PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR JANUARY 2011 – VOL. 27, No. 1

Can Drugs Make Americans Lose Weight? Not Likely

The following article was written by Martha Rosenberg. Ms. Rosenberg frequently writes about the impact of the pharmaceutical, food and gun industries on public health. Her work has appeared in The Boston Globe, San Francisco Chronicle, Chicago Tribune *and other outlets. This article originally appeared on alternet.com on July 26, 2010. It has been reprinted with permission.*

"I have taken this drug off and on for the past 10 years for weight loss. It works, but the results NEVER last, it makes you feel great for about six months, you lose weight, you have awesome energy to work out and then it begins to not work anymore. It's like you build up an immunity to it or something."

The comment is about phentermine (Fastin, Adipex, Ionamin), half of a new drug under consideration by the FDA [Food and Drug Administration], but it could apply to all the diet drugs. Thanks to humans' "thrifty gene," diet drugs work until they don't work, say scientists. When the body senses it's losing its adipose stores [fat], it actually changes the metabolic rules to retain saddlebags and love handles. Thanks for that.

So, even though two-thirds of American adults are overweight and a third obese, few drugs have been able to make a dent in our gross national product; they've proved to be ineffective and sometimes dangerous.

Fen-phen was withdrawn 13 years ago for killing at least 120 people ... and it didn't even work that well, people say.

Meridia, [another recently banned diet drug], was given heart attack and stroke warning from the FDA in 2010 and only works with diet and exercise anyway, users say. Both sound like the joke about the restaurant that had such bad food ... and such small portions. [Note: The FDA finally took Meridia off the market in October 2010, eight years after Public Citizen petitioned the agency to do so.]

And let's not even talk about Alli and Xenical, which, by blocking the body's absorption of fat, cause "oily bowels" and "anal leakage" yet produced no more weight loss than a placebo. (And the FDA just added a "severe liver injury" warning.) "With allies like this, who needs enemas?" comedians quipped.

So when an FDA advisory committee considered a new diet superdrug called Qnexa, many put down their Pirate's Booty and listened. Especially when patient Erin Aycock testified she lost 50 pounds during trials and others were said to lose 10 percent of their body weight.

Qnexa, made by California biotech Vivus, combines Topamax, an anti-seizure drug also given for pain and bipolar disorder, with phentermine (the phen in Fen-phen).

Topamax makes you lose weight all right, say patients on the drug-rating site askapatient.com — along with your memory, your word recall and your hair. In fact, Topamax's brain-zapping properties are so well-known it is referred to as "Stupamax" in the military where it is in wide use, according to *Army Times.*

Topamax's weight-loss properties may come from the fact that it makes food and beverages tastes bad, say 33 users. Last year, it received an FDA suicide warning (along with other seizure drugs) and a few years ago, a warning for acute myopia associated with a type of glaucoma.

What about the amphetamine-related phentermine, the other drug in Qnexa? "I honestly can't distinguish this drug from Adderall, or even cocaine. It might as well be called Prescription Coke," says one phentermine user. Users report losing 50 to 60 pounds (many gaining it back) while being unable to sleep and chewing gum — and the insides of their cheeks — constantly.

The FDA advisory committee voted 10 to 6 against Qnexa because of concerns about depression, memory loss, birth defects and lack of long-term data. [The FDA decided to reject Qnexa in October 2010.]

Meanwhile, two other diet drugs

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[came] before the FDA, also made by California biotech firms.

In December 2010, an FDA advisory committee considered Contrave, another combination of already approved drugs that mixes the well-known antidepressant bupropion (which is also an antismoking drug) and the drug naltrexone, which is used to manage opioid and alcohol addictions.

Contrave addresses "both physiological and behavioral drivers of obesity" says its manufacturer, Orexigen, though a cynic on the business site *Minyanville* writes, "An obesity drug that treats depression and addiction; why not just call it another antidepressant?"

In data presented [in June 2010] at the American Diabetes Association meeting, patients on Contrave for 56 weeks lost at least 5 percent of their body weight (under 5 percent is not considered better than diet and exercise) and in a 24-week study there was also an improvement in "depressive symptoms accompanied by weight loss and improved control of eating in overweight and obese patients with major depression." [The FDA rejected Contrave on Feb. 1, 2011.]

Bupropion (Wellbutrin, Zyban), one of the two drugs in Contrave, lacks the weight gain associated with other antidepressants (hopefully — if it's supposed to be a diet drug) but carries a risk of seizures. And before you suggest its manufacturer raid the competition's Topamax, Orexigen is way ahead of you and already developed a related diet drug with an antiseizure agent built in.

The other drug, called lorcaserin, is also antidepressant-like — ironically, it's similar to the mood-improving ingredient in Fen-phen that was withdrawn — and is also the only drug that is truly new. According to an article in the July 15, 2010, issue of *The New England Journal of Medicine*, almost half of patients on lorcaserin for a year lost 5 percent or more of their body weight and 70 percent maintained the weight loss in the second year (while still taking lorcaserin). The FDA worried that lorcaserin would cause heart problems since it's so similar to the withdrawn fenfluramine ("Fen") but it didn't in trials, says the manufacturer, Arena.

Clearly, lorcaserin and Contrave are safer than the superdrug Qnexa — but they also cause half the weight loss! Why must a diet drug risk your health to make you lose weight?

"We've found (over and over) that human feeding behavior is protected by multiple, overlapping redundant pathways," says chemist Derek Lowe on his blog, *In the Pipeline*. "We are the descendants of a long line of creatures that have made eating and reproducing their absolute priorities in life, and neither of those behaviors are going to be altered lightly. The animals that can be convinced to voluntarily eat so little that they actually lose weight, just through modifying a single biochemical pathway, are all dead. Our ancestors were the other guys."

That's why even though patient Erin Aycock told the FDA advisory committee that Qnexa was like "instant willpower" and she "had the ability for the first time in my life to say 'I don't even care if I eat that cookie,'" she gained the weight right back when she went off the drug.

And others gain the weight back while still on drugs. "Extreme weight loss!! I looked emaciated and everyone thought I was on drugs! My dad thought I had cancer, that's how skinny I became," writes a Topamax user on askapatient.com. "The weight loss died down though after about two years or so. Maybe more a year and half. Now I am as big as a house."

Until scientists find a way to trump the feeding behavior of our ancestral heritage with its "multiple, overlapping redundant pathways," new diet drugs will probably not be the solution for weight loss. And "bad food, small portions" will continue to be the problem. ✦

Aspirin-Induced Reye's Syndrome: A Preventable Cause of Death

The following article was originally published in the March/April 1985 Health Letter. *It discusses the Food and Drug Administration's (FDA) delay in recommending that all aspirin-containing products display a warning about the medicine's association with Reye's syndrome. We petitioned the FDA in 1985 to update aspirin's label to emphasize the strength of the relationship between aspirin and Reye's syndrome, but the agency did not order a label change until 1986 — after hundreds of children had been killed or injured.*

One Wednesday in February 1983, Linda came home from school complaining of a cold, runny nose and some aches. Her mother took her temperature, found it to be 101 degrees and decided to give Linda aspirin to make her more comfortable. Three days later, on Saturday, just as Linda was clearly getting over what was probably a case of flu, she started vomiting frequently and then, later that night, she became delirious and combative. The following day, Sunday, Linda was extremely hard to arouse, was rushed to the hospital and went into a coma. Linda died on Monday, another victim of Reye's syndrome.

But let us change the scenario. When Linda's mother decided to use aspirin, what if, upon picking up the bottle of aspirin, she had seen the following warning:

> WARNING: DO NOT GIVE THIS PRODUCT TO CHILDREN AGE 19 AND UNDER WHO HAVE CHICKEN POX, FLU OR FLU-LIKE SYMPTOMS WITHOUT FIRST CONSULTING A PHYSICIAN. THIS PRODUCT CONTAINS ASPIRIN, AN INGREDIENT STRONGLY ASSOCIATED WITH THE DEVELOPMENT OF REYE'S SYNDROME, A SERIOUS AND OFTEN FATAL DISEASE.

If they had seen such a warning label, there is no way Linda's mother, hundreds of other parents, and teenagers who treat themselves would risk a fatal adverse drug reaction and use aspirin or aspirin-containing products to treat flu, flu-like symptoms or chicken pox.

In 1981, a review of four earlier studies showed a strong association between the use of aspirin for treatment of flu or chicken pox and an increased risk of Reye's syndrome. Based on these studies, a Federal Advisory Committee of the Center for Disease Control (part of the Department of Health and Human Services) recommended to the FDA in December 1981 that aspirin and aspirin-containing medicines "should be avoided" for children with chicken pox or flu because of the association with Reye's syndrome.

Between 1982 and March 1985, when the evidence linking aspirin and Reye's should have prompted warning labels on all aspirin products, there were 610 cases of Reye's syndrome reported in the United States. One hundred and seventy-five of these children and teenagers are dead. Almost all of them had taken aspirin to treat chicken pox or flu, which preceded the development of Reye's syndrome. [In the five studies on Reye's syndrome that had been completed by the time this article was originally published, 97 percent of the children with Reye's had been given aspirin to treat their chicken pox or flu.]

Following a petition and lawsuit

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Current Information: Update on Reye's Syndrome

Following Public Citizen's FDA petition and lawsuit in 1982 to require warning labels on aspirin concerning Reye's syndrome, massive resistance from the aspirin industry prevented the labels from being required until 1986.

That this largely preventable epidemic of brain damage, liver damage and death was almost entirely caused by aspirin can be seen in the data showing the annual number of cases of Reye's syndrome. According to the federal Centers for Disease Control and Prevention (CDC), the peak number of reported cases of Reye's syndrome occurred in 1980, when 555 cases were reported to the government. From 1987, the year after the label was implemented, through 1993, no more than 36 cases were reported each year, and from 1994 through 1997, no more than two cases were reported each year. The number of new cases has remained similarly low during the past 13 years as well.

Close to 1,000 U.S. cases of Reye's syndrome were reported between 1982 and the eventual date of the FDA-mandated label requirement. The CDC estimates that about one-third of Reye's syndrome cases result in neurological damage or death. Thus it is certain that several hundred children either suffered brain damage or death because the aspirin industry resisted action concerning an unequivocally documented danger from their products.

Health Letter Volume Index, 2010

The following index lists all of the articles that appeared in *Health Letter* in 2010, by issue. For a cumulative index that lists all *Health Letter* articles by topic from 1985 to 2010, send a written request to Member Services at the address listed below.

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in 1982 by Public Citizen's Health Research Group and the American Public Health Association to force the FDA to require warning labels on all aspirin-containing products, the government announced in June 1982 that it would require such labels. But that November, under heavy pressure from aspirin makers and two of their front organizations, the Aspirin Foundation and the so-called Committee on the Care of Children, the Reagan administration canceled its plan for mandatory warning labels, saying that "another study" was needed. The results of the first part of this large, federally funded nationwide study on aspirin and Reye's were presented on Dec. 13, 1981, at a closed meeting in Washington, D.C.

Through the efforts of Michigan Congressman John Dingell [in 1984], we obtained the results of this study, which showed that children with chicken pox or flu who are given aspirin have a 25 times greater chance of developing the often-fatal disease, Reye's syndrome, than otherwise similar children with chicken pox or flu who are not given aspirin. This extraordinarily high risk ratio (also called odds ratio) is not only much higher than seen in any previous study on aspirin and Reye's, but is also one of the largest risk ratios found in any recent epidemiological study [as of 1985], emphasizing the strength of the relationship between aspirin and Reye's.

The tragic story of the Reagan administration's refusal ... to order warning labels on aspirin-containing products is a clear documentation of how effective the aspirin industry has been in postponing federal action and causing death or injury to hundreds of children.

The tragic story of the Reagan administration's refusal, for three years now [in 1985], to order warning labels on aspirin-containing products is a clear documentation of how effective the aspirin industry has been in postponing federal action and causing death or injury to hundreds of children. The record shows that the administration paid much more attention to baseless statements by the aspirin industry officials or their stooges in the Committee on the Care of Children than to the health needs of American children.

The Voluntary Campaign

Instead of requiring warning labels after a fifth study confirmed the strong association between aspirin and Reye's syndrome, the Reagan administration asked the aspirin companies to "voluntarily" label their products. There were several serious — literally life-threatening — problems with this half-hearted approach. First, only those companies who wanted to change their label would. None of them had to. Second, of the companies that had agreed to eventually change their label, none, with the possible exception of Plough, Inc., would acknowledge in the new label that aspirin is linked to Reye's or that Reye's is often fatal. Third, again with the possible exception of Plough, none of the companies that "volunteered" to change their label was willing to put warning stickers on the products already in distribution. As a result, almost all aspirin-containing products purchased during the rampant 1984-1985 flu season, and probably through the summer of 1985, would lack any kind of warning against aspirin use for treating flu or chicken pox.

What Can You Do?

To repeat, do not use any aspirin-containing product for treatment of chicken pox, flu or flu-like illnesses in anyone 19 years old or younger.

If symptoms or signs of Reye's syndrome occur following chicken pox, flu or flu-like illness (persistent vomiting, delirium, combativeness, coma) immediate hospitalization is needed to prevent death or brain damage. ✦

Product Recalls

December 15, 2010 – January 19, 2011

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

Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

Off Cycle II Hardcore Dietary Supplement Capsules, 5 mg, 90-count bottles. Volume of product in commerce: 2,294 bottles. Marketed without an approved new drug application; product contains "ATD," an aromatase inhibitor marketed as a dietary supplement. All lots. Atlas Operations, Inc.

Prolatis' (Polygonati Annum) Dietary Supplement Capsules, 2-count blister packs, 16- and 40-count bottles. Volume of product in commerce: 3,949,588 capsules. Marketed without an approved new drug application: Product found to contain sulfoaildenafil, an analogue of sildenafil, an active ingredient used for the treatment of male erectile dysfunction. All lots. Novacare, LLC.

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

Children's Benadryl Allergy, FastMelt Tablets, cherry flavored and grape flavored, 12.5 mg, 18 dissolving tablets. Volume of product in commerce: 4,357,390 boxes. CGMP deviations: Insufficient development of manufacturing process validation. Multiple lots. Mcneil Consumer Healthcare, Inc.

Chlor-Trimeton ® Allergy, 12 Hour, 12 mg, 24-count. Volume of product in commerce: 723,878 units. Specification results in dissolution testing. Lot #s: 9AAE12V, 9AAE13V, 9AAE14V, 9AAE15V, exp. date 11/2011; 0AAE02, exp. date 01/2012; 0AAE03, 0AAE04, exp. date 02/2012; 0AAE05, 0AAE06, exp. date 03/2012; 0AAE08, exp. date 05/2012; 0AAE07, exp. date 06/2012. Schering Canada, Inc.

Lipitor Tablets, 40 mg, 90-count bottle, Rx only. Volume of product in commerce: 19,182 bottles. Chemical contamination: Complaints of an uncharacteristic odor identified as 2,4,6-tribromoanisole. Lot #: 0836050, exp. date 04/2013. Pfizer Ireland Pharmaceuticals.

Lisinopril Tablets, 5 mg, 1,000-count bottles, Rx only. Volume of product in commerce: 2,376 bottles. CGMP deviations: Some of the white tablets exhibit a blue discoloration. Lot #: TE03074, exp. date 03/2012. Emcure Pharmaceuticals, Ltd.

Lorazepam Tablets, 0.5 mg, 90-tablet bottles, Rx only. Volume of product in commerce: 32,783 bottles. Adulterated presence of foreign tablets: A foreign tablet was discovered during the dispensing/counting of the medication. Lot #: 2134761, exp. date 02/2012. Ohm Laboratories, Inc.

Metoprolol Tartrate Tablets, 50 mg, 100 mg, 100-count bottles, 1,000-count bottles, Rx only. Volume of product in commerce: 2,767,674 bottles. Failed USP content uniformity requirements: Metoprolol batches may exhibit non-homogenous granulation. Multiple lots. Sandoz, Inc.

Motrin Junior Strength (Ibuprofen) Tablets, 100 mg, 24-count box. Volume of product in commerce: 695,400 boxes. CGMP deviations: Insufficient development during manufacturing. Lot #s: SDM046, exp. date 02/2011; SHM001, exp. date 03/2011; SLM121, exp. date 09/2011; SSM097, exp. date 11/2011; AAM053, exp. date 12/2011; BDM227, exp. date 01/2013. Mcneil Consumer Healthcare, Inc.

Tylenol 8HR Extended-Release Caplets, 650 mg, 50-count bottles. Volume of product in commerce: 127,512 bottles. Chemical contamination: Presence of a chemical called 2,4,6,-tribromoanisole. Lot #: BCM155, exp. date 12/2012. Mcneil Consumer Healthcare, Inc.

Valacyclovir Hydrochloride Tablets, 1 gram, 30-count bottle. Volume of product in commerce: 12,950 units. This recall is being conducted due to a stability failure on dissolution testing. All other product parameters were within specifications and there have been no adverse events reported for the affected lot. Lot # 059791A, exp. date 04/2010. Boehringer Ingelheim Roxane, Inc.

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 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

Arctic Cat Snowmobiles. The front lower suspension arm can crack during use, which could lead to loss of control, posing a risk of severe injury or death. Arctic Cat, Inc., (800) 279-6851 or www.arctic-cat.com.

Avalung Backpacks. The air intake tubing can crack under cold temperatures, causing the unit not to function as intended, posing a suffocation hazard. Black Diamond Equipment, Ltd., (801) 278-5533 or www.BlackDiamondEquipment.com/AvaLungRecall.

Baby Rattles. The baby rattle's beads can come off when the rattle is twisted or pulled forcefully, posing a choking hazard to young children. Kid O Products, LLC, (212) 366-5858 or www.kidoproducts.com.

Baby Socks and Leg Warmers. The leg warmers and socks have a heart appliqué that can detach, posing a choking hazard to small children. BabyUnited, LLC, (888) 791-6098 or www.babylegs.com.

Ceramic Piggy and Lion Banks. The yellow surface paint on the banks contains excessive levels of lead, which is prohibited under federal law. Oriental Trading Company, Inc., (800) 723-6155 or www.orientaltrading.com.

Children's Hooded Sweatshirts. The hooded sweatshirts have drawstrings through the hoods, which can pose a strangulation or entrapment 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. Alpha Industries, (866) 631-0719 or www.alphaindustries.com.

Children's Hooded Cardigans with Drawstrings. The cardigans have a drawstring through the hood, which can pose a strangulation hazard to young 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 at the neck and waist by drawstrings in upper garments, such as jackets and sweatshirts. Jean Bourget, Inc., 212-279-7672 or www.liligaufrette.com.

Children's Hooded Sweatshirts and Jackets. The children's hooded sweatshirts have a drawstring through the hood and/or waist that can pose a strangulation or entrapment 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 neck and waist drawstrings in upper garments, such as jackets or sweatshirts. Mejoong Corp., (888) 946-8546 or www.mejoong.com.

Classic BB Buggies. The off-road vehicles can accelerate without warning, posing a risk of injury to the user and/or bystanders. Bad Boy Enterprises LLC, (855) 738-3711 or www.badboybuggies.com.

Cool-It Soother Teething Rings by Vulli. If the teething ring is punctured, bacteria and mold can grow inside the teether's untreated liquid. This poses an ingestion hazard to infants and can lead to diarrhea and vomiting. Calisson Inc., (888) 318-9803 or www.sophiegiraffeusa.com.

Fagor Refrigerators. The refrigerator's control board can overheat, posing a fire hazard to consumers. Fagor America, Inc., (888) 354-4411 or www.fagoramerica.com.

Flow Pro, Airtech, Aloha Breeze and Comfort Essentials Heaters. The heaters can malfunction resulting in overheating, smoking, burning, melting and fire. Wal-Mart, (800) 925-6278 or www.walmart.com.

GE and Professional Series Brand Dehumidifiers. A component in the dehumidifier's compressor can short circuit, posing a fire hazard to consumers. GD Midea Air Conditioning Equipment Ltd., (877) 593-8721 or www.recallverification.com.

Girls' Hooded Zip Jackets and Vest Sets. The hooded zip jackets and the vest sets have drawstrings through the hoods which can pose a strangulation or entrapment 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. Splendid, (855) 640-2803 or www.splendid.com/safetynews.html.

Honda Snowblowers. The fuel tank joint and O-ring located on the underside of the fuel tank can seep or drip fuel over time, posing a fire hazard. American Honda Motor Co., Inc., (888) 888-3139 or www.hondapowerequipment.com.

Hoodie Footie™ Infant and Toddler Footed Pajamas. The metal snaps that attach the hood to pajamas can come off, posing a choking hazard to young children. The Vermont Teddy Bear Co., Inc./ Pajamagram at (800) 262-1162 or www.pajamagram.com.

CONSUMER PRODUCTS

Marker and Kästle Twin Cam 12.0 Ski Bindings. Steel springs in the heel pieces of the bindings could break, posing a fall hazard to consumers. Marker Völkl USA, (800) 453-3862 or www.markerusa.com. Kästle, (970) 390-4498 or at www.kastle-ski.com.

Men's Fleece Sherpa Shirts. The shirts fail to meet the federal flammability standard for wearing apparel and pose a risk of burn injury. Foria International, Inc., (888) 999-6568 or www.foria.com.

Metallic Spinning Candle Holders with 12 Soy Tea Lights. The candle holders can catch fire, posing a fire hazard to consumers. QVC, (800) 367-9444 or www.qvc.com.

Outdoor Hanging Lantern. The glass lantern can separate from the top support ring and fall, injuring people who are nearby. Quoizel, Inc., (877) 316-2589 or www.quoizel.com.

Oven Rack Guard. The firm has received nine reports of the product causing smoke or catching fire. Of those nine reports, three consumers reported property damage and five reported injuries, such as headache, sore throat, nausea and eye irritation from smoke. Christmas Tree Shops, (888) 287-3232 or www.christmastreeshops.com.

Paging Horn Loudspeakers. The speaker housing can crack at the mounting bracket, causing the speakers to fall from their mounting. This poses a risk of injury from impact to consumers. Higher failure rates have occurred in high-temperature and humid environments. TOA Electronics, Inc., (800) 733-4750 or www.toaelectronics.com.

Programmable Thermostats. The programmable thermostats constantly charge the backup AA batteries used to power the thermostat's clock. This can cause the batteries to leak, resulting in a fire hazard. White-Rodgers, (888) 624-1901 or www.regcen.com/thermostat.

Salsa Handlebar Stems. The handlebar stems can crack or break, posing a fall hazard to the rider. Quality Bicycle Products, (877) 774-6208 or www.salsacromotostem.com.

Silver Tree Tealight Candle Holders. The tealight cups are positioned where the flame from the candles can ignite other parts of the candle holder, posing fire and burn hazards to consumers. Michaels Stores, Inc., (800) 642-4235 or www.michaels.com.

SnoThro 30LE Deluxe Snow Thrower. Users trying to clear the collector or discharge chute while the machine is operating could be at risk of a finger or hand injury hazard. Ariens Co., (888) 927-4367 or www.ariens.com.

Sterno Portable Butane Stoves. The stove's "on-off" valve can fail to close completely when turned to the "off" position, causing butane to leak from the stove. This poses a fire and burn hazard to consumers. Sterno, (877) 478-3766 or www.sterno.com.

STIHL FS 310 Bike Handle Trimmer/Brushcutter. Vibration from the ignition module may cause the trimmer head to loosen and detach from the mounting, posing an injury hazard. STIHL, Inc., (800) 610-6677 or www.stihlusa.com.

STIHL MS 361C Chain Saws (C-Q version). The throttle trigger may stick after it has been released by the operator, which could cause the engine to continue to run at a speed that drives the saw chain. This can pose a risk of a laceration injury to the user or a bystander. STIHL, Inc., (800) 610-6677 or www.stihlusa.com.

Sump Pumps and Effluent Pumps. Sump pumps installed without ground fault circuit interrupter (GFCI) protection can pose an electric shock or electrocution hazard if touched by the consumer. IF YOU SUSPECT THAT YOU HAVE ONE OF THE RECALLED PUMPS AND IT IS PLUGGED IN, DO NOT TOUCH IT, THE WATER AROUND IT OR THE SURROUNDING FLOOR AREA. ITT Water Technology, Inc., (866) 325-4204 or www.goulds.com.

Toddler Talk Toy Mobile Phones. The clear plastic antenna can break off, posing a choking hazard to young children. Discovery Toys, LLC, (800) 426-4777 or www.discoverytoysinc.com.

Xantrex Grid Tie Solar Inverters. A component of the inverter can degrade, causing gas within the wiring compartment of the inverter. When arcing occurs, gas could build and force the compartment cover to be blown off. If the cover is blown off with sufficient force it can injure the user or person, or cause damage to property in close proximity to the inverter. Xantrex Technology, Inc., (800) 714-7176.

Youth Hooded Wind/Rain Jackets. The jackets have a drawstring through the hood, which poses 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 by drawstrings in upper garments, such as jackets and sweatshirts. Prairie Mountain, Inc., (800) 370-4941 or www.prairiemountain.net.

Zoom Buggy Car and Dream Pillow Star Educational Toys. The wheels on the Zoom Buggy cars and plastic beads on the Dream Pillow Star can detach, posing a choking hazard to young children. Kindermusik International, (800) 628-5687 or www.kindermusik.com.

If a Drug Is New, Does That Make It Better?

President Barack Obama wants an institute to be set up to guide reviews of the effectiveness of various health care decisions. Morton Mintz, a former Washington Post *reporter, points out that, for prescription drugs, a simple legislative test of effectiveness is easily available — one in which new drugs, to get Food and Drug Administration (FDA) approval, must be shown to be more effective than existing ones. This article originally appeared in the* Nieman Watchdog *(www.niemanwatchdog.org), a site dedicated to raising questions that the press should, but often does not, ask.*

Under the 1962 Kefauver-Harris amendments to the Food, Drug and Cosmetic Act, a manufacturer seeking approval of a new medicine need only demonstrate, with two clinical trials, its superiority to a dummy drug.

President Obama and Vice President Biden said in an election campaign statement that they want to give "Americans and their doctors ... accurate and objective information to make the best decisions for their health and well-being." They said they would seek, among other things, to "establish an independent institute to guide reviews and research on comparative effectiveness..."

A simple-as-all-get-out legislative fix, one requiring only a change of a few words in the prescription-drug law of 1962, is available, too. But it would be fiercely opposed by the pharmaceutical industry, Washington's largest lobby. Just in 2007, it had a $168 million lobbying effort, according to a Center for Public Integrity analysis.

Under the 1962 Kefauver-Harris amendments to the Food, Drug and Cosmetic Act, a manufacturer seeking approval of a new medicine need only demonstrate, with two clinical trials, its superiority to a dummy drug. "But patients and doctors need to know not just whether a new drug outperforms a placebo, but whether it's a real advance on what is already on the market," wrote Richard A. Friedman, a professor of psychiatry at Weill Cornell Medical College in a *New York Times* essay. "For that, we need head-to-head trials comparing new and standard treatments."

Lithium salts are an example. These "have been used to counter bipolar disorder since the 1950s, when it was discovered that they greatly reduced the intensity and frequency of mood swings in about 70 percent of patients with the disorder," Friedman wrote.

> While lithium must be taken with care — it is therapeutic in a narrow range of blood levels, and overdoses can be toxic — it is also the only psychotropic drug that has ever been shown to have specific anti-suicidal effects. That makes it especially valuable, given the high risk of suicide associated with mood disorders.
>
> But lithium is cheap and unpatented, so drug companies have little interest in it," Friedman points out. "Instead, they have made a new generation of mood stabilizers, some more tolerable than lithium, but none more effective." Friedman continues:
>
> And lithium is hardly the only unsexy but effective drug to fall by the wayside. New medical treatments are a bit like the proverbial new kid on the block: they have an allure that is hard to resist ... I don't know about you, but I'd opt for an old drug with a known track record of efficacy and safety over an expensive newcomer with no added benefit — any day of the week.

At least implicitly, Friedman raises this question for the Obama administration, particularly for Kathleen Sebelius, Secretary of Health and Human Services, and Margaret A. Hamburg, the new Commissioner of the FDA:

> Will you press Congress to change the drug law to require that to win FDA approval, a new drug must be shown in clinical trials to be superior not just to a placebo, but to medicines already stocked by your local pharmacy? ✦

Cholera in Haiti: A Look From the Trenches

The following article, by Dr. Erin Marcus, originally appeared on the Huffington Post *website on Jan. 11, 2011.*

To learn more about the current health situation in Haiti, I recently spoke with Dr. Andre Vulcain, co-director of the Justinien Hospital family medicine residency training program in Cap Haitien. Justinien Hospital is Haiti's second-largest public hospital, and the residency is a collaborative program between the University of Miami Haiti Project and the Haitian Ministry of Health.

Dr. Vulcain divides his time between Haiti and Miami and has advised the Haitian Ministry of Health's HIV care program. He was in Haiti during the earthquake, and provided immediate care in the aftermath of the disaster.

Q: You recently returned from a three-week trip to Haiti, where you were treating cholera patients. What was the situation you faced during this most recent trip?

When they announced there was a formal epidemic, we started putting together an embryonic cholera treatment center in Cap Haitien even before (the epidemic) got there. We expected 25 to 50 patients a day, but there was a quick escalation of the epidemic. It was a very difficult situation. The center was designed for 200 to 250 patients, and they were taking care of 600 patients.

The big problem was there was not enough trained human resources and not enough accommodations in terms of beds. I was in charge of a room with 80 patients with three to four nurses. Most of the patients we had were severely dehydrated, and 100 percent needed IV hydration. One week earlier, there was political agitation in the city, and for five or six days people were staying home or people died in the streets. It was a very difficult situation, but I think our results were good because the mortality rate was maintained below 1 percent in the whole center.

Q: You were in Haiti during the earthquake, and treated thousands of patients in the immediate aftermath of the disaster. Do you see things worsening from a public health perspective?

Before the earthquake, the public health system was falling apart. Since the earthquake, things are more challenging. We had to divert energy to the earthquake effort itself. The fact that we have to concentrate on the cholera epidemic displaces attention from other health care programs, which are already weak. Now, on top of that, you have this election that went bad.

During the past 25 years, Haiti has made progress only in one major indicator of health care status — the infant mortality rate, which has been reduced by 50 percent for the past 20 to 25 years.

All the other indicators (such as) maternal mortality, malnutrition of children, are steadily going up. The maternal mortality now has reached an astronomical level. It's over 600 maternal deaths for 100,000 live births — (and this was) prior to the earthquake.

Q: What were your primary objectives in treating cholera patients?

When you are dealing with cholera, you have to work with a two-pronged strategy. The two main things are first, that the patient needs to be treated to prevent fatality — that's the medical care. [It] is not rocket science — IV hydration for the patient who is severely dehydrated, or oral hydration salt for the patients who are moderately or lightly dehydrated.

The second aspect, which is very important, is to try to block the transmission of the cholera in the community, so you need to work on the education of the community and also, more challenging, see what you can do in the short term to mitigate the sanitation problem. Access to clean water is important.

We had mass communication education, and a lot of people were aware of what's going on, but you also need the kind of education that comes with a demonstration of what needs to be done. So what we did and what a lot of organizations are doing was to send community health workers who can teach people to make sure they understand how to apply preventive measures.

Q: What were some of the barriers you faced in caring for cholera patients?

The sheer number of patients was difficult to manage, even though the basic logistics were there. We definitely needed more human resources. But everybody was doing his best. [More generally], there is a lack of knowledge [about cholera] and skills among the health care workforce.

This is the first time that we have had cholera in Haiti. We have started a medical education program that will train most of the providers. We think that cholera is here to stay in Haiti for a long time, given the conditions, so it's important for the whole workforce to be familiar with the cholera epidemic.

Q: What are some of the misconceptions people in the U.S. may have about the cholera epidemic? Would you say things are better or worse than they are being depicted in the media?

From what I saw before I traveled to Haiti, the coverage was reasonably fair. I didn't see anything that was grossly distorted or any kind of misinformation. I have noticed since I came back that the election in Haiti has replaced cholera as

news, so they don't talk a lot about the cholera epidemic. But it's still a serious situation and we will have to go two to three more months before seeing it subside totally. Eventually we will have to face the endemicity of this epidemic.

Q: What are some of the misconceptions people in Haiti have about cholera?

Some people thought you could contract cholera through the air, and on the street some people were wearing medical masks. But I think the education that's being done has minimized that.

Some people thought that it could have been something intentional related to some political situation, or something else. The communities that are affected don't spend a lot of time speculating about those things -- they are more interested in how to protect themselves.

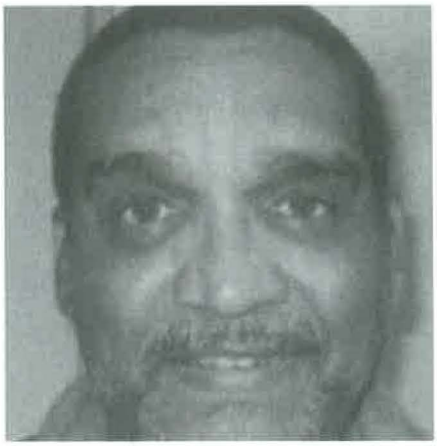
Cholera is, in large part, caused by inadequate infrastructure and unclean water.

Q: Do you see the epidemic abating anytime soon? Will it be possible for the government to end this epidemic soon, given the need for significant improvements in infrastructure?

Political instability has always had a negative effect on public health programs in Haiti. The ability of the state to provide for the needs of the people has been weakened. You need time to build a sanitation infrastructure. It's not going to happen tomorrow, it's more a long term thing.

Q: Did you have any concerns about your personal health as you cared for cholera patients?

I had some concerns. Even in the center, the sanitation wasn't optimal. The patients were on plastic sheets on the floor and I had to kneel to start IV's and to examine patients. Basically, I abided by some specific rules. I tried to never touch my face or mouth with my hands. Every hour or so I went outside



Dr. Andre Vulcain, co-director of the Justinien Hospital Family Medicine Residency Training Program.

of the tent, where you can wash your hands with chlorine solution.

Every day before leaving the center I decontaminated the soles of my sneakers. When I arrived home, I had a bucket with chlorine water into which I dropped my scrubs overnight for disinfection. I took good showers with a lot of soap. I think that those measures are very effective. The key is your hands, because that's what brings something to eat into your mouth, so I made sure my hands were constantly being washed and I never touched my face.

Q: What changes have you seen in Haitian society since the disaster?

I think people's fatalistic attitude has increased. The other thing that is worrisome is that you have so many people living in a tent city culture. Even in the slums, there was some organization, there was some sense of community, you knew the people close to you.

Under a tent, it's a new environment, new people, way less privacy, you are constantly exposed. It's very concerning in terms of how it's going to affect the values of this society, how people relate with other people, how people express their solidarity, how people are going to value self-reliance, because in those tents, people are totally assisted with food, water, medical care.

A child who spends five years under the tent — what kind of mentality does he have, what does he think of life, what is his vision of normalcy when he grows up, what kind of contribution will he be able to make when his reference frame has been to live under a tent for so many years? It's a big human issue.

A similar version of this article originally appeared on the New America Media *website.* ✦

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PUBLICCITIZEN Health Letter

Outrage of the Month! Governor Scott of Florida

What do the following two people have in common? The first is a person who, according to *Wikipedia*:

> In 1987 helped found the Columbia Hospital Corporation with two business partners; this merged with Hospital Corporation of America in 1989 to form Columbia/HCA and eventually became the largest private for-profit health care company in the U.S. He was forced to resign as Chief Executive of Columbia/HCA in 1997 amid a scandal over the company's business and Medicare billing practices.

The second is the person who was just elected governor of Florida.

The answer: they are the same person — Rick Scott.

Following his election in Florida last November, a profile by Rick Kroll, on the *Mother Jones* website, had the following additional information on now-governor Scott:

> Scott brings to the governor's mansion in Tallahassee quite a checkered past. For starters, there's that $1.7 billion federal fine — the largest of its kind [at that time] in American history — slapped on the hospital chain that Scott founded and led as CEO, Columbia/HCA, for health care overbilling. (Scott was not charged in the federal investigation, but the company pleaded guilty to 14 felony charges.) Since then, Scott has fended off similar accusations of overbilling by Solantic, the health clinic chain he subsequently founded and in which he's the majority investor.
>
> As for Scott's policy positions, they hew pretty closely to the Republican party line. He's pro-life. He opposes same-sex marriage rights. He's called for bringing an Arizona-type immigration law to Florida … And despite the BP Macondo well disaster, Scott wants to expand offshore drilling off of Florida's coastlines.

Good luck, Florida! May your residents, shores and beaches survive Gov. Scott. ✦