product in Commerce: Unknown. Marketed Without An NDA/ANDA: product contains undeclared steroids or steroid-like substances, making them unapproved new drugs. All lots, Lot 6597010. Innovative Health Products, Inc.

Ripped Tabs TR Tablets, Anabolic Amplifier Proprietary Blend, (Hoenelen, Buplurium, Bergamottin) 300 mg, Energy XT Proprietary Blend (Green Tea, Caffeine USP, Mateine) 425 mg, Anabolic Cutter Blend (1,3,7-trimethyl-1H-purine-2,6(3H,7H) dione, 19 Norandrosta 4, 9 diene 3, 17 dione, Juniper Berry, Cornsilk Stylus, Bulgarian Tribulus Terrestris (Standardized at a 25% saponin content), Fenugreek seed, Theine, Acetyl-L Carnatine, Zinc (as zinc aspartate), Stinging nettle leaf, Maca Root, Eurycoma Longifolia, Couchgrass Rhizome) 234 mg, 60-count Foil Packed Tablets in a box, UPC 6 75941 00162 3. Volume of Product in Commerce: Unknown. Marketed Without An NDA/ANDA: product contains undeclared steroids or steroid-like substances, making them unapproved new drugs. All lots purchased during or after 12/2008, Lot #: CW-20, CY-64. Innovative Health Products, Inc.

Rock Hard Weekend Capsules, 1 capsule per blister card (UPC 0 94922 14725 7), 3-count bottle (UPC 0 94922 20870 5), and 8-count bottle (UPC 0 94922 14724 0), Made in the USA. Volume of Product in Commerce: 250,000 capsules (blisters and bottles). Marketed Without an Approved NDA/ANDA: The product is an unapproved new drug because the product contains sulfoaildenfil. Blister Pack Lot #s T12 705 08 (exp. date: 10/2011); Lot # T12 705 09 (exp. Date: 03/2012, 08/2012); 3-ct Bottle (UPC 0 94922 20870 5): R417 0509 (exp. date: 09/2012); 8-ct Bottle (UPC 0 94922 14724 0): T237 0509 (exp. date: 06/2012). Atlas Operations, Inc.

Recalls and Field Corrections: Drugs – Class II

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

Benadryl Allergy (Diphenhydramine HCL / Antihistamine) Tablets, 25 mg, 148 Ultratab Tablets per bottle, NDC 505580-226-14. Volume of Product in Commerce: 258,720 bottles. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Lots #s: AAA422 exp. date 11/30/2010, AJA094 exp. date 05/31/2011, ABA392 exp. date 11/30/2010, and ALA034 exp. date 06/30/2011. McNeil Healthcare, LLC.

Digoxin Tablets, USP, 125 mcg (0.125 mg), 1000 count bottle Rx only; NDC 0143-1240-10. Volume of Product in Commerce: 3,894 bottles. Superpotent (Single Ingredient Drug): West-Ward received a complaint from a pharmacist stating that some tablets of Digoxin in a bottle of 1000 tablets were thicker than others. Lot # 66873A, exp. date 05/2011. West-ward Pharmaceutical Corp.

Diovan HCT (Valsartan and Hydrochlorothiazide) Tablets, USP, 320 mg/25 mg per tablet, 30 tablets count blister card, Rx only, NDC 0078-0472-15. Volume of Product in Commerce: 11,964 cartons of 6 shellpaks. Labeling: Incorrect Lot No(s): One of the two NDC numbers on the unit-dose blister-card is incorrectly printed as 0078-0471-15, which corresponds to Diovan HCT 320mg/12.5mg Tablets. Lot #s: F0172 (exp. date 02/2011), F0179 (exp. date 02/2011), F0179A (exp. date 02/2011), and F0198 (exp. date 05/2011). Novartis Pharmaceuticals, Corp.

Extra Strength Rolaids Antacid (Calcium Carbonate & Magnesium Hydroxide) Freshmint Tablets, 675 mg/135mg, 100-count bottle, NDC 50580-746-01, UPC 312547650212, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Extra Strength Rolaids Antacid (Calcium Carbonate & Magnesium Hydroxide) Fruit Tablets, 675 mg/135mg, 100-count bottle, NDC 50580-744-01, UPC 312547650243, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Extra Strength Rolaids Antacid (Calcium Carbonate & Magnesium Hydroxide) Tropical Punch Tablets, 675 mg/135mg, 100-count bottle, NDC 50580-745-01, UPC 312547654234, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Fluticasone Propionate USP Nasal Spray, 50 mcg per spray, 16 g net fill weight, 120 Metered Sprays per bottle, Rx Only; NDC 60505-0829-1. Volume of Product in Commerce: Unknown. Presence of Foreign Substance(s): Product is being recalled due to possible contamination with metal fragments. Lot #: JJ7064, exp. date 01/12. Apotex Inc.

Glycopyrrolate Tablets, USP, 1 mg, 100 count bottle, Rx only. NDC# 64980-131-01. Volume of Product in Commerce: Unknown.

Impurities/Degradation Products: An investigation had determined that some lots of Glycopyrrolate 1 mg and 2 mg Tablets have the potential to exceed specifications for Impurity-I content over the shelf life of the product. Lot #: CPA964 exp. date 12/2010; 100991 exp. date 05/2011; 101560 exp. date 06/2011. Corepharma LLC.

Glycopyrrolate Tablets, USP, 2 mg, 100 count bottle, Rx only. NDC# 64980-132-01. Volume of Product in Commerce: Unknown. Impurities/ Degradation Products: An investigation had determined that some lots of Glycopyrrolate 1 mg and 2 mg Tablets have the potential to exceed specifications for Impurity-I content over the shelf life of the product. Lot #: CPL7117 exp. date 01/2010, CPE854 exp. date 05/2010, CPF878 exp. date 06/2010, CPL823 exp. date 11/2010, CPA965 exp. date 12/2010, CPA966 exp. date 12/2010, 101039 exp. date 05/2011, exp. date 101540 06/2011. Corepharma LLC.

Metoprolol Tartrate Tablets, USP, 50 mg, 1000 count bottles, Rx only. NDC 63304-580-10. Volume of Produce in Commerce: 1,941 bottles. Tablet thickness: Metoprolol tablets may be out of specification for tablet thickness. Lot #: CGR9009AC, exp. date 05/2011. Ipca Laboratories Limited.

Motrin IB (Ibuprofen) Tablets, USP 200mg Coated Caplets, Pain Reliever/Fever Reducer (NSAID), a) 24-count bottles, NDC 50580-110-03, UPC 300450481030; b) 24+6-count bottle, NDC 50580-110-64, UPC 300450481641; c)50-count bottle, NDC 50580-110-02, UPC 300450481023; d) 100- count bottle, NDC 50580-110-01, UPC 3004850481016; e) 100+25-count bottle, NDC 50580-110-95, UPC 300450481955; f) 100+50-count bottle, NDC 50580-110-75, UPC 300450481757; g) 225-count bottle, NDC 50580-110-62, UPC 300450481627; h) 300-count bottle, NDC 50580-110-37, UPC 300450481375, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Motrin IB (Ibuprofen) Tablets, USP 200mg, Pain Reliever/Fever Reducer (NSAID), a) 24-count bottle , NDC 50580-109-02, UPC 300450463029; b) 50-count bottle , NDC50580-109-03, UPC 300450463036; c) 100-count bottle, NDC 50580-109-04, UPC 300450463043; d) 100+25-count bottle, NDC 50580-109-29, UPC 300450463296; e) 100+50-count bottle, NDC 50580-109-75, UPC 300450463753, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Motrin Junior Strength for Ages 6-11 (Ibuprofen) Tablets, 100mg, Pain Reliever/Fever Reducer (NSAID), Grape Flavored Chewable Tablets, 24-count bottle, NDC 50580-909-24, UPC 300450909244, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Motrin Junior Strength for Ages 6-11 (Ibuprofen) Tablets, 100mg, Pain Reliever/Fever Reducer (NSAID), Easy-to-Swallow Caplets, 24-count bottle, NDC 50580-498-24, UPC 300450498243, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Motrin Junior Strength for Ages 6-11 (Ibuprofen) Tablets, 100mg, Pain Reliever/Fever Reducer (NSAID), Orange Flavored Chewable Tablets, 24-count bottle, NDC 50580-207-24, UPC 300450494245, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Original Rolaids Antacid (Calcium Carbonate & Magnesium Hydroxide) Peppermint Tablets, 550 mg / 110 mg, 150-count bottle, NDC 50580-772-15, UPC 312547651185, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Rolaids Antacid (Calcium Carbonate & Magnesium Hydroxide) Cherry Tablets, 550mg / 110mg, 150-count bottle, NDC 50580-773-15, UPC 312547652421, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

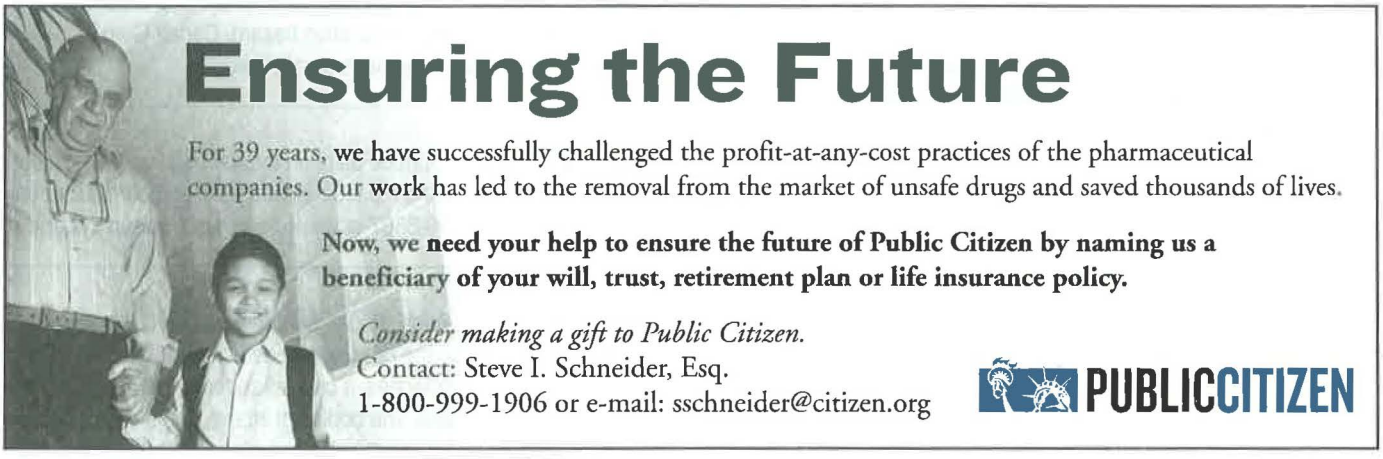
Rolaids MULTI-SYMPTOM Antacid & Antigas (Calcium Carbonate, Magnesium Hydroxide & Simethicone) Berry Tablets, 675 mg/135 mg/80 mg, 100-count bottle, NDC 50580-748-01, UPC 312547654579, OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Multiple lots. McNeil Healthcare, LLC.

Simply Sleep Nightime Sleep Aid Contains Diphenhydramine HCL, caplets. 25 mg, 100 count bottle, NDC 50580-843-10. Volume of Product in Commerce: 1,173,744 bottles. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2, 4, 6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. Lots #s: ADM015 exp. date: 02/28/2011, ADM016 exp. date 02/28/2011, AFM014 exp. date 12/31/2010, AFM352 exp. date 02/28/2011, AJM319 exp. date 05/31/2011, AJM364 exp. date 07/31/2011, ALM387 exp. date 07/31/2011, AMM436 exp. date 07/31/2011, and AMM438 exp. date 10/31/2011. McNeil Healthcare, LLC.

Spironolactone Tablets, USP 25 mg, 100-count bottle (NDC 0603-5763-21), 500-count bottle (NDC 0603-5763-28), Rx only. Volume of Product in Commerce: 20,413 bottles. Subpotent (Single Ingredient Drug): out of specification (OOS) stability results for assay 94.2% (specification 95.0-105.0%) at the 6-month time point. Lot #s: T118F09A, exp. date 08/2011; T118F09B, exp. date 08/2011. Vintage Pharmaceuticals, LLC.

St. Joseph Chewable Aspirin (Aspirin) Orange Flavored Chewable Tablet, 81 mg, a) 36-count bottle, NDC 50580-173-36, UPC 300450173362 b) 3x36- count bottle, NDA 50580-173-08, UPC 300450173089; OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. a) Lot # APM440, exp. date 06/30/2011; AMM325, exp. date 09/30/2011; and APM430, exp. date 10/31/2011; b) AFM360, AHM423, exp. date 06/30/2011; ALM346, exp. date 08/31/2011; and AMM434, exp. date 09/30/2011. McNeil Consumer Healthcare.

St. Joseph Safety Coated Aspirin (Aspirin) Enteric Coated Tablet, 81 mg, a) 36-count bottle, NDC 50580-126-36, UPC 3 0045012636 8; b) 100-count bottle, NDC 50580-126-10, UPC 3 0045012610 8; c) 180-count bottle, NDC 50580-126-18, UPC 300450126184 d) 300- count bottle, NDC 50580-126-03, UPC 30045012630; OTC. Volume of Product in Commerce: Unknown. Chemical Contamination: The product recall was initiated after identifying an uncharacteristic smell and taste associated with the presence of a chemical called 2,4,6,-tribromoanisole. The source of this chemical is believed to be from the breakdown of a chemical compound used to treat the wood pallets that are used for the transportation and storage of packaging materials. a) Lot # AFM026, AHM327, exp. date 04/30/2011; AHM432, exp. date 06/30/2011; AJM321, ALM327, exp. date 07/31/2011; AMM324, exp. date 08/31/2011; APM349, and APM420 exp. date 10/31/2011; b) Lot #.AEM050, exp. date 03/31/2011; AHM374, exp. date 06/30/2011; AJM320, AJM402, exp. date 07/31/2011; ALM341, AMM365, exp. date 08/31/2011; AMM366, AMM367, exp. date 09/30/2011; APM350, and APM351, exp. date 10/31/2011; c) Lot # AMM323, AMM433, exp. date 08/31/2011; and APM304, exp. date 09/30/2011; d) Lots #: AHM368, ALM377, exp. date 06/30/2011; ALM378, AMM354, exp. date 08/31/2011; and APM427, exp. date 09/30/2011. McNeil Consumer Healthcare.



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 CPSC call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Recall Information

2010 26" Epic and 26" Era Bicycles. The shock absorber mount can break and the shock absorber can make contact with the wheel spokes, posing a fall hazard to the rider. Specialized Bicycle Components Inc., (877) 808-8154 or www.specialized.com.

Baby Swimsuits. The swimsuits have halter straps that were manufactured too short causing the plastic ring located at the neck of the swimsuit to press against the child's throat and obstruct the airway. This poses a strangulation hazard to the child. Gap Inc., (888) 747-3704 or www.gap.com.

Baby Walkers. The walkers can fit through a standard doorway and are not designed to stop at the edge of a step. Babies can be seriously injured or killed. Le Hing Inc., (626) 575-8566.

"Best Friends" Charm Bracelet Sets. The heart lock charms attached to the bracelets contain high levels of cadmium. Cadmium is toxic if ingested by children and can cause adverse health effects. Claire's Boutiques Inc., (866) 859-9281 or www.claires.com.

BRP Ski-Doo Snowmobiles. The drive pulley bolts on the snowmobiles can break due to oil contamination during the assembly process. This can cause debris to come off the vehicle and act as projectiles, posing a laceration hazard to riders or bystanders. Bombardier Recreational Products Inc., (800) 366-6992 or www.brp.com.

Buoyancy Compensators Used for Scuba Diving. The buoyancy compensator seal ring could crack, posing a drowning hazard to divers. Ocean Management Systems Inc., (877) 791-0315 or www.omsdive.com.

Chain Sets Sold With Metalux Light Fixtures. An "S" hook on the chain connecting the fixture to the ceiling can straighten when subjected to high impact forces, resulting in the light fixture falling. This poses an injury hazard to consumers. Cooper Lighting LLC, (800) 954-7228 or http://www.metalux-lighting.com/.

Children's Hooded Sweatshirts With Drawstrings. The sweatshirts have a drawstring through the hood that can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Gogo Sports Inc., (877) 785-1915 or www.gogofleece.com.

Children's Hooded Sweatshirts With Drawstrings. The sweatshirts have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Polar Bear Gift Shop, (907) 274-4387 or www.polarbeargifts.net.

Children's Hooded Sweatshirts. The children's jackets have drawstrings through the hood which pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. GJC International of Florida Inc., (954) 581-4646.

Children's Hooded Velour Sweatshirts With Drawstrings. The hooded sweatshirts have a drawstring at the neck which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. JD Fine & Company, (925) 521-3300 or www.sweettartgirl.com.

Chopper-Style Bicycles. The bicycle stem on the handlebars can crack and cause the rider to lose control, posing a risk of serious fall and injury. Nirve Sports Ltd., (888) 296-4783 or www.nirve.com.

Compact Hair Dryer. The spinning fan within the hair dryer can break apart, striking the hair dryer's plastic shell. This causes the plastic to shatter, creating a laceration hazard. Conair Corp., 800-687-6916 or www.babylissus.com/recall052.

Double Egg Shakers. Surface paint on the red eggs contains excessive levels of lead, violating the federal lead paint standard. Discount School Supply, (800) 606-3807 or www.discountschoolsupply.com.

Drop-Side Cribs. The cribs' drop-side hardware can disengage from the tracks, causing the drop side to detach from the crib. When the drop-side partially detaches, it creates space between the drop side and the crib mattress. The bodies of infants and toddlers can become entrapped in the space, which can lead to strangulation and/

or suffocation. Complete detachment of the drop sides can lead to falls from the crib. In addition, slats can detach from the sides of the cribs. Infants and toddlers can then become entrapped, strangle or fall out of the crib. C&T International/Sorelle, (877) 791-9398 or www.candtinternational.net.

Girls' Hooded Jackets. The hooded jackets have a drawstring through the hood that can pose a strangulation hazard to children. The sweater jackets have a drawstring through the waist that can pose an entanglement hazard to children. In February 1996, CPSC issued guidelines (which were incorporated into an industry voluntary standard in 1997) to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Trendset Originals LLC, (800) 908-8308 or www.trendsetny.com.

Girls' Hooded Sleeveless Vests. The garments have a drawstring through the hood which can pose a strangulation hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. MIM-PI USA LLC, (407) 492-8361 or www.mim-pi.com.

Graco®-Branded Drop Side Cribs Made by LaJobi. The drop side hardware can break or fail, allowing the drop side to detach from the crib. When the drop side detaches, a hazardous gap is created between the drop side and the crib mattress in which infants and toddlers can become wedged or entrapped, posing a risk of suffocation and strangulation. In addition, children can fall from the cribs when the drop side detaches or fails to lock. LaJobi Inc., (888) 842-2215 or www.LaJobi.com.

Mares Nemo Air Dive Computers. An O-ring in the high pressure air connector can fail and leak air, causing a continuous but slow loss of breathing gas, which could require a diver to surface quickly, posing a drowning hazard to divers. Mares USA, (800) 874-3236 or www.mares.com.

Mattress Sets (Mattresses and Mattresses with Foundations). The mattress sets fail to meet mandatory federal open flame standard and pose a fire hazard to consumers. Tropical Bedding Mfg., (787) 586-1139.

Nordic Track Revitalize, Gold's Gym, and Weider Club Inversion Benches. The ankle clamp can release unexpectedly or the strap used to limit rotation can break, posing a fall hazard to consumers. ICON Health & Fitness Inc., (866) 506-9095 or www.iconfitness.com.

Rechargeable Batteries Sold With Portable DVD/CD/MP3 Players. The rechargeable batteries can overheat, posing a hazard to consumers. Coby Electronics Corp., (866) 945-2629 or www.cobyusa.com.

Roberta Roller Rabbit Children's Kimono Robe, Lounge Sets and Slumber Short Sets. The recalled sleepwear fails to meet the federal children's sleepwear flammability standard, posing a burn hazard to children. Roberta Roller Rabbit, (877) 449-0604 or www.RobertaRollerRabbit.com.

Roman Shades. Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Blair LLC, (877) 392-7095 or www.blair.com.

SCAN Andersen 10 Wood Burning Stove. The stove's door can dislodge and fall from its hinges, posing a risk of injury to consumers. Jotul North America, (800) 797-5912, ext. 108 or www.jotul.com.

Sport Cap 2.0 Water Bottle Spouts. The water bottle spouts can break or crack, posing a choking hazard. Klean Kanteen Inc., (877) 546-9063 or www.kleankanteen.com/safetynotice.

Step2® Basic Rhythms Drums™. The plastic clips used to attach the drumsticks to the drum can break. The small broken pieces present a choking to young children. The Step2 Company LLC, (866) 860-1887 or www.step2.com.

Targus Universal Wall Power Adapters for Laptops. Faulty wiring can cause the connector tips to heat and melt the plastic encasing the connector tips, posing a burn hazard to consumers. Comarco Inc., (877) 781-5186 or www.regcen.com/comarcorecall.

TechnoSkin Foam Balls and Sportime TechStitched Soccer Balls. Surface paints on the sports balls contain excessive levels of lead which is a violation of the federal lead paint standard. Sportime, (888) 388-3224 or www.schoolspecialty.com.

Yamaha All-Terrain Vehicles (ATVs). The steering column support assembly can crack and cause the rider to lose steering control, posing a risk of injury or death to riders. Yamaha Motor Corporation U.S.A., (800) 962-7926 or www.yamaha-motor.com.

A Doctor's Word: How to Keep Your Blood Pressure Down

By Erin N. Marcus, M.D.

Erin N. Marcus is a general internist at the University of Miami Miller School of Medicine and a freelance writer whose work has appeared in The New York Times, The Washington Post, *and* The New England Journal of Medicine's *Perspective section. She is the recipient of a Ford Foundation grant to write about health issues affecting disadvantaged populations, and writes a regular health column for New America Media, the nation's largest association of ethnic media outlets.*

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When her gynecologist told her she had high blood pressure, Marie Alcindor had a simple solution: switch doctors. After all, she had gone to him for a different problem, and this was the first time he had ever checked her blood pressure.

"He said, 'Oh my God, you're like a bomb waiting to explode.' I said, 'I didn't come here for that, I came here for something else,' " she explained.

Two years later, Marie went to see her general medical doctor, who was also a family friend. "He looked me dead in my face and said, 'I've known you since you were a teenager and you don't want to die. Would you like somebody to be wiping the dribble from your mouth, would you like to walk with a dragging foot?' "

This time, she heeded her doctor's warning. She began the medications he prescribed, even though she didn't like taking pills. She also began making changes in her everyday life. These behavioral changes, or "lifestyle modifications," are recommended by the federal government's National High Blood Pressure Education Program (NHBPEP). The program also recommends these changes for people with "pre-hypertension," blood pressure that's above normal but not yet in hypertensive range (120-139 for the top, or systolic, number, and 80-89 for the bottom, or diastolic, number).

Lifestyle changes alone aren't sufficient for many people with high blood pressure. But combined with medicine, they worked for Marie. After two years, her blood pressure fell to the normal range, and she no longer needs pills. The headaches and shortness of breath that she used to experience have also receded.

High blood pressure is rampant, and it's one of the most common reasons why people develop strokes, heart problems and kidney failure.

High blood pressure is rampant, and it's one of the most common reasons why people develop strokes, heart problems and kidney failure. It usually does its damage insidiously, and many people with high blood pressure don't have any symptoms until they have a stroke or heart trouble. Below are lifestyle modifications recommended by the NHBPEP, which have helped people like Marie. Please note that while these lifestyle changes are important, they are not a substitute for medication, if that's what your doctor recommends.

Lose weight

If you are overweight, getting your weight to a normal range is one of the most potent things you can do to lower your blood pressure. The NHBPEP recommends that people ideally get their weight down to normal range, which they define as a Body Mass Index (BMI) of 18.5 to 24.9 (there are many online tools to help you calculate your BMI). If that's not possible, even losing 10 pounds can help many people lower their systolic blood pressure (the top number) by five to 20 points (millimeters of mercury, to be exact). Marie lost 75 pounds by exercising and ending her lifelong habit of eating lunch at McDonald's and drinking soda. "It was like a wake-up call," she said. "I just did a 180."

Follow the DASH diet

The DASH diet consists of fruits, vegetables, low-fat dairy products, and foods that are low in fat. According to the NHBPEP, adopting the DASH diet will drop systolic blood pressure about eight to 14 points in most people. The DASH diet contains a lot of potassium, and people with kidney problems should check with their doctors before adopting it, since they are at risk of developing dangerously high potassium levels. Marie began cooking more fish and vegetables, and learned to include more vegetables and less oil in her favorite Bahamian dishes.

Restrict sodium

According to the NHBPEP, lowering sodium intake to 2.4 grams a day (about one teaspoon of salt) will lower systolic blood pressure by two to eight points. For many people, following an even lower sodium diet – 1600 mg, combined with following the DASH diet — can be as effective at lowering blood pressure as a prescription medicine, according to the NHBPEP. The quickest way to lower your sodium intake is to stay away from canned and processed foods, and limit your eating at restaurants.

Your taste buds will adapt to a low-sodium diet, even though it's tough at first. "It was very very hard," Marie said of her experience cutting sodium from her diet. "But once you give it a week, you start developing a taste for it."

Aerobic physical activity

Brisk walking or some other regular aerobic physical activity (at least 30

minutes per day) will lower systolic blood pressure by four to nine points, according to the NHBPEP. After getting her heart checked by her doctor, Marie began walking for 30 to 45 minutes every day. She also increased her walking by parking in a more distant space at the grocery store.

Limit alcohol consumption

For men, this means no more than two drinks a day, and for women, no more than one drink a day. (A drink is one 12-ounce beer, 5-ounce glass of wine or 1.5-ounces of whiskey.) The NHBPEP says this will lower systolic pressure by two to four points on average.

Don't smoke

Smoking can trigger heart problems, and the combination of smoking and high blood pressure is dangerous. It can seem difficult to quit, but it is possible to escape the smoking trap.

Manage how you respond to stressful situations

There's good evidence that people who respond angrily to stressful situations are more likely to develop heart problems. Marie said she used to have tantrums before when she got frustrated, but now she takes life one day at a time. "You can't change things, so you have to relax and let it go," she said.

Keep track of your blood pressure.

Many fire departments will check blood pressure for free, either at regular screenings or on a drop-in basis. Check with your local department. The National Heart, Lung and Blood Institute has a useful card that can help you understand what the reading means.

Don't skip your medications

Of all the medications doctors prescribe, blood pressure medicine is one of the most important. Skipping a dose on your own can be dangerous. If you're having side effects, call your doctor or nurse practitioner right away. It's also important to tell them if you're worried about paying for prescriptions, since many highly effective, first-line blood pressure medicines are available in generic form, at a relatively low cost.

Making these changes can not only help you live healthier, but also transform other aspects of your life. Marie now works as a health educator and believes others can succeed at making these changes in their daily lives, if they are motivated. "I'm not only teaching it, I lived it," she said recently. "I'm not telling you anything I didn't experience myself." ✦

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OUTRAGE from page 12

off-label uses — such as for weight loss, alcohol dependence, eating disorders, and mood and anxiety disorders — despite serious risks to patients' health.

This is not the first time Johnson and Johnson has been caught illegally marketing drugs. The same is true for most other large pharmaceutical companies. Unfortunately, this lawlessness will not stop until the government penalizes the companies with amounts that are equal or near-equal to the ill-begotten gains they have derived from the illegal activity, not just small fractions. It also must be stated that in none of these cases involving large pharmaceutical companies have any corporate officials been jailed. ✦

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PUBLICCITIZEN Health Letter

Outrage! Crime in the Pharma Suites

It never ends. Not a month seems to go by without another major drug company agreeing to pay tens, if not hundreds, of millions of dollars (some more than $1 billion) to the Justice Department to "resolve criminal and civil claims" concerning its illegal behavior.

Unlike pure economic fraud, in which people lose money because of company shenanigans, in these cases people are risking (and possibly losing) their lives and health because of illegal promotion of drugs for which there is no evidence that the benefits outweigh the risks. This so-called off-label promotion, meaning the promotion of a drug approved for treating a certain medical problem for a different disease for which it has never been approved, makes up a significant proportion of the recent crescendo of government cases against the drug industry.

The most recent case involved the company that made Band-Aid, their brand name for bandages, a household term: Johnson and Johnson. This time they were caught and will pay more than $81 million to resolve civil and criminal claims about their illegal, off-label promotion of the drug topiramate (Topamax), approved for treating seizures but promoted for various unapproved uses.

Whistleblower Dr. Gary Spivack, who initiated the case against Johnson and Johnson, said: "I found it outrageous that Ortho-McNeil [a Johnson and Johnson subsidiary] would try to pay doctors to influence them to prescribe a drug for uses that clearly endangered patients' health. Doctors need impartial and accurate information to make decisions on the best treatment for their patients, but that's not what Ortho-McNeil provided." Dr. Spivack alleged in his lawsuit that Ortho-McNeil paid doctors kickbacks to encourage them to prescribe Topamax for a wide range of

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