



# Proton Pump Inhibitors: Dangerous and Habit-Forming Heartburn Drugs

Robert Kuttner, co-editor of *The American Prospect* magazine, had experienced a few bouts of mild heartburn, when a particularly severe episode sent him to the emergency room. After his doctor prescribed Prilosec (omeprazole), a common heartburn therapy, he thought that this would resolve his condition. He never imagined that this drug — intended to treat his symptoms — would actually make them worse, and that he would become dependent for years on ever-increasing doses of the medication in a dangerous cycle ending only after he stopped taking Prilosec and switched to other, safer therapies.

This story is likely all too common among patients placed on a widely used class of medications known as proton pump inhibitors (PPIs) — Prilosec being the most common — which suppress stomach acid and are used to treat conditions such as heartburn and other, more severe illnesses. The drugs have traditionally been considered largely harmless by patients and physicians alike. Yet PPIs have been increasingly associated with a range of dangerous, and sometimes fatal, side effects and can even cause, as in Mr. Kuttner’s case, long-term dependence.

In August 2011, Public Citizen filed a petition with the Food and Drug Administration (FDA) to put **black box warnings** on all PPIs to warn doctors and patients of these life-threatening side effects and to remind doctors that there are many safer alternatives for everyday conditions, such as acid reflux, that often work just as well. (To read the

## PPIs Available in the U.S.

Prescription PPIs	
Generic Name	Brand Name
dexlansoprazole	Dexilant
esomeprazole	Nexium
esomeprazole and naproxen	Vimovo*
lansoprazole	Prevacid
omeprazole	Prilosec
omeprazole and sodium bicarbonate	Zegerid
pantoprazole	Protonix
rabeprazole	Aciphex
Over the Counter PPIs	
Generic Name	Brand Name
omeprazole	Prilosec OTC
omeprazole and sodium bicarbonate	Zegerid OTC
lansoprazole	Prevacid 24-Hr

\* *Vimovo is a combination of the PPI esomeprazole and the nonsteroidal anti-inflammatory drug (NSAID) naproxen.*

petition, visit: <http://www.citizen.org/petition-asking-fda-to-add-warnings-to-ppis>.) The petition was supported by Mr. Kuttner and Dr. Helge Waldum, a physician-researcher and author of 135 scientific papers, among them the first study showing that patients could become dependent on PPIs.

The absence of prominently displayed risk information in PPI labels is likely a key contributor to the vast amount of overuse of the drugs, as doctors may not be aware that such serious risks exist and thus resort to PPIs as a first option for even mild cases of heartburn. Most patients on the drugs do not even have

a documented need for the therapy, and many more could easily be switched to safer options.

## PPIs available in the U.S.

There are currently eight different prescription PPI medications and three over-the-counter medications available on the U.S. market. (See the “PPIs Available in the U.S.” table on this page.)

Some of the FDA-approved uses for prescription PPIs are treatment of gastric ulcers and erosive esophagitis, and prevention of upper gastrointestinal bleeding, commonly seen with nonsteroidal anti-inflammatory drug (NSAID) use. One of the most common conditions for which PPIs are prescribed is gastroesophageal reflux disease (GERD), or heartburn.

Many people have experienced GERD at some point in their lives, and for some, it is so severe that they seek out, and often need, medication for relief. But, for most, the symptoms are mild and fluctuate with lifestyle or diet, and minor modifications to either could alleviate symptoms. Yet studies show that many of these people are placed on PPIs unnecessarily — and once they’re

[see PPI, page 2](#)

## In This Issue

Preventing Diabetes on a Budget .....	6
RECALLS.....	8
OUTRAGE!.....	12

**PUBLIC CITIZEN**  
**Health Letter**

SEPTEMBER 2011  
Vol. 27, No. 9

*Editor*

Sidney M. Wolfe, M.D.

*Managing Editor*

Cynthia Williams

*Contributors*

Sidney M. Wolfe, M.D.  
Sammy Almashat, M.D.

*Graphic Designer*

Erin Hyland

*Public Citizen President*

Robert Weissman

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C., to fight for the public's health and give consumers more control over decisions that affect their health.

Annual subscription rate is  
\$18.00 (12 issues).

Material in the *Health Letter* may not be reprinted without permission from the Editor. Send requests, subscription and address changes to:

*Health Letter*  
1600 20th St. NW  
Washington, DC 20009

Copyright © *Health Letter*, 2011  
Published monthly by Public Citizen's  
Health Research Group  
All rights reserved. ISSN 0882-598X

**PPI, from page 1**

on, they may have a hard time getting off the drugs.

**History and popularity of PPIs**

PPIs first emerged on the scene in the 1980s, at a time when patients often medicated for heartburn on an as-needed basis, using safe antacid therapies or modifying their daily routines in ways that often worked to relieve symptoms, such as raising the head of the bed or avoiding certain foods in excess. The need for long-term, once-daily acid-suppressing therapy was relatively uncommon and reserved for severe cases of acid reflux. Histamine-2 receptor antagonists (H2As) — such as cimetidine (Tagamet) and ranitidine (Zantac) — were the drugs of choice for quelling excessive acid production in these cases. These drugs work by suppressing acid production in the stomach, but not as profoundly as do PPIs. They, therefore, carry a lower risk for serious adverse effects.

However, following their introduction in the U.S., PPIs rapidly rose in popularity over the next two decades. This was due in part to their considerable effectiveness for certain serious conditions, such as peptic ulcer disease, but much more so to their widespread inappropriate use for indications for which there is no evidence of benefit and their (incorrectly) perceived lack of side effects. PPI use increased more than eight-fold from 1995 to 2006, and in 2009, there were 119 million prescriptions filled for the medications.

Contributing to this explosion in PPI use were massive promotional campaigns and a disturbing trend of older PPIs being repackaged in new, slightly tweaked but otherwise identical forms. Nexium (esomeprazole) is a poster child of this trend. Nexium, the so-called “purple pill,” was simply a reformulation of a previously approved drug, Prilosec (omeprazole), whose patent was expiring around the time of Nexium's introduction. In 2001, drug manufacturer AstraZeneca released

Nexium amid a large-scale promotional campaign, with a half-billion dollars spent on marketing in just the first year. In response, sales predictably climbed to astronomical levels. By 2009, Nexium was easily the top-selling PPI and ranked second in both retail sales (\$5 billion) and number of prescriptions filled (26.5 million) among all brand-name drugs in the country.

This trend of repackaging older PPIs in slightly modified (and much more expensive) forms continued with the recent approval of Dexilant (dexlansoprazole — a repackaging of Prevacid, or lansoprazole, which is now available as a generic and much cheaper). Nexium and Dexilant are prime examples of the decreased innovation seen in the pharmaceutical industry in recent years, and of the desperate — and wildly successful — attempts of the industry to get doctors to prescribe, and patients to use, exorbitantly priced drugs that are essentially identical to older, cheaper versions.

**Relief at a high cost**

Due in large part to these promotional campaigns, PPI sales have skyrocketed. But what are the costs of such widespread use? And do these costs outweigh the benefits?

The economic cost of PPI use is high enough, with \$13.6 billion spent on the drugs in one year alone (2009), making them the third highest-selling class of drugs in the country. By contrast, safer H2A therapies are not even among the 15 top-selling drug classes, not to mention the lower prices of antacids and the safest of all options: diet and lifestyle changes.

Unfortunately, this higher spending on PPIs does not confer any increase in safety or, in most cases, effectiveness. As discussed below, most people with heartburn can do just fine using safer alternatives. Moreover, PPIs have serious safety issues not seen with other heartburn therapies. Of most concern to patients contemplating PPI therapy, due to the absence of prominent

[see PPI, page 3](#)

## PPI, from page 2

warnings in the drugs' labels, even doctors may not be aware of these potentially fatal side effects prior to writing a prescription.

Furthermore, new side effects are constantly being found. In just the past year and a half, the FDA has released two safety alerts warning that PPI use was associated with potentially fatal side effects: osteoporotic fractures (of the hip, spine and wrist) and severe magnesium deficiency. These are two of many serious adverse reactions that have been associated with PPI therapy, as detailed in our petition and summarized below.

### Dangerous side effects

PPIs are so named because of the mechanism they use to shut off the production of stomach acid, which they do very well. So well, in fact, that a multitude of side effects can occur, in part as a result of this shutdown of one of the body's most basic functions. As Dr. Waldum observed in his statement in support of our petition, many scientists and physicians "dismiss the alteration by PPIs of central biological functions [of stomach acid] and believe that some of these basic functions can be removed without adverse consequences."

This perception has now been refuted by an increasing body of research showing that PPIs do, in fact, have unintended consequences. The drugs cause a wide range of side effects, and although some of these are already included in the labels, none (including those that are life-threatening) are displayed prominently as black box warnings. Thus, physicians who routinely prescribe PPIs as initial therapy for GERD may not be aware of these serious risks when deciding whether to start patients on the drugs.

The major side effects of PPI therapy documented in our petition include:

- **Bone fracture.** In 2010, the FDA announced that it was requiring a change in prescription and over-the-counter labeling of PPIs to

---

**In August 2011, Public Citizen filed a petition with the FDA to put black box warnings on all PPIs [such as Prilosec] to warn doctors and patients of ... life-threatening side effects and to remind doctors that there are many safer alternatives for everyday conditions, such as acid reflux, that often work just as well.**

---

include safety information warning patients about the risk of hip, spine and wrist fractures after using PPIs for a year or more. This announcement came after a review by the FDA of seven large studies showing that the drugs were linked with a higher rate of these serious fractures in women with osteoporosis. A few months later, the labels of all PPIs were changed to reflect this new information, although no (more prominent) black box warning in the labels was required. Women with osteoporosis are already at high risk for fractures, especially hip fractures, which are often fatal. This risk should be seriously considered by these women before starting long-term therapy.

- **Infection.** PPIs increase the risk for certain serious, and often fatal, infections, such as pneumonia and a severe type of diarrhea known as *Clostridium difficile*, which is normally seen only in severely ill patients or those on antibiotics. Maintaining normal amounts of stomach acid is important in preventing harmful bacteria from colonizing the intestinal lining. As PPIs work by largely eliminating this acid, bacteria can thrive and cause infections in the intestines or even the lungs. There is currently only limited risk information on *Clostridium difficile* infection, and no information at all on pneumonia risk, in PPI product labels.
- **Magnesium deficiency.** In March 2011, the FDA released a safety alert warning that long-term use of PPIs may cause severe magnesium

deficiency. Magnesium is an essential electrolyte, and a decrease in levels can be life-threatening, causing dangerous heart-rhythm disorders and seizures. Certain patients, especially the elderly, may be taking other medicines that decrease magnesium levels (such as diuretics for high blood pressure) or medications (e.g., digoxin) that can prove fatal in the presence of low magnesium. Patients on long-term PPI therapy, especially those taking these other medications, should have magnesium levels checked both before starting therapy and periodically throughout treatment.

- **Drug-drug interactions.** In 2009, the FDA released a warning that taking omeprazole, one of the oldest and most popular PPIs, could diminish the effectiveness of another widely used drug to prevent heart attacks and strokes, clopidogrel (Plavix). The warning was based on multiple studies that showed increased rates of heart attacks in patients who took both medicines compared to those who took only Plavix. The FDA restricted its warning solely to omeprazole, even though studies have shown that other PPIs could also be implicated in this interaction. PPIs have also been shown to reduce levels of the immune suppressants methotrexate (Folex, Trexall) and mycophenolate mofetil (Cellcept), potentially reducing their effectiveness in treating cancer and preventing organ transplant rejection, respectively. Patients taking any of these medications should talk with [see PPI, page 4](#)

## PPI, from page 3

their doctors before starting (or continuing) PPI therapy.

- **Vitamin B12 deficiency.** Vitamin B12 is an essential vitamin needed for nerve signaling and production of blood cells, among other functions. PPIs may cause Vitamin B12 deficiency, leading to anemia or serious neurological dysfunction. Elderly patients and others (such as vegans) at risk for low B12 levels may need to reconsider PPI therapy with their doctors or at least monitor B12 levels before and during treatment.
- **Acute interstitial nephritis.** The risk for a serious kidney disease known as acute interstitial nephritis (AIN) may be increased with long-term use of PPIs. In 60 case reports describing AIN after PPI use, one-third of patients required steroid therapy, and three were placed on dialysis (one permanently). Although it's unclear whether the PPI use actually caused the kidney disorder, patients with existing kidney disease should talk with their doctors about this potential side effect before starting PPI therapy.

## PPIs may be habit-forming, causing the condition they are supposed to treat

The previously mentioned serious side effects are all the more likely to occur given that people tend to use PPIs for much longer than originally intended. When first developed, the drugs were designed for short-term relief of GERD, and on almost all PPIs, the recommended therapy for uncomplicated heartburn is only four to eight weeks. However, recent studies have shown that patients are increasingly staying on the drugs for years, in part because these seemingly innocuous medications may be habit-forming.

Research shows that after using PPIs

for a month or more, patients who stop taking the drug make even more stomach acid than they did before they started the drug, a phenomenon known as rebound acid hypersecretion, which causes acid reflux symptoms to return at an even greater intensity than before therapy. The symptoms prompt patients to begin taking the PPI again, creating a long-term dependence on the medication. This is particularly worrisome for the large number of patients who did not even need the drugs in the first place. In other words, PPIs actually cause the symptoms they are intended to treat — even in previously healthy patients.

Mr. Kuttner's story is a case in point. After years of unsuccessfully trying to control his symptoms with ever-higher doses of a PPI, the reflux resolved only after a physician tapered him off the drug to safer therapies. Now largely symptom free, Kuttner concludes:

“My experience certainly seems to confirm the pattern of PPI medication causing — or in my case, seriously aggravating — the condition that it supposedly treats. In my case, the PPI seemed to have primed my system to produce increasing amounts of acid so that over time I was more prone to more attacks triggered by ever more minor departures from a very low fat diet. The ever increasing amounts of PPI helped only temporarily and required dependence on even higher doses, and so on, over several cycles.

*Only getting off the PPI reversed what seemed to be a chronic and progressive condition.*” [emphasis in original]

## For most patients, serious risks come with no benefit

While PPIs do benefit many patients with serious illnesses, such as peptic ulcer disease, or those taking certain medications (e.g., NSAIDs) known to harm the stomach lining, many more people are taking PPIs for no reason at all.

In fact, one of the main reasons for

---

## There are currently eight different prescription PPI medications and three over-the-counter medications available on the U.S. market.

---

the rapid rise in popularity of PPIs has been their widespread inappropriate use for indications for which there is no evidence of benefit. For most patients, this overutilization of PPIs has serious adverse consequences, but not many benefits, when compared to alternative heartburn therapies. Here we outline four key reasons for the massive overuse of PPIs, followed by recommendations on how to treat heartburn symptoms without resorting to this risky therapy:

- **Inappropriate prescribing.** PPIs are meant to be taken for serious conditions (e.g., peptic ulcer disease and rare diseases where stomach acid secretion is greatly increased) and to protect against the harmful effects of NSAIDs on the stomach lining. For these conditions, they have been proven to be of benefit. But patients taking PPIs for these reasons are a minority. Studies have shown that one-half to two-thirds of all patients on PPIs do not, in fact, have an appropriate indication for treatment, and many become dependent on the drugs, taking them much longer than indicated for mild cases of heartburn.
- **Unnecessarily high doses and daily therapy.** Another problem, even in patients for whom PPIs are indicated, is the use of unnecessarily high doses. Most patients on PPIs are prescribed high doses to be taken on a daily basis, but these high doses are often neither necessary nor more effective than lower doses. Multiple studies have confirmed that lower doses (often only half the dose

[see PPI, page 5](#)

recommended in the label) and less frequent use (every other day) are in many cases just as effective as higher doses, and put patients at a lower risk for some of the serious side effects mentioned above. On-demand therapy (where PPIs are not taken regularly, but only when symptoms arise) is also effective for many patients.

- **PPIs as the first choice for GERD.**

In this age of overreliance on medications for almost every minor condition, it is not surprising that PPIs are often thought of as the first option in treating heartburn. Even the professional association of gastroenterologists (the American Gastroenterological Association) has recommended that PPIs be used as initial therapy for GERD. However, as shown above, there are many safer alternatives that are often just as effective as, and much cheaper than, daily-dose PPI therapy. In fact, studies show that most patients wouldn't even need PPI therapy were they to follow the "step-up" regimen outlined in the "Recommendations for relieving heartburn symptoms" section for treating heartburn. The regimen starts with lifestyle changes and progresses gradually to more intense therapy, with PPIs indicated only if these other treatments fail to relieve symptoms.

- **Starting PPIs unnecessarily during hospitalization.** Estimates vary, but anywhere from 20 to 70 percent of patients admitted to the hospital will be unnecessarily started on a PPI. This has become common practice in hospitals, where starting a PPI is as easy as checking a box on the admission checklist. And many, if not most, of these patients are continued on the drugs for no apparent reason after discharge. In one study, up to half of all hospitalized patients

---

**PPIs first emerged on the scene in the 1980s, at a time when patients often medicated for heartburn on an as-needed basis, using safe antacid therapies or modifying their daily routines [with practices] such as raising the head of the bed or avoiding certain foods in excess.**

---

inappropriately placed on acid-suppressing drug therapy (most commonly PPIs) were still on the drugs six months after being sent home.

### **Recommendations for relieving heartburn symptoms**

Heartburn is an extremely common condition, and for most people, symptoms come and go depending on changes in diet or lifestyle. While anyone experiencing symptoms should see a doctor first to rule out more serious conditions, very few people actually end up needing to be on medications for heartburn. Most people can resolve their symptoms through minor diet and lifestyle changes, and for those who cannot, there are other, safer therapies that should be tried before resorting to PPIs. After consulting with their doctors, patients should opt for the following safer "step-up" regimen to avoid many of the risks that come with PPI therapy:

- **Diet and lifestyle changes.** First, patients suffering from heartburn should try making slight changes in their daily routines. These changes can be as simple as raising the head of the bed at night and avoiding excessive amounts of alcohol, coffee, chocolate, or foods high in fat, and can go a long way toward relieving heartburn symptoms.
- **Antacids: the oldest and safest remedies.** If lifestyle changes do not produce relief, antacid therapy should be started whenever symptoms arise. Antacids are the oldest and safest therapies for

heartburn, and because they only act on the stomach and — by and large — do not get absorbed into the bloodstream, they cause very little in the way of side effects. However, those with kidney disease should avoid antacid therapy until consulting their doctors. Everyone else can start these therapies on their own, on an as-needed basis.

- **H2As.** Should antacids fail to provide sufficient relief, then it is reasonable to pursue more potent medicines, such as H2As. In a recent comprehensive review of studies of heartburn therapies, H2As were shown to work effectively in most patients who took them. Because H2As don't shut off stomach-acid production as profoundly as PPIs do, they do not result in as much dependence on therapy, making it easier for patients to wean themselves off once they feel they are ready. The drugs also don't pose as many serious risks as do PPIs, making them a safer, and often just as effective, option.
- **PPIs (but lower and less frequent doses).** Those unrelieved by all other therapies should then begin PPIs, but at a lower intensity than is commonly prescribed. Patients should ideally start therapy at half the dose indicated in the label, on an as-needed basis, increasing the dose and/or frequency of therapy only if symptoms are not relieved. Due to the potential for dependence, it should be remembered that one can always increase the dose or frequency of the PPI as symptoms

[see PPI, page 7](#)

# Preventing Diabetes on a Budget

*The following article, by Erin Marcus, originally appeared on The Huffington Post. It has been reprinted with permission.*

By all accounts, Frances Vasquez ought to be a diabetic. Raised on a diet of fried steak, fried pork chops and lots of rice, her father, mother and two sisters suffered from the disease. At age 47, Frances herself was overweight and was already experiencing high blood sugar.

But over the past 11 years, Frances has been able to avoid diabetes, and her sugars are now normal. By participating in a ground-breaking, government-funded study, she learned how to make exercise and a healthy diet an integral part of her life, avoiding the insulin injections and heart and kidney problems that plagued her parents when they were in their 50s.

“At first it was hard, but I took it as a religious (type of) thing,” she said recently. “If I hadn’t done this, I’d be a diabetic for sure.”

The study, called the Diabetes Prevention Program, included more than 3,000 adults, all of whom were overweight and had sugars that were high but not yet in diabetic range. Diabetes is a condition in which the body is unable to control blood sugar, and it often leads to heart disease, kidney failure, blindness and circulation and other problems.

About nine out of 10 diabetics have what’s called type 2 diabetes — their bodies make insulin (which regulates blood sugar), but their cells don’t respond to it adequately. Having a family history and carrying too much weight increase a person’s risk of developing type 2 diabetes. In recent years, diabetes has become an epidemic in the U.S., mainly because many more Americans are overweight and obese.

Nearly half of the people who participated in the Diabetes Prevention Program were of ethnic minority ancestry, including African Americans,

---

**Diabetes is a condition in which the body is unable to control blood sugar, and it often leads to heart disease, kidney failure, blindness and circulation and other problems.**

---

Native Americans, Asian Americans, Latinos and Pacific Islanders. People in the study were assigned to one of three groups. The people in Frances’ group received intensive counseling on their food intake and physical activity. Another group got information on healthy food and exercise and took a diabetes pill called metformin twice a day. A third group was given healthy food and exercise information and took a placebo (or inactive) pill twice a day.

At the end of three years, the people in the intensive lifestyle group cut their risk of developing diabetes by more than half. People in the metformin group also reduced their risk, but by a smaller amount. A 10-year follow-up study found that the people in the intensive lifestyle group delayed developing diabetes by four years and people in the metformin group delayed developing the disease by two years, on average. People in both groups also lost weight, and their blood pressures and cholesterol levels improved.

People in the lifestyle group were expected to walk briskly for 30 minutes a day and write down everything they ate in a journal. They met with a counselor for an hour every week for two years, then less frequently, and attended classes that taught them about different types of food and how to read a nutrition label. They worked with a physical trainer, who showed them how to do simple exercises, such as stretches and jumping jacks, and went for regular walks together. They also received a pedometer and were expected to walk 10,000 steps every day.

As a result of what she learned in the study, Frances stopped going to fast food restaurants. She now bakes meats and fish instead of frying them, and

she avoids juices and sodas unless they are sugar-free. She eats two slices of 40-calorie Pepperidge Farm bread, with sugar-free all-fruit jam for breakfast, instead of a bagel with cream cheese. She packs a turkey and tomato sandwich for lunch most days, and goes for a walk during her lunch break from her job as an examiner for the Department of Motor Vehicles. She looks at newspaper ads to see which grocery stores are having specials on fruits and vegetables, and she never goes grocery shopping when she is hungry, because she is more likely to buy something rich or sugary. She still eats rice sometimes, but she prepares it with a small amount of olive or canola oil and flavors it with garlic and onions.

Frances now weighs 10 pounds less than she did a decade ago, though she still would like to lose another 10 pounds to reach a goal weight of 137. (She is five feet tall). She admits to losing her will-power at parties and while on vacation cruises, and says keeping the weight off is tough. But she has enlisted many of her coworkers to walk with her at lunchtime and follow a healthier diet, and she recently bought 99 cent pedometers for 10 of her co-workers who are participating in a weight loss program that she is organizing.

“When you get friends to go [walking] with, it makes it better,” she said. “It’s hard, but if you take 15 minutes out of your lunchtime to exercise, even if you just walk around the block where you work, and avoid the drive-through and learn how to eat, you can do it. It’s very important to take action while you can because being overweight is a walking time bomb.” ♦

## PPI, from page 5

dictate, but it may not be as easy to taper down from a high dose. As with any medication, patients should not alter their dose before first consulting with their doctors.

### **PPIs: helpful for some, but unnecessary and risky for most**

PPIs are now one of the most widely used classes of prescription drugs, with an estimated one out of every 20 people in the developed world currently taking one of these medications. However, given that the majority of this use is probably inappropriate, with minimal or no benefit to the patient, and that new, life-threatening risks with long-

term therapy are continually emerging, it is time for the medical community to re-evaluate the role of PPIs in everyday practice.

As a critical first step, FDA-approved black box warnings are needed, so doctors and patients can be made aware, in a clear and prominent manner, of the risks of PPI treatment in order to make an informed decision on whether to start therapy, especially in cases where there exist much safer and less expensive alternatives (e.g., in the case of heartburn). PPIs may indeed prove to be the only treatment option for many patients but should not be the first option for mild cases of heartburn.

PPIs were never intended to be taken for such long periods of time for minor symptoms, and people had been dealing

with heartburn safely and effectively for decades prior to the arrival of PPIs on the market. This key point has gone by the wayside as doctors and patients increasingly rely on quick fixes for symptoms such as heartburn, which often require only minor changes in everyday habits. The overreliance on PPIs has needlessly exposed millions of people to serious harms, many of whom did not even need the drugs to begin with.

With this risk information in mind, patients considering PPI therapy — and those already taking the drugs — for heartburn should raise these safety concerns with their doctors and ask about the safer, just as effective, options. ♦

# Are your medicines **SAFE?**



Find out which drugs are safe — and which you should avoid — with Public Citizen's *WorstPills.org* and *Worst Pills, Best Pills News*.

To subscribe to *WorstPills.org*, our online database, for only \$15 a year, visit [www.WorstPills.org](http://www.WorstPills.org) and type in promotional code **PNSEP11** when prompted.

To subscribe to the monthly print edition of *Worst Pills, Best Pills News* for only \$10 a year, please mail a check payable to "Pills News" to 1600 20th St. NW, Washington, DC 20009.

[www.WorstPills.org](http://www.WorstPills.org)



# Product Recalls

## August 3, 2011 – August 31, 2011

This section includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements ([www.fda.gov/Safety/Recalls/EnforcementReports/default.htm](http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm)), 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

**Amantadine Hydrochloride Tablets**, 100 mg, 100-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Amlodipine Besylate Tablets**, 5 mg, 90-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Androxy Tablets** (fluoxymesterone), 10 mg, 100-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Baclofen Tablets**, 10 mg a) 90-count bottle, b) 100-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Bethanechol Chloride Tablets**, 5, 10 and 25 mg, 100-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Citalopram Tablets**, USP, 10 mg, 100-count bottle. Volume of product in commerce: 720 bottles. Labeling: Label mix-up — bottles of finasteride 5-mg tablets (90 count) have been found to be incorrectly labeled

as citalopram 10-mg tablets (100 count). The lot number F10510058-A appears on both the citalopram 10-mg labels and the finasteride 5-mg labels. Lot #: F10510058-A, expiration 09/2012. Aurobindo Pharma L.

**Extenze Nutritional Supplement Tablets**, packaged in 4-count blister cards and 2 x 15-count blister cards. Volume of product in commerce: 26,511 retail units. Marketed without an approved NDA/ANDA: Some packages bearing lot numbers 0709241 and 0509075 are counterfeit products containing undeclared tadalafil, sildenafil and sibutramine. Lot #: 0709241 and 0509075. Biotab Nutraceuticals Inc.

**Jantoven** (warfarin sodium), 1, 2, 2.5, 3, 4, 5, 6, 7.5 and 10 mg, 100-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Oxybutynin Chloride Tablets**, 5 mg, 100-count bottle. Volume of product in commerce: Unknown. Report of a bottle labeled as Jantoven 3-mg tablets, Rx only, anticoagulant, actually contained Jantoven 10-mg tablets. Recall expanded on Feb. 18, 2011, to include additional products that were packaged on the same packaging line. Lot #: Multiple lots affected. Contact your pharmacist. Upsher Smith Laboratories Inc.

**Pandora**, Sexual Enhancer for Women, one capsule per blister pack. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: Laboratory analysis identified an analogue of sildenafil, an ingredient in an FDA-approved drug to treat erectile dysfunction, in the products. That makes the products unapproved new drugs. Lot #: 100378, expiration date 03/2013. Protech Nutraceuticals Inc.

**RockHard Weekend**, Sexual Performance Enhancer for Men, sold one capsule per blister pack, 3-count bottle and 8-count bottle. Volume of product in commerce: Unknown. Marketed without an approved NDA/ANDA: Laboratory analysis identified an analogue of sildenafil, an ingredient in an FDA-approved drug to treat erectile dysfunction, in the products. That makes the products unapproved new drugs. Lot #: 100159, expiration date 01/2012, and 100260, expiration date 03/2012. Protech Nutraceuticals Inc.

## DRUGS AND DIETARY SUPPLEMENTS (continued)

**Svelte**, 30 capsules, 30-count bottle. Volume of product in commerce: 25 units. Marketed without an approved NDA/ANDA. Product found to contain sibutramine. Lot #s: All lots. Hainan Resurgence Natural Healthy F.

**U-Prosta Natural Support for Prostate Health Dietary Supplement Capsules**, 900 mg packaged in a) one-capsule blister pack, b) 30-capsule bottle and c) 60-capsule bottle. Volume of product in commerce: 914,800 capsules (estimated). Marketed without an approved NDA/ANDA: product found to contain undeclared terazosin, the active ingredient of an FDA-approved new drug to treat Benign Prostatic Hyperplasia (enlarged prostate). Lot #s: All lots. U.S.A Far Ocean Group 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

**Alprazolam XR**, extended-release tablets, 2 mg, 60-count bottle. Volume of product in commerce: 20,112 bottles. Failed USP Dissolution Test requirements: The 24-month stability testing yielded an out-of-specification result for dissolution. Lot #: C090023, expiration date 11/2011. Pfizer Pharmaceuticals LLC.

**CorePharma Glyburide Tablets**, USP, a) 2.5 mg, 100 tablets, and b) 1 mg, 100 tablets. Volume of product in commerce: 19,368 bottles. Glyburide tablets, USP, 2.5 mg were found to be incorrectly labeled with a “Ropinirole Hydrochloride Tablets” label. Lot #: 105912, expiration date 11/2013. Corepharma LLC.

**Fanapt** (iloperidone), 12 mg, 60-count bottle. Volume of product in commerce: 12,974 bottles. Failed tablet hardness: During stability testing, a low out-of-specification result for mean hardness was obtained; this decreased hardness could result in tablet friability, leading to tablet breakage. Lot #s: V0230A001, V0230A001S and V0230A001S2, expiration date 05/31/2012. Patheon Inc.

**Gabapentin Tablets**, USP, 600 mg, 100-count bottle. Volume of product in commerce: 37,589 bottles. Presence of foreign substance: potential for small glass particles. Lot #s: 24G473, 24G474, 24G475 and 24G476. Teva Pharmaceutical Industries.

**Glipizide Tablets**, USP, 5 mg, 100-tablet bottle. Volume of product in commerce: Unknown. Impurities/degradation products: Out-of-specification impurity result. Lot #s: BFA16A and BFA97A. Teva Pharmaceuticals USA Inc.

**Glipizide Tablets**, USP, 10 mg, 500-tablet bottle. Volume of product in commerce: Unknown. Impurities/degradation products: Out-of-specification impurity result. Lot #s: BFA17A and BFH64A. Teva Pharmaceuticals USA Inc.

**Levothroid Tablets** (levothyroxine sodium, USP), 175 mcg, 100-count bottle. Volume of product in commerce: 19,142 bottles. Subpotent (single ingredient) drug: The product had low assay testing at the nine-month stability time point. Lot #: 1071287, expiration date 05/2011. Lloyd Inc.

**Levoxyl Tablets** (levothyroxine sodium, USP), 75 mcg, 100-count bottle. Volume of product in commerce: 1,009 bottles. Adulterated presence of foreign tablets: The firm repacked Levoxyl tablets, USP,

75 mcg, lot #60809, which has been recalled by King Pharmaceuticals. King Pharmaceuticals received a complaint of a single 200-mcg Levoxyl tablet comingled in a 1,000-count bottle of Levoxyl tablets, USP, 75 mcg. Lot #: 74476, expiration date 03/2012. Rx PAK.

**Losartan Potassium Tablets**, USP, 50 mg, 90-count bottle. Volume of product in commerce: 34,368 bottles. Impurities/degradation products: Product did not meet specification for impurities at the nine-month stability station. Lot #: 3103450, expiration date 07/2012. Lupin Ltd.

**Metformin Hydrochloride Tablets**, 500 mg, 60-count bottle. Volume of product in commerce: 35,532 bottles. Presence of foreign substance(s): Metformin tablets may be adulterated with foreign matter. Lot #: 204210, expiration date 10/30/2012. Sandoz Inc.

**Metoprolol Tartrate Tablets**, USP, 50 mg, 100-count bottle and 1,000-count bottle. Volume of product in commerce: 4,920 bottles. Failed USP Content Uniformity requirements: Individual tablets may be outside of specification for content uniformity. Lot #s: L-1979 (100-count) and L-1979A (1,000-count), expiration date 06/2012. Sandoz Inc.

**Metoprolol Tartrate Tablets**, USP, 100 mg, 100-count bottle and 1,000-count bottle. Volume of product in commerce: 3,524 bottles. Failed USP Content Uniformity requirements: Individual tablets may be outside of specification for content uniformity. Lot #s: L-1980 (100-count) and L-1980A (1,000-count), expiration date 06/2012. Sandoz Inc.

**Metronidazole Tablets**, USP, 500 mg, 500-count bottle. Volume of product in commerce: 1,902 bottles. Presence of foreign substance(s): Some tablets may contain foreign material. Lot #: 317480, expiration date 06/2013. Teva Pharmaceuticals USA Inc.

**Procardia XL Extended-Release Tablets** (nifedipine), 30 mg, 100-count and 300-count bottles. Volume of product in commerce: 763. Failed dissolution specification. Lot #s: V110327 and V110314, expiration date 08/2015. Pfizer Pharmaceuticals LLC.

**Propranolol HCl Tablets, 10 mg** a) 100-count bottle and b) 1,000-count bottle. Volume of product in commerce: Unknown. Low tablet weight: Tablets do not conform to weight specifications. Lot #s:

## DRUGS AND DIETARY SUPPLEMENTS (continued)

a) 314383, expiration date 10/2012, and b) 317058, expiration date 06/2013, and 703661, expiration date 05/2013. Teva Pharmaceuticals USA Inc.

**Propranolol HCl Tablets**, 20 mg a) 1,000-count bottle and b) 100-count bottle. Volume of product in commerce: Unknown. Low tablet weight: Tablets do not conform to weight specifications. Lot #s: a) 317059, expiration date 02/2013, and b) 317225, expiration date 04/2013, and 14160310A, expiration date 07/2013. Teva Pharmaceuticals USA Inc.

**Propranolol HCl Tablets**, 40 mg, 1,000-count bottle. Volume of product in commerce: Unknown. Low tablet weight: Tablets do not conform to weight specifications. Lot #s: 317063, expiration date 03/2013, and 14151110A, expiration date 07/2013. Teva Pharmaceuticals USA Inc.

**Propranolol HCl Tablets**, 60 mg, 100-count bottle. Volume of product in commerce: Unknown. Low tablet weight: Tablets do not conform to weight specifications. Lot #s: 317068, expiration date 03/2013, and 34112810A, expiration date 05/2013. Teva Pharmaceuticals USA Inc.

**Propranolol HCl Tablets**, 80 mg a) 100-count bottle and b) 500-count bottle. Volume of product in commerce: Unknown. Low tablet weight: Tablets do not conform to weight specifications. Lot #s: a) 315151, expiration date 01/2013, and b) 317065, expiration date 04/2013. Teva Pharmaceuticals USA Inc.

**Simvastatin Tablets**, USP, 10 mg, 500-count bottle. Volume of product in commerce: Unknown. Chemical contamination: Certain batches of simvastatin tablets are being recalled due to complaints received from consumers who found that the tablets smelled musty or moldy. Firm's investigation revealed the contaminants to be TBDMS, TCA and

TBA in trace amounts. Lot #: C008115, expiration date 11/2012. Dr. Reddy's Laboratories Inc.

**Simvastatin Tablets**, USP, 40 mg a) 90-count bottle and b) 500-count bottle. Volume of product in commerce: Unknown. Chemical contamination: Certain batches of simvastatin tablets are being recalled due to complaints received from consumers who found that the tablets smelled musty or moldy. Firm's investigation revealed the contaminants to be TBDMS, TCA and TBA in trace amounts. Lot #s: a) C008195, C008196, C008198 and C008200, expiration date 11/2013; b) C008197 and C008199, expiration date 11/2013. Dr. Reddy's Laboratories Inc.

**Simvastatin Tablets**, USP, 80 mg, 30-count bottle. Volume of product in commerce: 25, 896 bottles. Chemical contamination: One lot of simvastatin tablets (80 mg, USP) is being recalled due to multiple product complaints that tablets had an off odor. Firm's investigation revealed that the odor is associated with trace amounts of TBDMS, TCA and TBA. Lot #: C002496, expiration date 03/2012. Dr. Reddy's Laboratories Ltd.

**Thyro-Tab Tablets** (levothyroxine sodium, USP), 0.175 mg, bulk drums intended for repackaging. Volume of product in commerce: 1,922,036 bulk tablets. Subpotent (single ingredient) drug: The product had low assay testing at the nine-month stability time point. Lot #: HA31409, expiration date 05/2011. Lloyd Inc.

**Tylenol Extra Strength** (acetaminophen) 225 caplets, 500 mg each. Volume of product in commerce: 60,504 bottles. Chemical contamination: presence of a chemical called 2,4,6-tribromoanisole. Lot #: ABA619. McNeil Healthcare, LLC.

## CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the CPSC, call its hotline at (800) 638-2772. The CPSC website is [www.cpsc.gov](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

### Name of Product; Problem; Recall Information

**"Metoo" Clip-on Chair.** Missing or worn clamp pads allow the chairs to detach from a variety of different table surfaces, posing a fall hazard. In addition, when the chair detaches, children's fingers can be caught between the bar and clamping mechanism, posing an amputation hazard. Also, user instructions for the chairs are inadequate, increasing the likelihood of consumer misuse. Phil&teds USA Inc., at (855) 652-9019 or [www.philandteds.com/support](http://www.philandteds.com/support).

**Browning Air Pistols.** Under a variety of circumstances, the safety will not prevent the gun from firing. This poses a risk of serious injury to the user or bystanders. Umarex USA Inc., at (866) 503-3389 or [www.umarexusa.com](http://www.umarexusa.com).

**EnergySaver a/k/a Marathon or Marathon Classic Compact Fluorescent Dimmable Reflector Lamps.** The glue that attaches the glass outer envelope or globe to the body of the lamp can fail, allowing

the glass outer envelope to fall and strike persons and objects below and posing a laceration hazard to consumers. Philips Lighting Co., at (866) 622-6372 or [www.recall.philips.com/en\\_us.html](http://www.recall.philips.com/en_us.html).

**Fiskars SmartPower String Trimmers.** Engine vibration during use of the trimmers can cause wear on the fuel line, leading to a propane fuel leak. The Straight Shaft Trimmers' propane canister can crack at the neck during use. In addition, high temperatures may develop near the Curved Shaft Trimmers' plastic cutting guard, causing the guard to deform and fall off. These issues pose burn, fire and laceration hazards to the user. Fiskars Brands Inc., at (877) 495-6645 or [www.fiskars.com](http://www.fiskars.com).

**GRIGRI 2 Belay Device With Assisted Braking.** Excessive force on the handle can cause it to become stuck in the open position. When stuck open, the assisted braking function is disabled, posing a fall

## CONSUMER PRODUCTS (continued)

hazard to consumers. Petzl America Inc., at (800) 932-2978 or <http://www.petzl.com/us/outdoor/us/recall-replacement-grigri-2>.

**Itasca Fusion Hiker Boots.** The boots could fail to provide the intended protection against compression and impact, posing the risk of a foot injury to consumers. The boots have hard composite toe material rather than steel. C.O. Lynch Enterprises Inc., at (800) 225-2565 or [itascacol@aol.com](mailto:itascacol@aol.com).

**LED Night Lights.** The LED night lights can overheat, smolder and melt, which may cause minor burns to consumers. Corvest Acquisition Inc., at (877) 924-4624 or [www.camsingglobal.com](http://www.camsingglobal.com).

**LHQM LED Exit Signs With Emergency Lights.** The fixtures can malfunction and fail to illuminate in the event of a power failure. This could result in a failure to provide adequate lighting to guide building occupants to an exit in the event of an emergency. Best Lighting Products, at (800) 334-8694 or [www.lithonialighting.com](http://www.lithonialighting.com).

**Love.Hugs.Peace Lapel Pins.** Surface paints on the lapel pin contain excessive levels of lead, which is prohibited under federal law. Build-A-Bear Workshop, at (866) 236-5683 or [www.buildabear.com](http://www.buildabear.com).

**Martha Stewart Collection Enamel Cast Iron Casseroles.** The enamel coating on the cast-iron casseroles can crack or break during use. This can cause the enamel to crack and fly off as a projectile, posing a risk of laceration or burn hazard to the user or bystanders. Macy's Merchandising Group, at (888) 257-5949 or [www.macys.com](http://www.macys.com).

**NexTorch NT123A Flashlight Batteries.** Batteries can overheat and rupture, posing a fire and burn hazard to consumers. NexTorch Inc., at (877) 867-2415 or [www.nextorch.com](http://www.nextorch.com).

**Playsafe Dartmouth Swing Set.** The sling-style swing seats can crack or split prematurely, posing a fall hazard to consumers. Pacific Cycle Inc., at (877) 564-2261 or [www.pacific-cycle.com](http://www.pacific-cycle.com).

**Pogoplug Video File-Sharing Device.** The unit can overheat or catch fire, emitting excessive heat, sparks, smoke or flames. Cloud Engines Inc., at (866) 582-6651 or [www.pogoplug.com](http://www.pogoplug.com).

**Realspace PRO 3000 Series Desk Chairs.** A consumer's finger can get caught in an opening in the chair's tilt mechanism, posing a pinch hazard to consumers. Huichang Furniture Co. Ltd., at (855) 259-5093 or [www.officedepot.com/customerservice/errata.do](http://www.officedepot.com/customerservice/errata.do).

**Scarpa Wood and Glass Round Dining Tables.** The wooden table base can split and/or collapse, causing the glass table top to fall. This poses collapse and impact hazards to consumers. EQ3 Ltd., at (888) 988-2014 or [www.EQ3.com](http://www.EQ3.com).

**Scout 'n Zoom Children's Riding Toy.** The riding toy can tip over, allowing a child to fall forward while riding and posing a fall hazard to young children. Radio Flyer, at (800) 621-7613 or [www.radioflyer.com](http://www.radioflyer.com).

**Step Stools With Storage.** The wooden step stools can break apart or collapse under the weight of the user, posing a fall hazard. Target Corp., at (800) 440-0680 or [www.target.com](http://www.target.com).

**Toy Keys With Remote.** The metal toy keys and the plastic key ring can break, posing a choking hazard. Battat Inc., at (866) 665-5524 or [www.battatco.com](http://www.battatco.com).

**Twirla Wooden Rattle.** The toy's U-shaped parts can break, posing a choking hazard. Manhattan Group LLC, at (800) 541-1345 or [www.manhattantoy.com](http://www.manhattantoy.com).

### OUTRAGE, from page 12

and that he may have **positions** in the stocks listed in his columns.

It is unfortunate that while citizens who may be adversely affected by an impending disaster are taking steps to prepare to cope with the aftermath or to get out of harm's way, some hedge fund managers and financial analysts are looking for a way to make a quick buck. ♦



### Advocates for the people since 1971

Make a contribution to support Public Citizen

For 40 years, Public Citizen has been fighting the abusive practices of the "fat cats" — whether it's Wall Street, Big Oil or Big Pharma.

We depend on the generosity of concerned citizens like you to help continue the fight. Join us today!

To contribute, visit [www.citizen.org/donate](http://www.citizen.org/donate)



## Outrage of the Month! Profiting from Disasters

Last month's hurricane reminded me of an article I read in the April 12, 2010, *Wall Street Journal* entitled "Profiting From Disasters: Afraid of a Hurricane? Pandemic? Global Warming? Consider These Stocks."

One common game played by Wall Street is referred to as short-selling and is a specialty of many hedge funds. This activity makes money because stocks *decrease* in value. The gist of short-selling is knowing (or guessing) in advance that a stock will lose a significant amount of value and betting that this will occur. When you short-sell a stock, your broker will lend it to you. The broker then sells "your" borrowed shares and the proceeds are credited to your account. Sooner or later, you must "close" the short by buying back the same number of shares and returning them to your broker. If the price drops, you can buy back the stock at the lower price and make a profit on the difference.

In contrast, *The Wall Street Journal* article discussed why it is a good idea to hold stocks that are likely to *increase* in value in the face of various disasters. The theme is that "the best way to guard against each of these fears is to insulate your portfolio with stocks that have the tendency to go up when that particular fear rears its ugly head."

The article's author, James Altucher, reviewed information from

*The Wall Street Journal* article discussed why it is a good idea to hold stocks that are likely to *increase* in value in the face of various disasters.

the 10 most expensive hurricanes in the U.S. and found that three stocks increased in value following the storms: Campbell Soup Co., Nucor Corp. (manufacturer of steel used in bridge and building repair) and Hill-Rom Holdings Inc. (manufacturer of hospital beds and medical equipment).

What about profiting from pandemics, worldwide epidemics of infectious diseases? Altucher noted that every year the strain of flu virus changes and vaccines created the previous year to combat the virus can be ineffective. Should a more serious pandemic arise, stocks that would possibly profit include GlaxoSmithKline, the largest manufacturer of flu vaccines, as well as Sanofi-Aventis. Another company that could profit from such an outbreak is Alpha Pro Tech, maker of masks that protect against airborne contagions.

In the interest of full disclosure, Altucher reveals that he is a managing partner of Formula Capital, an alternative asset-management firm,

see [OUTRAGE](#), page 11

NONPROFIT ORG  
U.S. POSTAGE  
PAID  
FREDERICK, MD  
PERMIT #999

Health Letter, Public Citizen Health Research Group  
1600 20th Street, N.W., Washington, D.C. 20009



MOVING? SUBSCRIPTION? ADDRESS CORRECTION?  
Please enter corrections or subscription information below. Return current mailing label. Mail to the address above.

NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY, STATE, ZIP \_\_\_\_\_

### SUBSCRIPTION

One year \$18  Two year \$30  Three year \$42

Enclose your check or money order made out to *Health Letter* CHA444

Printed on recycled paper.