PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR FEBRUARY 2011 – VOL. 27, No. 2

Breast Implants and Cancer Revisited: Plastic Surgeons Cover Up New Evidence of Human Cancer From Implants

On Feb. 3, 2011, the American Society of Plastic Surgeons and the American Society of Aesthetic Plastic Surgery hosted a members-only webinar essentially urging members to inaccurately downplay the risks of breast implant-related cancer when speaking to female patients.

Public Citizen's Health Research Group sent a letter to Food and Drug Administration (FDA) Commissioner Margaret Hamburg and Device Director Jeffrey Shuren, objecting to the extraordinarily misleading information distributed during the webinar. Below are excerpts from the letter:

> Dear Drs. Hamburg and Shuren,
>
> A concerned plastic surgeon has just sent us portions of a transcript from a members-only webinar held on February 3, in which the presidents of the two leading plastic surgery organizations, the American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastic Surgery (ASAPS), essentially urged members to inaccurately downplay the significance of recent evidence about the risks of breast implant-related cancer when speaking to female patients.
>
> The webinar was held just a week after the Food and Drug Administration (FDA) announcement on January 26 that there have been a growing number of published cases — now 34 — documenting an unusual kind of cancer (anaplastic large cell lymphoma (ALCL)) surrounding the breast in women with implants.

When recommending during the webinar how to respond to patients who were concerned about this, Dr. Phil Haeck, president of ASPS, said, in referring to ALCL in association with breast implants:

> [Y]es it's classically a malignant tumor, but it has such a benign course that when we were discussing ways to talk to the media we decided that we would call this a condition when we talked to the media, not a tumor, not a disease and certainly not a malignancy. Um, because, and I would recommend that you use the same terms with your patients rather than disturb them by saying this is a cancer, this is a malignancy. The best word is this is a condition. If you develop this condition here's how we are going to treat it, the way we are going to diagnose this condition is this, and that's very reassuring when you are using that word and not using the word cancer or malignancy. And I think you are certainly justified, with what we know now, in downplaying the malignant potential of these.

In addition, the webinar also stated that "surgery was curative."

Advising against the use of the words "cancer" or "tumor," stating that this "condition" has a "benign course" and stating that "surgery is curative" when speaking to women are all strongly contradicted by evidence from the published cases.

Our detailed review of the 34 published case reports of women who developed breast implant-associated ALCL 1-18 reveals the following:

- For 17 patients (50 percent), the reported treatment included chemotherapy (nine patients), chemotherapy and radiation therapy (seven patients), or radiation therapy (one patient). (For most of the other patients, the course of treatment was not adequately described.)
- For 15 of these 17 patients, there were follow-up data, indicating that three patients were reported to have recurrent disease after initial treatment.
- Two additional patients (not among the 17 mentioned above) had recurrent disease after initial unspecified therapy, underwent stem cell transplantation, and were disease-free two years after transplantation. Thus, a total of five patients, of the 20 for whom follow-up data were available, 25 percent, had recurrence of their cancer.

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National Cancer Institute's Helpline: A Valuable, Underused Resource

The following article was written by Erin N. Marcus, M.D., and originally appeared on the website of New America Media. *It has been reprinted with permission.*

Brenda Bryant learned that she had breast cancer while she was sitting alone in her car in the parking lot of her grandson's day care center. It was early evening on a Friday two years ago, and her surgeon called to tell her the results of a biopsy. "He just gave me my results and that was it," says Bryant, who lives in Northern Virginia. "It was like there was this big knot in my throat. I was lost, and I didn't know who to go to. I just started going crazy."

Searching the Internet for more information about the disease, Bryant found the telephone number of the National Cancer Institute's Cancer Information Service (1-800-4-CANCER or 1-800-422-6237). The woman who answered told her about local support groups and medical specialists in her area and shared her own story of having breast cancer. "The person on the other line was really comforting," Bryant says. "It made me feel like I might have some hope."

Despite its 35-year history, the NCI's free service remains under the radar to many. The helpline handles about 78,000 calls a year, in English as well as in Spanish, from patients, family members and others who have questions about different types of cancer. By contrast, in 2007, some 11.7 million Americans were living with the disease.

The service is especially underused in ethnic minority communities, according to Dr. Nancy Burke, a researcher at the University of California, San Francisco. "There's an issue of awareness, and there's also the comfort issue of seeking information over the phone," she says. "But once we introduce people to it, they love it. Cancer patients are often overwhelmed by information, and the line can help them sort through it."

The cancer line fields a wide variety of queries, including what to expect after different diagnoses; what to ask doctors; where to get help with financial, legal and transportation problems that might interfere with treatment; the benefits and side effects of different treatment options; and what clinical trials are available for different diagnoses.

Callers are encouraged to share as many details as possible about the exact type and stage of their cancer, so that the staff can tailor the information they provide. "But if they don't know this, we can help them formulate questions they can take to their doctor," says Mary Anne Bright, a former oncology nurse who directs the program. "We will spend as much time with somebody as they need."

Unlike many other toll-free helplines, "we're not a pharmaceutical company, and we're not collecting donations," Bright adds. "We're all about reporting the most accurate and up-to-date information about cancer and the results of research in a way that people can understand."

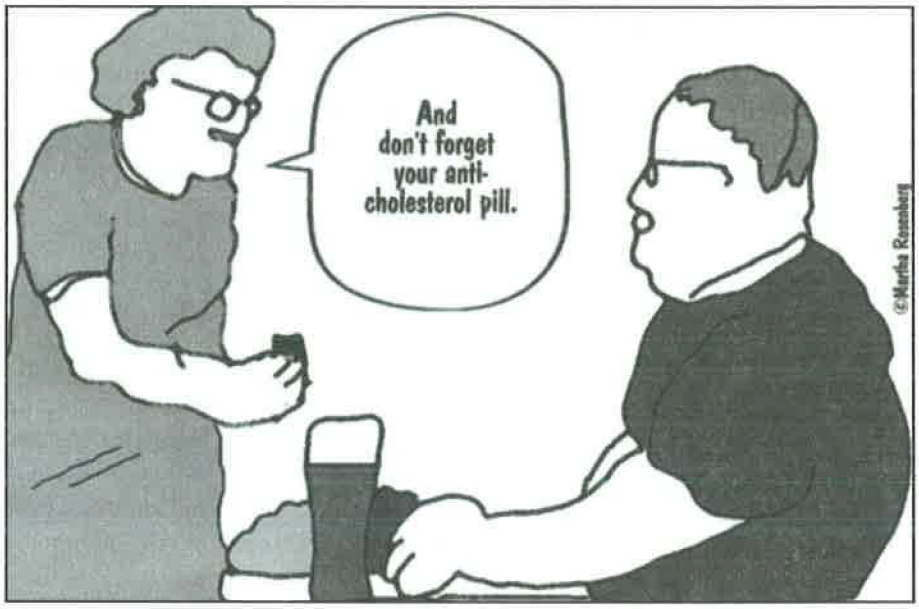
The phone line is open Monday through Friday, from 8 a.m. to 8 p.m. Eastern time. Callers aren't asked for their name, unless they want to receive printed material in the mail, and only their area codes are collected. They are asked some basic demographic questions at the end of the call, but can choose not to answer, and "it won't have an impact on how we deliver our service," she says.

The Cancer Information Service also handles questions by e-mail and by instant messaging. Recently, the line has been answering more questions about where to get financial help, how to pay for treatment, and where to get free or low-cost screening tests, such as mammograms.

Burke says one unexpected benefit of the call line is the confidence it instills in patients navigating the medical system. "It was empowering for people ... going into their appointment with questions and information to discuss," she says. ✦

Pharma's War on Kids

The following article, by Martha Rosenberg, originally appeared on OpEdNews.com. It has been reprinted with permission.



Kids with adult diseases — and adult pills illustration by Martha Rosenberg

The patient was overweight and had type-2 diabetes. He was on Crestor for cholesterol, Atacand for hypertension, the proton pump inhibitor Protonix for GERD (gastro-esophageal reflux disease), Axert for migraines and Singulair for asthma. The patient was eight years old.

Since Pharma discovered the ka-ching in pediatric psychopharmacology, millions of kids are on ADHD meds and other mental drugs for conduct disorders, depression, bipolar disorder, oppositional defiant disorder, mood disorders, obsessive-compulsive disorders, mixed manias, social phobia, anxiety and assorted "spectrum" disorders. They are even treated for seizure spectrum disorders with no seizures.

But according to new data from IMS health in a *Wall Street Journal* article, just as many kids are being treated for non-psychiatric conditions that are often "adult diseases."

Since 2001, high blood pressure meds for kids have risen 17 percent, respiratory meds 42 percent, diabetes meds 150 percent and heartburn/GERD meds 147 percent. Fifty percent of pediatricians also prescribe kids insomnia drugs, according to an article in the journal *Pediatrics.*

In fact, 25 percent of children and 30 percent of adolescents now take at least one prescription for a chronic condition says Medco, the nation's largest pharmacy benefit manager, making the kid prescription market four times as strong as the adult in 2009.

Why? Well one reason is the ped population is suffering from "middle age spread," just like the adult population, from too many calories and too little exercise. Over a third of U.S. kids are overweight and 17 percent are obese — which for a 4-foot-10 inch child would be 143 pounds — which predisposes someone to diabetes, hypertension, high cholesterol, sleep apnea, gallbladder disease and the osteoarthritis and musculoskeletal disorders kids are also contracting from carrying around too much weight.

But another reason is the direct-to-consumer drug advertising on TV, which began over a decade ago. In between ads for M&Ms, Reese's Peanut Butter Cups, Oreos, Hershey's Milk Chocolate and Doritos, kids and their parents saw $108 million worth of ads for Prilosec, $100 million for Claritin and $91 million for Zocor in 2000 — when the national "epidemics" of GERD, "seasonal allergies" and "statin deficiencies" began.

Nor are the meds kids are taking even deemed safe for children.

Kids react differently to medicines, says Duke University pediatrics professor Danny Benjamin in *The Wall Street Journal* — and in a third of FDA studies, what was thought to be the right dose for a kid wasn't. Long-term safety in kids is also "almost never known," says Dr. Benjamin since ped studies, like all drug studies, are of short duration.

(Wait seven years before taking a new drug unless you want to be an uncompensated tester, say drug safety advocates, unless it is truly a breakthrough drug.)

Consider statins like Lipitor, the world's top selling medication, which was approved for U.S. children in 2008 and recently in a chewable form in Europe. (Move over Fruit Loops and Flintstone gummies.)

Overprescribed, of debatable effectiveness in reducing heart attack, less desirable than lifestyle changes to lower cholesterol and expensive, statins are six times more likely to cause liver dysfunction, acute kidney failure, cataracts and muscle damage in adult patients, according to a 2010 article in the *British Medical Journal.* Let's give them to kids?

Statins are also linked to nerve damage, memory loss, sleep disturbances, impotence, breasts in men, a lupus-like syndrome and acute, usually mild, pancreatitis in an observational study, says the *Medical Letter,* though cause and effect are not clear.

"Plenty of adults down statins regularly and shine off healthy eating because they know a cheeseburger and steak can't fool a statin," writes Dr. Michael J. Breus on *The Huffington*

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- In addition, a total of five patients (some also in the above groupings) had evidence of ALCL involvement outside the implanted breast before or at the time that breast ALCL was diagnosed.

The ASPS and the ASAPS have ignored the currently available facts from published case reports of breast implant-associated ALCL. There are no data to support their assertion that surgery alone is curative. For most patients, chemotherapy and/or radiation therapy will be part of the recommended treatment plan. Furthermore, even with chemotherapy and radiation therapy, ALCL recurrence and spread to additional sites can occur. The findings from review of these published cases are therefore inconsistent with phrases such as a "benign course" or a "condition" rather than cancer, a tumor or a malignancy.

Such statements grossly misrepresent what is currently known about the treatment of this cancer and mislead both patients who may have received breast implant or those who may be considering undergoing breast implant surgery and the physicians who may provide care to such patients.

Finally, the literature case reports likely represent a minority of actual cases, and the total number of cases, as well as the number of ALCL patients with recurrence following treatment and spread of disease beyond the site of the breast implant is likely to be much higher.

In summary, two large national organizations representing plastic surgeons have attempted to trivialize the significance of the findings of increased numbers of cases of breast implant-related lymphomas. This campaign is misleading, dangerous and unethical. For the FDA to continue to work with these organizations, the agency should require them to stop such activities. For the breast implant registry that has been proposed, its control needs to be very carefully monitored by the FDA. The agency also needs to undo the misleading "educational" campaign, one of the main goals of which must be to keep women in the dark so they will continue to ask for breast implants, unaware of this serious risk.

We look forward to a prompt response to this information which, as far as the contents of the webinar, we assume you have been previously unaware.

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Regulatory Actions Surrounding This Issue

1988: Public Citizen petition to ban silicone gel breast implants

In November 1988, after reviewing many FDA documents leaked out to us that September by scientists concerned about the cancer risk of silicone breast implants, Public Citizen's Health Research Group petitioned the FDA to ban silicone gel breast implants.

The FDA scientists' concerns centered around studies by Dow Chemical, then the leader in the silicone breast-implant industry, showing that 23 percent of animals (rats) in whom small implants had been inserted developed highly malignant tumors, none of which developed in the control animals without silicone implants.

Among the recommendations made by FDA staff was a general medical alert warning the public about the possibility of malignancy development after long-term use of these implants. The agency also provided leaflets describing the risks (such as rupture) and the results of these cancer studies to past, present and future (potential) users of implants.

1992: FDA moratorium on sale

Since silicone breast implants had never been approved by the FDA because their marketing preceded the 1976 Device Law, and because the existing information about the implants was insufficient to assure safety, the FDA denied approval of the devices for use in augmentation. But the agency found that the continued availability of the devices for patients undergoing breast reconstruction or replacement of existing silicone gel-filled breast implants (revision) was necessary for the public health. A moratorium on their marketing was imposed in 1992, but implantation in the groups mentioned above was allowed on an investigational basis.

2006: FDA approves implants and lifts moratorium

In November 2006, the FDA issued letters to Mentor and Allergan (the two silicone gel-filled breast implant manufacturers at that time), approving their applications for the marketing of the implants.

2011: FDA announces review of cases of cancer associated with implants

After consulting with plastic surgery organizations, on Jan. 26, 2011, the FDA announced that there were 34 published cases in medical journals of a specific, rare type of cancer (anaplastic large cell lymphoma — ALCL) in women who had previously received implants. The location of the cancer was in the scar tissue that usually forms around the implant as part of the body's reaction to this foreign material.

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Sincerely,

Sidney Wolfe, M.D.
Director

Michael Carome, M.D.
Deputy Director, Public Citizen's Health Research Group

When *Health Letter* went to press, we had not yet heard if the FDA was going to insist that this dangerously misleading campaign should end. Interestingly, the president of the American Society for Aesthetic Plastic Surgery, Dr. Felmont Eaves, when confronted with the attempted trivializing of implant-related cancer by his colleague Dr. Haeck, told a reporter that "advising doctors to use the word "condition" instead of "cancer" wasn't the "best wording."✦

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Post. "Imagine a 10-year-old who loves his fast food and who knows he can get away with it if he pops his pills."

And asthma/allergy drugs? The FDA now warns that the heavily advertised Serevent, Foradil, Advair and Symbicort shouldn't be used if an inhaled corticosteroid (like Flovent) is already working to control asthma and shouldn't be used at all without an inhaled corticosteroid. (And they were approved why?)

These asthma drugs, long-acting beta-agonists or LABAs, billed as add-on drugs to "control asthma," turn out to sometimes worsen asthma and cause asthma-related intubation and death — exactly what they were supposed to prevent! Who is at the highest risk for harm and death from the drugs? Children 4-11 years old, according to the FDA.

Singulair, another allergy/asthma drug marketed for kids with simple allergies like hay fever that could be treated with over-the-counter antihistamines? In addition to FDA warnings about psychiatric side effects and published suicides of children on the drug, Singulair is believed to be linked to the aggression, hostility, irritability and other behavioral symptoms that are diagnosed as ADHD, says Fox News. Will pediatric Singulair patients join the 4.5 million on ADHD medicines and suffer those side effects too?

Still, Pharma's most insidious war on children is probably trying to get babies on GERD medicine.

Even though the approximately 71 times a day that babies spit-up is considered perfectly normal and does not damage the esophagus, the number of GERD prescriptions for babies has recently quadrupled, writes pediatrician Darshak Sanghavi. The drugs don't treat baby reflux but they "may increase brain bleeds and gut damage in preterm infants as well as the risk of food allergies in older infants," says Dr. Sanghavi, author of the bestselling "A Map of the Child." Oops.

Since the pricey "Purple Pill" heartburn drug Prilosec debuted over a decade ago, followed by Nexium, proton pump inhibitor drugs (PPIs) that switch off stomach acid-producing cells have become veritable "purple crack" say U.S. doctors.

And even though heartburn is not a valid indicator of GERD — it can exist without esophageal damage and vice versa — and PPIs are often prescribed for intestinal tract pain where no hydrochloric acid even exists, half of all hospital inpatients are now put on PPIs, writes Dr. Sanghavi. (The head of Medicaid and Medicare admonished AMA doctors in 2003, "You should be embarrassed if you prescribe Nexium, because it increases costs with no medical benefits.")

And just because PPIs are prescribed for people who don't need them or can't benefit from them doesn't mean they're not also unsafe.

Like asthma "control" drugs, PPIs can cause exactly what they are supposed to prevent — heartburn and reflux — when patients try to quit. They increase the risk of bone fractures in women by 25 percent, angioplasty-related deaths and intestinal infections. (Infections with Clostridium difficile are sometimes treated with — sorry! No euphemism! — fecal transfusions to replenish lost bacteria.)

And in kids? Common adverse effects of PPIs in children include headache, abdominal pain, nausea, constipation, diarrhea and increased risk of community-acquired pneumonia, say medical sources.

So why is Pharma picking on the child patient?

"Children are known to be compliant patients and that makes them a highly desirable market for drugs," says former Pharma rep Gwen Olsen, author of "Confessions of an Rx Drug Pusher." She continues:

> Children are forced by school personnel to take their drugs, they are forced by their parents to take their drugs, and they are forced by their doctors to take their drugs. So, children are the ideal patient-type because they represent refilled prescription compliance and 'longevity.' In other words, they will be lifelong patients and repeat customers for Pharma.

There is also "clinical laziness," says Dr. Sanghavi. "Nexium is over-prescribed for the most banal of reasons: It's less work to write a prescription and pretend the problem is solved."

The same could be said of drugs for other kids' diseases — the "adult" ones and the psychiatric ones.

An earlier version of this report appeared on AlterNet.org. ✦

Product Recalls

January 26, 2011 – February 23, 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

4-AD Dietary Supplement Capsules, 60-count bottles, sold individually and as part of promotional kits. Volume of product in commerce: 1,389 bottles. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor, which is not a dietary ingredient. All lots. Dcd, LLC.

Aroma-XL Dietary Supplement Capsules, 100-count bottles, sold individually and as part of promotional kits. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor, which is not a dietary ingredient. All lots. Dcd, LLC.

Arom-X Dietary Supplement Capsules, 60-count bottles and 80-count bottles, sold individually and in promotional kits. Volume of product in commerce: 9,208 bottles. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor, which is not a dietary ingredient. All lots. Dcd, LLC.

Arom-X UTT Solution Dietary Supplements, 60-mL bottles, sold individually and as part of promotional kits. Volume of product in commerce: 8,501 bottles. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor, which is not a dietary ingredient. All lots. Dcd, LLC.

Arom-XL Solution Dietary Supplements, 120-mL bottles, sold individually and as part of promotional kits. Volume of product in commerce: 4,518 bottles. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor, which is not a dietary ingredient. All lots. Dcd, LLC.

Aziffa Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Decavol Dietary Supplement Capsules, 63-count bottles. Volume of product in commerce: 7,867 bottles. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor, which is not a dietary ingredient. All lots. Dcd, LLC.

Erex Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Eyeful Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Hard Drive Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Libidinal Dietary Supplement Capsules, 15-count bottles and 30-count bottles. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an

FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Maxyte Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Mojo Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Monster Excyte Dietary Supplement Capsules, 15-count bottles. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Novedex XT Dietary Supplement Capsules, 60 mg, 60-count bottles. Volume of product in commerce: 1,399,535 bottles. Marketed without an approved new drug application; product contains 3,17-keto-etiochol-triene as an ingredient on the label, which is a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor which is not a dietary ingredient. All lots distributed between 1/22/2005 and 10/4/2010. Bronson Nutritionals, LLC.

OMG Dietary Supplement Capsules, 15-count bottles and sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

OMG-45 Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Prolatis' Dietary Supplement Capsules, 2-count blister packs, 16-count bottles, 40-count bottles or sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Que She, 60-capsule bottles packaged in yellow boxes. All labeling is in Chinese. Volume of product in commerce: Unknown. Marketed without an approved new drug application: The product contains multiple prescription and/or banned ingredients, making it an unapproved new drug. All lots. Bouncing Bear Botanicals.

Red Magic Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Size Matters Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Stiff Nights Dietary Supplement Capsules, 2-count blister packs, 6-count bottles and 30-count bottles. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Straight Up Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Verect Dietary Supplement Capsules, 2-count blister packs and 15-count bottles. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

WOW Dietary Supplement Capsules, 10-count bottles, 20-count bottles, 50-count bottles or sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Xaitrix Dietary Supplement Capsules, 15-count bottles and sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Xytamax Dietary Supplement Capsules, sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Zilex with Golden Spear Dietary Supplement Capsules, 15-count bottles. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. Novacare, LLC.

Zotrex Dietary Supplement Capsules, 2-count blister packs, 15-count bottles, 30-count bottles, 45-count bottles or sold in bulk. Volume of product in commerce: Unknown. Marketed without an approved new drug application; product may contain sulfoaildenafil, an analogue of sildenafil, the active ingredient used in an FDA-approved product for the treatment of male erectile dysfunction. All lots with manufacturer or distribution dates prior to June 17, 2010. 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

Amoxicillin and Clavulanate Potassium Tablets, 250 mg/125mg, 500 mg/125mg, 875 mg/125mg, 20-tablet bottles and 30-tablet bottles, Rx only. Volume of product in commerce: 45,016 units still within expiry. Subpotent; clavulanate potassium (15-months stability). Lot #s: JG5743, JG1533, JF0481, JF0482. Apotex, Inc.

ArimaDex Dietary Supplement Capsules, 442 mg, 60-count bottles. Volume of product in commerce: 13,686 bottles. Marketed without an approved new drug application; product has been found to contain 3, 17-keto-etiochol-triene, a synonym for the same ingredient, commonly known as ATD. ATD is an aromatase inhibitor not considered a dietary ingredient. Lot #s: S9H042, exp. date 09/2011; S9A102, exp. date 02/2011. Watson Industries, Inc.

Armour Thyroid Tablets, 30 mg (1/2 grain), 100-count bottles. Volume of product in commerce: 31,172 bottles. Labeling: Label error on declared strength; some bottles are mislabeled as containing 1/2-grain tablets but actually contain 1-grain tablets. The entire lot is being recalled even though some bottles are labeled correctly because bottles of 1/2-grain and 1-grain could be shrink-wrapped together. Lot #: 1077413, exp. date 9/2011. Forest Pharmaceuticals, Inc.

Assured Cherry Menthol Cough Drops, 48-drop plastic bag, 36 bags per case. Volume of product in commerce: Unknown. The menthol-containing cough drops were not manufactured in compliance with cGMPs and USP Menthol Lozenges monograph label requirements, exceeding the firm's specification upper limit for menthol. Lot #s: A9362-A9351, B9357-A9351, B9362-A9351, A10005-A9349, A10006-A9349, B0288-A0244. Primrose Candy Co.

Assured Honey Lemon Cough Drops, 48-drop plastic bag, 36 bags per case. Volume of product in commerce: Unknown. The menthol-containing cough drops were not manufactured in compliance with cGMPs and USP Menthol Lozenges monograph label requirements, exceeding the firm's specification upper limit for menthol. Multiple lots. Primrose Candy Co.

Assured Sugar Free Black Cherry Cough Drops, 26-drop plastic bag, 36 bags per case. Volume of product in commerce: Unknown. The menthol-containing cough drops were not manufactured in compliance with cGMPs and USP Menthol Lozenges monograph label requirements, exceeding the firm's specification upper limit for menthol. Multiple lots. Primrose Candy Co.

Assured Sugar Free Honey Lemon Cough Drops, 26-drop plastic bag, 36 bags per case. Volume of product in commerce: Unknown. The menthol-containing cough drops were not manufactured in compliance with cGMPs and USP menthol Lozenges monograph label requirements, exceeding the firm's specification upper limit for

DRUGS AND DIETARY SUPPLEMENTS

menthol. Lot #s: A0019-B0018, A0020-B0018, A0022-B0018. Primrose Candy Co.

Expanded Glycosaminoglycans (GAG). Volume of product in commerce: Unknown. Testing of lot indicated a small amount of oversulfated chondroitin sulfate (OSCS). Lot #: 1049-0087. Scientific Protein Laboratories, LLC.

Fentanyl Transdermal System, 25 mcg/hr, 5-count carton, Rx only. Volume of product in commerce: 75,525 cartons. Miscalibrated and/or defective delivery system: Defective product may result in decreased efficacy. Lot #: 264085A exp. date 01/2012. Watson Laboratories, Inc.

Heparin Sodium, Rx only. Additional testing of retained samples of this API lot indicated a small amount of oversulfated chondroitin sulfate (OSCS). Other API lots are being recalled because additional testing of retained samples of crude heparin contained in these lots indicated a trace amount of oversulfated chondroitin sulfate (OSCS). Lot #s: 1035-0771, 1035-0778, 1035-0780. Scientific Protein Laboratories, LLC.

Hyland's Teething Tablets, 50 tablets, 125 tablets, 145 tablets, clip strip 6x125 tablets, T-6 sample packets. Volume of product in commerce: 963,789,242 tablets. Lack of blend uniformity. All lots. Standard Homeopathic Company, Inc.

Ibuprofen Tablets, 800 mg, 500-tablet bottles, Rx only. Volume of product in commerce: 785 bottles. Adulterated presence of foreign tablets: Some bottles of 800-mg ibuprofen tablets may contain one or more 400-mg ibuprofen tablets. Lot #: 10AL03A. Shasun Chemicals & Drugs, Ltd.

OSR#1 (Oxidative Stress Relief), 3 g capsules, blister-packed; 9 g powder pouches, 250 g powder bottles. Volume of product in commerce: 62,971 units. Marketed without an approved new drug application: product makes claims that it affects the body's structures and functions. Lot #s: 090306-01, 100121-01, 090862-01, 091203-01. PCI Synthesis, JLM Pharmatech, Inc. and Maco Bag Corp.

Refenesen Expectorant Tablets (Leader Cough Tabs Expectorant), 200 mg, 60-count bottle. Volume of product in commerce: 337 bottles. Labeling: Label mix-up; some bottles labeled to contain guaifenesin 200-mg tablets may actually contain acetaminophen 325 mg, phenylephrine 5 mg and chlorpheniramine maleate 2 mg tablets. Lot #: 091612, exp. date 05/2011. Contract Pharmacal Corp.

Sular Extended Release Tablets, 17 mg, 25.5 mg, 100-tablet bottles, Rx only. Volume of product in commerce: 24,362 units. The product failed dissolution testing at four hours at the 12-month stability testing time point. Lot #s: 2020210, 2020569. Shionogi Pharma, Inc.

Triamterene and Hydrochlorothiazide Capsules, 50 mg/25 mg, 100-capsule bottles, Rx only. Volume of product in commerce: 515,466 bottles. CGMP deviations; firm reported use of a blender with a slightly different inside geometry than the blender used during process validation. Using a blender that has not been validated indicates CGMP deviations. Lot #s: 172570, exp. date 12/2010; 176302, exp. date 05/2011; 178590, exp. date 06/2011; 179318, exp. date 08/2011; 180013, exp. date 10/2011; 181796, exp. date 12/2011; 183307, exp. date 02/2012; 184758, exp. date 04/2012; 187339, exp. date 06/2012; 188628, exp. date 08/2012; 190119, exp. date 10/2012; 191984, exp. date 02/2013; 194254, 196706, 197756, exp. date 03/2013; 198604, exp. date 07/2013.

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

2011 Felt Adult Bicycles. The bicycle's fork can break, causing the rider to lose control, fall and suffer injuries. Felt Bicycles, (866) 433-5887 or www.feltracing.com.

Air Compressors. The air compressor motor can overheat, posing a fire hazard. DeVilbiss Air Power Co., (866) 220-5627 or www.porter-cable.com.

B.O.B.® Single and Double Strollers. A drawstring on the stroller can get wrapped around a child's neck, posing a strangulation hazard. B.O.B. Trailers Inc., (855) 242-2245 or www.bobcanopy.com.

Briggs & Stratton Model 40 V-Twin Engine. Wear on misrouted wiring may cause it to disconnect from the shut-off device, allowing the engine to continue running when the key is in the "OFF" position or when the operator gets off the seat while the mower is engaged, posing an injury hazard to consumers. Briggs & Stratton Corp., (866) 927-3349 or www.briggsandstratton.com/engines/support/contact.

CONSUMER PRODUCTS

BT SA-17 Paintball Gun/Marker. When users attempt to pierce the CO2 cartridge by closing the lever to the cartridge chamber, the cartridge can fly out of the marker, posing an injury hazard to consumers. KEE Action Sports, LLC, (800) 220-3222 or www.paintballsolutions.com.

Burlington Basket Company Bassinets. If the cross-bracing rails are not fully locked into position, the bassinets can collapse, causing the infant to fall to the floor or fall within the bassinet and suffer injuries. Burlington Basket Company, (800) 553-2300 or www.burlingtonbasket.com.

Butterfly Push Toy. The plastic balls on the butterfly's wings can break, causing small metal balls inside to come free. These metal balls pose choking and aspiration hazards to young children. Kang Sheng Group, (877) 485-7285.

Cachet Swivel Chairs. The front seat support part of the chair can crack and fail, posing a fall hazard to consumers. Steelcase, Inc., (800) 391-7194 or http://recall.steelcase.com.

Children's Light-Up Watches. Watch battery current interacting with nickel in the watch's stainless steel back can cause skin irritation and/or burning sensations to children who are allergic to nickel. Walt Disney Parks and Resorts, (877) 560-6477 or www.waltdisneyworld.com.

Convertible Clothes Iron. The iron can overheat and cause a fire because of a wiring issue, posing a risk of burn injury to consumers. Sunbeam Products, Inc., (800) 656-9708 or www.sunbeamconvertible.com.

Food Dehydrators with Digital Timers. The screws that secure the motor to the back panel can come loose, causing the motor to fall on the heating element. This poses a fire hazard. LEM Products, (877) 425-4509 or www.lemproducts.com.

Frontgate Closet Ladders. The ladders can unexpectedly break, posing a fall hazard to consumers. Frontgate, (888) 298-4651 or www.regcen.com/frontgateladder.

Hoover® WindTunnel Canister Vacuums. The power cord between the power nozzle and the wand connector can short-circuit, posing fire and shock hazards to consumers. This condition can occur even if the vacuum has been turned off but left plugged in. Hoover, Inc., (888) 564-2066 or www.hoover.com/windtunnelcanisterrecall.

Jogging Strollers. When folding and unfolding the stroller, a consumer's finger can become caught in the hinge mechanism, posing amputation and laceration hazards. phil&teds USA, (877) 432-1642 or www.philandteds.com/support.

Kristi G Go & Grow Chair. The chair can tip over, posing a fall hazard. SwimWays Corp., (888) 559-4653 or www.swimways.com.

Le Creuset Glass Lids. The glass lids can crack or break during use, posing a laceration hazard to consumers. Le Creuset of America, Inc., (866) 747-0186 or www.lecreuset.com/en-us/.

LED Lamps. When used without a Class II transformer, the lamp can overheat, posing a fire hazard. Eco-Story, (207) 699-5727 or www.eco-story.com.

LED Night Lights. An electrical short circuit in the night light can cause it to overheat and smolder or melt, which can burn consumers or result in fire. American Tack & Hardware Co., Inc. (AmerTack), (800) 420-7511 or www.amertac.com.

Men's and Women's Jackets. The jackets fail to meet the federal flammability standard for wearing apparel, posing a fire hazard to consumers. James Perse, (800) 430-8559 or www.jamesperse.com.

NESCO American Harvest Gardenmaster Food Dehydrator. A defective capacitor in the electronic control module can overheat, posing a smoke and fire hazard. NESCO, (800) 726-4457 or www.nesco.com.

Newborn Keepsake Mittens. Decorations on the mittens can be pulled off, posing a choking hazard. Nurses Choice Corp., (800) 747-7076 or www.nurses-choice.com.

Novara Fusion Bicycles. The alloy steerer tube could separate from the fork causing the rider to lose control, posing a fall hazard to consumers. REI (Recreational Equipment, Inc.), (800) 426-4840 or www.rei.com/help/recall/index.html.

Outdoor Playsets. The swing seats on the playsets can crack and break in half, causing the user to fall to the ground. Escalade Sports, (800) 742-6009 or www.escaladesports.com.

OUTER EDGE Snow Bikes. The front ski can crack or break, causing the snow bike to stop suddenly and posing a fall hazard to consumers. Tech 4 Kids, Inc., (866) 287-4761 or www.outeredgeindustries.com/safetynotice.

Perfect Pullup. The plastic handle on the recalled product can crack posing a fall injury hazard for the user. Perfect Fitness, (877) 974-7733 or www.perfectonline.com/handleexchange.

CONSUMER PRODUCTS

Pool Safety Vacuum Release System. Improper plastic material found inside the recalled product has been attributed to vacuum release failures, which create an entrapment hazard to swimmers and bathers. Vacless Systems, Inc., (818) 899-1755 or www.vacless.com.

Portable Electric Heater. An electrical connection in the base of the unit can overheat, causing it to melt and expose the electrical connection, posing a fire hazard to consumers. Lasko Products, Inc., (800) 363-8044 or www.laskoproducts.com.

Portable Space Heaters. The space heater can overheat due to loose electrical connections, posing a fire hazard to consumers. PD Sixty Distributor, Inc., (866) 367-4538 or www.CHSrecall.com.

Poulan Pro Generators. The carburetor can fail allowing gasoline to leak, posing a fire hazard to consumers. Husqvarna Professional Products, Inc., (877) 257-6921 or www.husqvarna.us/december2010alert.

Pre-Lit Artificial Christmas Trees. Christmas trees advertised before Dec. 21, 2010, as indoor/outdoor were supplied with extension cords rated for indoor use only, posing an electrical shock hazard if used outside. Balsam Hill, LLC, (877) 694-2752 or www.balsamhill.com/recalls.

Propane (LP) Gas Sold in Portable Cylinders and Delivered to Storage Tanks. Some of this propane does not have sufficient levels of the odorant that is added to propane to help alert consumers to a gas leak. Failure to detect leaking gas can present fire, explosion and thermal burn hazards to consumers. Aux Sable Liquid, (866) 473-7612 or www.propanegasalert.com.

Rechargeable Batteries Sold with Certain Slim and Secure™ Video Monitors. The battery in the handheld video monitor can overheat and rupture, posing a burn hazard to consumers. Summer Infant, (800) 426-8627 or www.summerinfant.com.

Refreshing Rings Infant Teethers/Rattles. Small pieces of the plastic ball can detach as a result of children chewing on the teether/rattle, posing an ingestion hazard. Sassy, Inc., (800) 323-6336 or www.sassybaby.com.

Remote Control Systems for Entertainment Electronics. If the battery falls from the remote control during handling, it can rupture and smoke or ignite, posing a fire hazard. Niles Audio Corp., (800) 667-3991 or www.nilesaudio.com/recall.

Remote-Controlled Toy Tanks. The tank's controller can overheat and melt, posing a burn hazard to consumers. Family Dollar Services, Inc., (800) 547-0359 or www.familydollar.com.

Resistance Stretch Tubing. The handle on the tubing, also called bands, can break or detach while in use, causing the tubing or handle to strike the user and posing an injury hazard. EB Brands, (800) 624-5671 or www.ebbrands.com.

Rosebud Drop-Side Cribs. The drop-side rail hardware on the cribs 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 rail and the crib mattress in which infants and toddlers can become wedged or entrapped, posing risks of suffocation and strangulation. In addition, children can fall out of the crib when the drop-side rail falls unexpectedly or detaches from the crib. Drop-side rail failures can also occur due to incorrect assembly or with age-related wear and tear. The Land of Nod, (800) 933-9904 or www.landofnod.com.

RUND Clear Glass Mugs. The inner walls of the double-walled glasses can break during use, posing a laceration hazard to consumers. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Simplex Fire Alarm Control Panel. The recalled fire alarm control panels can fail to send a signal to alert monitoring centers in the event of a fire. SimplexGrinnell, (866) 565-6322 or www.simplexgrinnell.com.

SNIGLAR Cribs. The four bolts provided with some SNIGLAR cribs to secure the mattress support are not long enough. This can cause the mattress support to detach and collapse, creating a risk of entrapment and suffocation to a child in the crib. IKEA Home Furnishings, (888) 966-4532 or www.ikea-usa.com.

Sno-Tek Snow Blowers. The snow blower's engine is missing a safety shield above the side mounted electric starter, posing a laceration hazard to the consumer's fingers. Liquid Combustion Technology, LLC, (800) 552-8094 or www.LCTUSA.com.

TrueLiving Heater Fans and Portable Quartz Radiant Heaters. These heaters have caught fire, posing a fire hazard to consumers. Atico International USA, (866) 448-7856 or www.aticousa.com.

Windbreaker Jackets. The jackets contain drawstrings, which pose strangulation and entrapment hazards to young children. In February 1996, the 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. MIKI HOUSE USA, Inc., (877) 747-7653.

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PUBLICCITIZEN Health Letter

Outrage of the Month! War's Adverse Impacts

From a health perspective, U.S. wars in other countries are multiply dangerous — not only because of deaths and disability involving civilians and military troops in those countries — but also because of the wars' enormous financial drain on our economy, especially when budget deficits are causing draconian cuts to be proposed, endangering the health of Americans.

Let's first examine the toll on people in one country where war has been waged. A recently published paper used the most reliable and conservative methods to estimate deaths during the Iraq war and concluded that there were 92,614 Iraqi civilian deaths from armed violence occurring from March 20, 2003 through March 19, 2008. This, of course, does not count the much larger numbers of severely disabled civilians, nor does it include any of the deaths or disability of Iraqi or U.S. troops.

The domestic impacts that result from war-necessitated budget cuts include the weakening of government programs and regulations, such as worker health and safety programs, Medicaid for those who cannot otherwise afford to purchase health insurance, environmental protections and product safety regulations.

The connection between wars' direct toll of deaths and injuries and the damage to people in this country because of budget cuts is, not surprisingly, "simply" a matter of money. The most recent estimate of the cost this fiscal year of waging the war in Afghanistan is $116 billion. Current estimates are that by the end of this year we will have spent approximately $1 trillion on the Iraq and Afghanistan wars.

An increasing number of elected representatives from across the political spectrum have supported ending the Afghanistan war, now the longest war in U.S. history. Democratic Rep. Barbara Lee of California joined conservative Reps. Ron Paul of Texas and Walter Jones of North Carolina to support a much faster withdrawal from Afghanistan. Congressman Jones summed it up quite well, saying that the conflict "is breaking the military." He added, "We are trying to take a country that's never had a national government and make them a democracy. It just doesn't work."

For the sake of the lives and health of people in the countries where the U.S. is waging devastating wars — and for the sake of the lives and health inevitably lost here at home from programs cut in order to pay for these wars — enough is enough.