



## Know When Antibiotics Work

**A**lthough colds are caused by viruses, for which antibiotics are useless, some doctors unfortunately still convince some patients that the use of antibiotics for the treatment of colds is a good idea.

This leads to the larger topic of the dangerous and expensive overuse of antibiotics in general, not just for colds. They are dangerous for two reasons: the side effects of drugs that should not have been used in the first place and the major role of over-prescribing of antibiotics in causing antibiotic-resistant bacteria. They are expensive because any amount, often as much as \$50 dollars or more, for a prescription you do not even need is an insult to anyone's pocketbook.

The Centers for Disease Control and Prevention (CDC), part of the Department of Health and Human Services (HHS), has recently added to its website important information on the topic of antibiotics: "Get Smart: Know When Antibiotics Work" (the URL : [www.cdc.gov/getsmart/antibiotic-use/symptom-relief.html](http://www.cdc.gov/getsmart/antibiotic-use/symptom-relief.html)).

Although we disagree with some of the CDC's suggestions about the use of certain, usually over-the-counter, drugs in treating colds or coughs (our more conservative approach will be in next month's *Health Letter* conversation with Marlo Thomas), the sections on the problems of antibiotic resistance are very accurate and informative. The following information is taken from the CDC website:

### Quick facts

- Increasing use of antimicrobials in humans, animals, and agriculture has resulted in many microbes developing resistance to these powerful drugs.
- Many infectious diseases are increasingly difficult to treat because of antimicrobial-resistant organisms, including HIV infection, staphylococcal infection, tuberculosis, influenza, gonorrhea, candida infection and malaria.
- Between 5 and 10 percent of all hospital patients develop an infection, leading to an increase of about \$5 billion in annual U.S. health care costs.
- About 90,000 of these patients die each year as a result of their infection, up from 13,300 patient deaths in 1992.
- People infected with antimicrobial-resistant organisms are more likely to have longer hospital stays and may require more complicated treatment.

### About antimicrobial resistance: a brief overview

Antibiotics and similar drugs, together called antimicrobial agents, have been used for the last 70 years to treat patients who have infectious diseases. Since the 1940s, these drugs have greatly reduced illness and death from infectious diseases. Antibiotic use has been beneficial and, when prescribed and taken correctly, its value in patient care is enormous. However, these drugs have been used so widely and for so long that the infectious organisms the antibiotics are designed

to kill have adapted to them, making the drugs less effective. Many fungi, viruses and parasites have done the same. Some microorganisms may develop resistance to a single antimicrobial agent (or related class of agent), while others develop resistance to several antimicrobial agents or classes. These organisms are often referred to as multidrug-resistant or MDR strains. In some cases, the microorganisms have become so resistant that no available antibiotics are effective against them.

### Drug resistance is everywhere

Antimicrobial drug resistance occurs everywhere in the world and is not limited to industrialized nations. Hospitals and other health care settings are battling drug-resistant organisms that spread inside these institutions. Drug-resistant infections also spread in the community at large. Examples include drug-resistant pneumonias, sexually transmitted diseases (STDs), and skin and soft tissue infections.

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# PUBLIC CITIZEN Health Letter

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## The effects of drug resistance are far-reaching

People infected with drug-resistant organisms are more likely to have longer and more expensive hospital stays, and may be more likely to die as a result of the infection. When the drug of choice for treating their infection doesn't work, they require treatment with second- or third-choice drugs that may be less effective, more toxic, and more expensive. This means that patients with an antimicrobial-resistant infection may suffer more and pay more for treatment.

## Trends in drug resistance

Reports of methicillin-resistant *Staphylococcus aureus* (MRSA) — a potentially dangerous type of staph bacteria that is resistant to certain antibiotics and may cause skin and other infections — in persons with no links to healthcare systems have been observed with increasing frequency in the United States and elsewhere around the globe.

Multi-drug resistant *Klebsiella* species and *Escherichia coli* have been isolated in hospitals throughout the United States.

Antibiotic-resistant *Streptococcus pneumoniae* infections have significantly declined but remain a concern in some populations.

Antimicrobial resistance is emerging among some fungi, particularly those fungi that cause infections in transplant patients with weakened immune systems.

Antimicrobial resistance has also been noted with some of the drugs used to treat human immunodeficiency virus (HIV) infections and influenza.

The development of antimicrobial resistance to the drugs used to treat malaria infections has been a continuing problem in many parts of the world for decades. Antimicrobial resistance has developed to a variety of other parasites that cause infection.

## What the CDC's site is about

Part of CDC's mission is to track the emergence of antimicrobial-resistant microorganisms and to limit their spread. The agency also has several efforts to prevent the development and transmission of infections that are caused by these organisms through educational programs, campaigns to promote the proper use of antimicrobial agents, and advocacy for vaccine use. Each one of us has a role to play in limiting the development and spread of antimicrobial-resistant microorganisms. This site will give you some ideas on how you can help.

## Questions about bacteria, viruses, and antibiotics

**Q:** What are bacteria and viruses?

**A:** Bacteria are single-celled organisms usually found all over the inside and outside of our bodies, except in the blood and spinal fluid. Many bacteria are not harmful. In fact, some are actually beneficial. However, disease-causing bacteria trigger illnesses, such as strep throat and some ear infections. Viruses are even smaller than bacteria. A virus cannot survive outside the body's cells. It causes illnesses by invading healthy cells and reproducing.

**Q:** What kinds of infections are caused by viruses and should not be treated with antibiotics?

**A:** Viral infections that should not be treated with antibiotics include:

- Colds
- Flu
- Most coughs and bronchitis
- Sore throats (except for those resulting from strep throat)
- Some ear infections

**Q:** What is an antibiotic?

**A:** Antibiotics, also known as antimicrobial drugs, are drugs that fight infections caused by bacteria. Alexander Fleming discovered the first antibiotic, penicillin, in 1927. After the first use of antibiotics in the 1940s, they transformed medical care and

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dramatically reduced illness and death from infectious diseases.

The term “antibiotic” originally referred to a natural compound produced by a fungus or another microorganism which kills bacteria which cause disease in humans or animals. Some antibiotics may be synthetic compounds (not produced by microorganisms) that can also kill or inhibit the growth of microbes. Technically, the term “antimicrobial agent” refers to both natural and synthetic compounds; however, many people use the word “antibiotic” to refer to both. Although antibiotics have many beneficial effects, their use has contributed to the problem of antibiotic resistance.

### Questions about antibiotic resistance

**Q:** What is antibiotic resistance?

**A:** Antibiotic resistance is the ability of bacteria or other microbes to resist the effects of an antibiotic. Antibiotic resistance occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals or other agents designed to cure or prevent infections. The bacteria survive and continue to multiply, causing more harm.

**Q:** Why should I be concerned about antibiotic resistance?

**A:** Antibiotic resistance has been called one of the world’s most pressing public health problems. Almost every type of bacteria has become stronger and less responsive to antibiotic treatment when it is really needed. These antibiotic-resistant bacteria can quickly spread to family members, schoolmates and co-workers — threatening the community with a new strain of infectious disease that is more difficult to cure and more expensive to treat. For this reason, antibiotic resistance is among CDC’s top concerns.

Antibiotic resistance can cause significant danger and suffering for children and adults who have common infections, once easily treatable with

antibiotics. Microbes can develop resistance to specific medicines. A common misconception is that a person’s body becomes resistant to specific drugs. However, it is microbes, not people, that become resistant to the drugs.

If a microbe is resistant to many drugs, treating the infections it causes can become difficult or even impossible. Someone with an infection that is resistant to a certain medicine can pass that resistant infection to another person. In this way, a hard-to-treat illness can be spread from person to person. In some cases, the illness can lead to serious disability or even death.

**Q:** Why are bacteria becoming resistant to antibiotics?

**A:** Antibiotic use promotes development of antibiotic-resistant bacteria. Every time a person takes antibiotics, sensitive bacteria are killed, but resistant germs may be left to grow and multiply. Repeated and improper uses of antibiotics are primary causes of the increase in drug-resistant bacteria.

While antibiotics should be used to treat bacterial infections, they are not effective against viral infections like the common cold, most sore throats and the flu. Widespread use of antibiotics promotes the spread of antibiotic resistance. Smart use of antibiotics is the key to controlling the spread of resistance.

### Antibiotics kill bacteria, not viruses

**Q:** How do bacteria become resistant to antibiotics?

**A:** Antibiotic resistance occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to cure or prevent infections. The bacteria survive and continue to multiply, causing more harm. Bacteria can do this through several mechanisms. Some bacteria develop the ability to neutralize the antibiotic before it can do harm, others can rapidly pump the antibiotic out, and still others can change the

antibiotic attack site so it cannot affect the function of the bacteria.

Antibiotics kill or inhibit the growth of susceptible bacteria. Sometimes one of the bacteria survives because it has the ability to neutralize or escape the effect of the antibiotic; that one bacterium can then multiply and replace all the bacteria that were killed off. Exposure to antibiotics therefore provides selective pressure, which makes the surviving bacteria more likely to be resistant. In addition, bacteria that were at one time susceptible to an antibiotic can acquire resistance through mutation of their genetic material or by acquiring pieces of DNA that code for the resistance properties from other bacteria. The DNA that codes for resistance can be grouped in a single easily transferable package. This means that bacteria can become resistant to many antimicrobial agents because of the transfer of one piece of DNA.

Over time, the use of antimicrobial drugs will result in the development of resistant strains of bacteria, complicating clinicians’ efforts to select the appropriate antimicrobial for treatment.

**Q:** How can I prevent antibiotic-resistant infections?

**A:** By visiting the CDC’s website, you are taking the first step to reducing your risk of getting antibiotic-resistant infections. It is important to understand that, although they are very useful drugs, antibiotics designed for bacterial infections are not useful for viral infections such as a cold, cough or the flu. Some useful tips to remember are:

1. Talk with your health care provider about antibiotic resistance:

- Ask whether an antibiotic is likely to be beneficial for your illness
- Ask what else you can do to feel better sooner.

2. Do not take an antibiotic for a viral infection like a cold or the flu.

3. Do not save some of your antibiotic for the next time you get sick. Discard any leftover medication once you have

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# HHS Report Is a Wake-Up Call to Fix National Patient Safety Crisis

**M**ore than a decade ago, the Institute of Medicine (IOM) alerted the nation to a crisis of medical errors in hospitals. Today, we learn that nothing has changed and that patients are suffering needless injuries and deaths from preventable medical mistakes. The Inspector General's office of the Department of Health and Human Services (HHS) has reconfirmed what has been reported repeatedly over the years: that the country is in a patient safety crisis, and that medical professionals, lawmakers and regulators must do significantly more to avert it.

The IOM's 1999 landmark report, "To Err is Human," dropped the first bombshell, reporting that between 44,000 and 98,000 Americans die in hospitals each year from medical mistakes, costing an estimated \$17 billion to \$29 billion annually. HHS' new finding that medical mistakes kill 15,000 Medicare patients a month equates to 180,000 Medicare deaths per year - more than the IOM's estimate, which attempted to cover all patients

in the United States. That means that the annual death toll in this country caused by mistakes in hospitals is well over 250,000 deaths a year. But perhaps the most startling finding by HHS is that a significant number of patients

suffered injuries or died needlessly, as 44 percent of the medical errors were preventable.

We can no longer turn a blind eye to the patient safety emergency facing us as the lives and national health care costs rack up on a daily basis. Given that 1.6 million Medicare patients suffer injuries every year from medical mistakes with an annual taxpayer price tag of at least \$4.4 billion, the National Commission on Fiscal Responsibility and Reform should consider

ways to reduce the federal budget deficit by preventing medical errors.

The president's deficit commission should focus on patient safety rather than the dangerous "tort reform" proposals offered last week by its co-chairs Erskine Bowles and Alan Simpson. Making health care safer would be a far more effective and just

means of saving money than curtailing the rights of malpractice victims or insulating doctors from accountability for wrongdoing. Shielding doctors from liability for their errors only exacerbates the patient safety crisis and promotes higher health care costs. Malpractice payments are at the lowest they have ever been since they were first recorded in 1990, which means that despite the epidemic of medical errors, fewer victims are receiving compensation for their injuries and fewer medical providers are being held accountable for the harm they cause. In fact, there are nearly 10 times as many injuries caused by medical negligence as there are malpractice claims.

The only workable solution to preventing unnecessary deaths and injuries is to combine much more patient-protective hospital protocols with much better scrutiny by hospitals of physicians and other health care providers, and to appropriately discipline those whose performance results in preventable patient harm.

Congress and the federal agencies should treat the HHS report as a wake-up call. Instead of flirting with ways to eliminate patients' legal rights, they must save costs and lives by taking affirmative steps to help patients. ♦

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**"The Inspector General of HHS has reconfirmed what has been reported repeatedly over the years: that the country is in a patient safety crisis, and that medical professionals, lawmakers and regulators must do significantly more to avert it."**

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completed your prescribed course of treatment.

4. Take an antibiotic exactly as the health care provider tells you. Do not skip doses. Complete the prescribed course of treatment even if you are feeling better. If treatment stops too soon, some bacteria may survive and re-infect.

5. Do not take antibiotics prescribed for someone else. The antibiotic may not be appropriate for your illness. Taking the wrong medicine may delay correct

treatment and allow bacteria to multiply.

6. If your health care provider determines that you do not have a bacterial infection, ask about ways to help relieve your symptoms. Do not pressure your provider to prescribe an antibiotic.

**Q:** How can health care providers help prevent the spread of antibiotic resistance?

**A:** Prevent the spread of antibiotic resistance by:

- Only prescribe antibiotic therapy when

likely to be beneficial to the patient

- Use an agent targeting the likely [disease-causing bacteria] pathogens
- Use the antibiotic for the appropriate dose and duration.

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In next month's issue of *Health Letter*, we will bring you a conversation between Dr. Sidney Wolfe and actress/activist Marlo Thomas with more details about how to (and how not to) treat a cold. ♦

# The Risks of Tranquility

HEALTH LETTER LOOKS BACK

*The following article originally appeared in Health Letter 25 years ago, in the September/October 1985 issue. The data cited in this piece are therefore out of date. However, the article's focus on the dangers of benzodiazepine use is still pertinent today. In fact, many benzodiazepines remain high on the list of the 200 most frequently prescribed drugs — and now hundreds of millions of them are prescribed each year.*

For years, Librium [chlordiazepoxide], (which preceded Valium [diazepam]), and its sister drugs — Ativan [lorazepam], Centrax [prazepam], Dalmane [flurazepam], Paxipam [halazepam], Restoril [temazepam], Serax [oxazepam], Tranxene [clorazepate], and Xanax [alprazolam] — have been the most prescribed drugs in the United States [in 1985].

Although many of these are no longer as popular as they once were, Americans continue to consume millions of tablets of these drugs, and a newer one called Halcion [triazolam], every day. In 1984, for example, Americans filled 78 million prescriptions for these drugs. The peak use of these addicting benzodiazepine tranquilizers and sleeping pills was in 1975 when 91.4 million prescriptions were filled for these drugs. As the public and the medical profession belatedly learned about the addictive properties and other dangers of these drugs, the sales fell, “bottoming out” in 1982 (but are now [in 1985] beginning to rise slowly). Too little recognized is that because all these drugs belong to the same closely knit chemical family, the benzodiazepines, they can be dangerous to your health.

## Valium, Xanax and their cousins are addicting

Some benzodiazepines are promoted as tranquilizers; others (like Dalmane, Restoril and Halcion) as sleep aids. For whatever purpose they are advertised, they can be both psychologically and physically addictive, and it is all too

easy to get hooked on them. According to the Food and Drug Administration, in fact, 1.5 million Americans have taken one or more of these medications long enough to be in serious danger of addiction.

Just how long is long enough is not entirely clear. What is known, however, is that benzodiazepine addiction sends thousands of people to hospital emergency rooms each year and that it is because they have become hooked on benzodiazepines that at least 4,000 Americans annually enter addiction treatment centers for the first time [figures from 1985].

The manufacturers of these drugs stoutly maintain that the chances of addiction are minimal if [the drugs] are used at the recommended dosages and for no longer than specified by the informational leaflets (known as package inserts) the companies provide to physicians. However, scientific studies suggest otherwise. With the passage of time, there has been growing evidence that benzodiazepine dependency can occur even if the manufacturers' instructions are followed to the letter and that, indeed, some patients get hooked on even low doses of benzodiazepines in as little as three or four weeks.

One might suppose, as some benzodiazepine manufacturers have claimed, that it is chiefly the “abuse-prone” — people who have long-standing emotional or psychological problems — who are at greatest risk here. Again, it doesn't seem to work out that way. Anyone who takes a benzodiazepine at the high end of the recommended dose range or anyone who takes it for a month or more at any dose can get hooked.

That being the case, HRG [the Public Citizen Health Research Group] is strongly in favor of using benzodiazepines very sparingly, if at all. And HRG is not alone.

Recently [in 1985], for example, Drs. Jose Catalan and Dennis H. Gath —

both of Oxford University Department of Psychiatry — ran an interesting experiment. In the experiment, half of a group of patients with minor affective (mood) disorders such as anxiety, depression and insomnia, were randomly assigned treatment with benzodiazepines. The rest of the patients with the same complaints were chosen by lot to get brief counseling instead. Although the counseling took no more of the doctors' time or the patients' than the benzodiazepine therapy, the rate of improvement in the two groups — both at one month and at seven months after treatment — was the same.

Similarly, another study looked at what happened when patients going to the offices of a surgeon, an internist or an obstetrician-gynecologist were treated for anxiety with either Valium, one of two other benzodiazepine tranquilizers or a placebo (dummy pills).

Weekly evaluations were made both by the patients themselves and by professional evaluators with neither the patients nor the evaluators knowing at the time who was getting which type of medicine. At the end of a month, it turned out that all four treatments — including treatment with dummy pills — were equally effective.

Said another way, it was not whether or not the patients had taken a benzodiazepine that made them feel better, but the opportunity the study had given them to talk with someone about their anxiety that gave them relief.

Nonetheless, there are some doctors — and good ones — who sometimes prescribe benzodiazepines to counter muscle spasm for the relief of anxiety or to help their patients through occasional sleepless nights. If your doctor is one of them and you want to take Valium or some other drug in this family, play it smart by asking the physician to write No Refill on the prescription and to order the pharmacist to give you no more than 20 pills.

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## HEALTH LETTER LOOKS BACK

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Both of these requests to your doctor are for your own protection. Twenty pills of a benzodiazepine are typically enough for about seven days of use; too short of a period for there to be much risk of addiction. And with the addition of the No Refill stipulation, you will not have the opportunity to refill the prescription several times without seeing a doctor should you find yourself beginning to crave how the tablets make you feel.

Most importantly, however, urging your doctor to put limitations on your prescription for benzodiazepines is a signal to him (or her) that coping with your anxiety is your first priority and that you in no way just want to let the situation ride without reevaluating it soon and at regular intervals.

In the meantime, you can facilitate the process by doing some evaluating of your own. At the end of the first day and the end of every day you take any of these medicines, review for yourself what you have done — by yourself or by talking with others — to find out what is making you anxious so you can alter the internal or external circumstances that are to blame.

Keep a record of these evaluations. And as soon and as often as possible, in consultation with your doctor, try reducing the amount of benzodiazepine you are taking.

But what if this advice comes too late and you suspect you may already be hooked on Valium or one of its close relatives? How can you tell?

Some of the warning signs of benzodiazepine addiction are:

- Feeling that you can't cope without the pills or that you're not at your best unless you take them every day.
- Needing to take more pills as time goes on to get the same effect as taking higher doses than your doctor prescribed.
- Being unable to quit.

When you are physically dependent on

Valium, quitting suddenly can make you downright sick. You feel tense and can't sleep, and you may go on to develop a full-blown withdrawal reaction — shakiness, headache, nausea, vomiting, changes in sensation, and at times, hallucination or seizures. When you resume taking Valium, the symptoms usually go away within 24 hours.

Withdrawal symptoms are a very serious danger sign. If you are physically addicted to benzodiazepines, you should taper off these drugs gradually and under a doctor's care. Do not attempt to quit cold turkey or on your own; it is always dangerous and can be fatal.

### Other hazards of benzodiazepines

As if it weren't bad enough that benzodiazepines can be addictive, they also can have other side effects. Feeling drowsy, for example, is to be expected when taking these drugs and they also often take their toll on memory, learning and attention span. Moreover, some people, instead of being calmed by these medications, become very hostile from using them and fly into attacks of rage.

Particularly important to keep in mind is that benzodiazepines interfere with muscular coordination, so you should not drive or operate other powerful machinery when under their influence. And speaking of being under the influence, benzodiazepines and alcohol are an especially dangerous mix.

These two "downers" potentiate each other. Thus an overdose of benzodiazepines alone or in combination with alcohol, or, for that matter, barbiturates and certain other drugs can be fatal.

Worth mentioning, too, is that benzodiazepines can cause profound confusion, particularly in the elderly who may then be falsely diagnosed as senile.

Indeed, many doctors recommend that these drugs not be prescribed

for people over 65. At the very least, older people should take only half the usual dose. And if you have narrow angle glaucoma or serious lung disease — chronic bronchitis, for example — benzodiazepines are not for you, whatever your age.

Other people who should not take these drugs or, at least not without bringing it to the attention to their doctors, are those on a variety of other medications. These medications include: antidepressants, antihistamines, barbiturates, narcotics, psychiatric drugs, anticonvulsants (epilepsy drugs), and non-benzodiazepine tranquilizers.

In addition, Tagamet (cimetidine), a best-selling drug [in 1985] for ulcers, and Antabuse [disulfiram] for the treatment of alcoholism should not be used in combination with any benzodiazepines except Ativan or Serax.

Also avoid the use of benzodiazepines in combination with the drugs widely prescribed for Parkinson's disease. Benzodiazepines can make these drugs — Larodopa [levodopa], Sinemet and Sinemet CR [levodopa and carbidopa] — less effective.

Finally — although this is by no means an exhaustive list of the dangers of these drugs — some cautions for women of childbearing age:

If you are (or may be) pregnant, taking benzodiazepines may increase the risk of the child's having birth defects. Besides, use of these drugs near delivery has been linked to the so-called "floppy baby" syndrome. Infants with this syndrome are weak, suck poorly and may have serious breathing problems.

In addition, continuous use of benzodiazepines in late pregnancy can cause infants to suffer from withdrawal symptoms as newborns.

Valium and other benzodiazepines also get into mothers' milk. A nursing infant whose mother is taking any of these drugs will be groggy and, over time, may eat poorly and lose weight. ♦

# Product Recalls

## October 6, 2010 - November 30, 2010

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

### DRUGS AND DIETARY SUPPLEMENTS

#### Recalls and Field Corrections: Drugs – Class I

Indicates a problem that may cause serious injury or death

**1, 4 AD (1, 4 Androstadiene-3, 17-Dione) Capsules**, 200 mg, 60-count bottle. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements, but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**1, 4 AD BOLD, iFORCE NUTRITION**, 200 mg, 60-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**2A, 17A Methadrol Capsules**, 10 mg, 90-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Anabolic Xtreme 3-AD Capsules**, 90-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**D-DROL Capsules, D-Drol Complex, Liver Support Complex**, 300 mg, 60-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Diene Drone Capsules**, 50 mg, 60-count bottle. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed

as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**DYMETHAZINE Capsules**, 15 mg, 60-count box. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Ejaculoid XXTREME, Natural Male Explosions**, 30-capsule bottles. Volume of product in commerce: 4,788 bottles. Unapproved drug: The product was found to contain sulfoildenafil, an analogue of Sildenafil. Sildenafil is an active ingredient of an FDA-approved drug for male erectile dysfunction. Lot #: 79935, exp. date 12/2012. Nutraloid Labs, Inc./Goliath Labs, Inc.

**Halodrol Liquigels**, 480 mg, 60-count gels per box. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**HyperDROL X2 Capsules, X2 Support Matrix**, 50 mg, 260 mg, 120-count bottle. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Joyful Slim™ Natural Herb for Weight Loss**, Herb Supplement, 30-capsule bottles. Volume of product in commerce: approximately 15,000 bottles. Marketed without an approved New Drug Application; found to contain undeclared N-desmethyl and traces of sibutramine. Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss. Multiple lots. J & H Besta Corp.

## DRUGS AND DIETARY SUPPLEMENTS

**MasXtreme Herbal Supplement for Men Capsule**, 450 mg, 1-count blister pack. Volume of product in commerce: 115,890 blister packs. Marketed without an approved New Drug Application: FDA analysis has determined the product contains undeclared amounts of aminotadalafil, an analog of tadalafil. Tadalafil is an FDA-approved drug used to treat erectile dysfunction, making MasXtreme an unapproved new drug. Lot #: 907043, exp. date 09/2011. Florida Supplement Corp.

**M-DROL Capsules**, 10 mg, 90-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: these products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Methyl-1, 4 AD Capsules**, 30 mg, 60-count bottle. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: these products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**MONSTER CAPS Capsules**, 60 mg, 60-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Novedex XT Capsules**, 60 mg, 60-count bottle. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**P-PLEX Capsules**, 10 mg, 90-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application:

These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Slim-30™ Natural Herb for Weight Loss**, Herb Supplement, 30-capsule bottles. Volume of product in commerce: 10,011 bottles. Marketed without an approved New Drug Application; found to contain undeclared N-desmethyl and traces of sibutramine. Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss. Multiple lots. J & H Besta Corp.

**Stimuloid II, Explosive Stimulation**, Maximum Sexual Power, Ridiculous Performance, 30-capsule bottles. Volume of product in commerce: 5,146 bottles. Unapproved drug: The product was found to contain sulfoildenafil, an analogue of Sildenafil. Sildenafil is an active ingredient of an FDA-approved drug for male erectile dysfunction. Lot #: 79936, exp. date 12/2012. Nutraloid Labs, Inc./Goliath Labs, Inc.

**Testra Flex Capsules**, 25 mg, 90-count metal cans. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

**Vialipro Capsules, (Prostancus HCl)**, 375 mg, 10-count blister packs. Volume of product in commerce: 370,000 capsules. Marketed without an approved New Drug Application: product contains sulfoildenafil, an analogue of Sildenafil, an active ingredient used in the treatment of erectile dysfunction. All lots. Desert Rose Manufacturing, Inc.

**X-TREN Capsules**, 30 mg, 90-count bottles. Volume of product in commerce: unknown. Marketed without an approved New Drug Application: These products are being recalled because they are marketed as dietary supplements but have been found to contain steroids or steroid-like substances, making them unapproved new drugs. Multiple lots. Musclemaster.com, Inc.

## Recalls and Field Corrections: Drugs – Class II

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

**Dronabinol Capsules**, 2.5 mg liquid-filled gelatin capsule. Volume of product in commerce: 180 units. Temperature abuse: The product was stored in below freezing conditions for 10 to 12 hours. Liquid-filled gelatin capsules that are subjected to conditions below freezing have an increased possibility of leaking due to the gelatin becoming brittle or the volume of the liquid inside shrinking and expanding. Lot #: 103869B, exp. date 06/2012. Pharmaceuticals International, Inc.

**Lipitor (Atorvastatin Calcium) Tablets**, 40 mg, 90-count bottle, Rx only. Volume of product in commerce: 4,607,808 bottles. Chemical contamination: complaints of an uncharacteristic odor identified as 2, 4, 6 tribromoanisole. Lot #: 0855020, 0819020, 0842020, 0843020, 0854020, exp. date 01/2013. Pfizer, Inc.

## DRUGS AND DIETARY SUPPLEMENTS

**PhosLo (Calcium Acetate) GelCaps**, 667 mg, 200-gelcaps bottle, Rx only. Volume of product in commerce: 8,076 bottles. Failed USP dissolution test requirements: product fails dissolution and may result

in hyperphosphatemia. Lot #: 1308035, 1308039, exp. date 03/2011. Braintree Laboratories, Inc.

## CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call its hotline at (800) 638-2772. The CPSC website is [www.cpsc.gov](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

**2010 Hunter Safety System Ultra-Lite Carabiners.** The pins in the carabiners can detach, causing a climbing strap to break free from the safety harness. This can result in the climber falling. Hunter Safety System, (877) 296-3528 or [www.hssvest.com](http://www.hssvest.com).

**Alexander Designs Ltd. Brand Drop-Side Cribs.** The drop-side rail hardware on the cribs can break or fall, 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 also can occur due to incorrect assembly or with age-related wear and tear. Jardine Enterprises, Ltd., (800) 295-1980 or [www.jdservice.biz/jcp-safety-notice](http://www.jdservice.biz/jcp-safety-notice).

**Ameristep Plastic Strap-On Tree Step.** The plastic portion of the step can break, posing a fall hazard to the user. Primal Vantage Co., Inc., (866) 972-6168 or [www.treestandcustomerservice.com](http://www.treestandcustomerservice.com).

**Angel Line Drop-Side Cribs.** The crib's drop-side rail hardware can malfunction, detach or otherwise fail, causing part of the drop-side rail to detach from the crib. When the drop-side rail partially detaches, it creates a space between the drop side and the crib mattress. An infant or toddler's body can become entrapped in the space, which can lead to strangulation and/or suffocation. A child also can fall out of the crib. Drop-side incidents also may occur due to incorrect assembly and with age-related wear and tear. Angel Line, (800) 889-8158 or [www.angelline.com](http://www.angelline.com).

**Bathtub Subs.** The intake valve on the bottom of the submarine toy can suck up the loose skin, posing a laceration hazard to children. Munchkin, Inc., (877) 242-3134 or [www.munchkin.com](http://www.munchkin.com).

**Bicycles with 2010 EC90 Zero-Seat Posts.** The carbon top clamp of the seat post can crack, posing a fall hazard to the user. Easton Sports, (866) 892-6059 or [www.eastonbike.com](http://www.eastonbike.com).

**Black & Decker® Model and Haier® Model Chest Freezers.** The freezer's circuitry can overheat, posing a fire hazard. Haier America Trading, LLC, (877) 878-7579 or [www.chestfreezerrecall.com](http://www.chestfreezerrecall.com).

**Bravo Sports Trampolines.** Incorrect assembly can allow the top rails and legs to bend or break during normal use, resulting in partial collapse of the trampoline. This poses a fall hazard to consumers. Bravo Sports, (877) 500-2459 or [www.airzonevariflex-recall.com](http://www.airzonevariflex-recall.com).

**Carhartt® Infant's Overalls.** The overalls have snaps that could come loose and pose a choking hazard to young children. Lollytogs, Ltd., (800) 637-9035 or [www.ltapparel.com](http://www.ltapparel.com).

**Castalon Frying Pans.** The enamel coating of the pan can crackle and break off after a few uses, posing a burn hazard to consumers. Tabletops Unlimited, (888) 239-2021 or [www.ttucorp.com](http://www.ttucorp.com).

**Claire-Sprayway Fabric Protector.** Overexposure to fumes, vapor or spray mist from the product can pose a respiratory hazard to consumers. Claire-Sprayway, Inc., (877) 416-7324 or [www.clairemfg.com](http://www.clairemfg.com).

**Craftsman Riding Mowers.** These riding mowers came to consumers with the side discharge chute not fully secured to the mower. Bolts can be forcefully discharged from mower if not properly tightened, posing an injury hazard to consumers. Sears, (800) 859-7026 or [www.sears.com](http://www.sears.com).

**Ethan Allen Drop-Side Cribs.** The crib's drop-side rail hardware can malfunction, detach or otherwise fail, causing part of the drop-side rail to detach from the crib. When the drop-side rail partially detaches, it creates a space between the drop side and the crib mattress. An infant or toddler's body can become entrapped in the space, which can lead to strangulation and/or suffocation. A child also can fall out of the crib. Drop-side incidents also may occur due to incorrect assembly and with age-related wear and tear. Ethan Allen, (888) 339-9398 or [www.ethanallen.com](http://www.ethanallen.com).

## CONSUMER PRODUCTS

**Falls Creek Infant Boy Shoes.** The shoe lace toggles can detach, posing a choking hazard to young children. Meijer, (800) 927-8699 or [www.meijer.com](http://www.meijer.com).

**Fire Alarm Control Panel.** The recalled fire alarm control panels used with an SLC-2LS expander module can fail to sound an alarm in the event of a fire. Fire-Lite Alarms, (800) 627-3473 or [www.firelite.com](http://www.firelite.com).

**Fisher-Price Baby Playzone™ Crawl & Cruise Playground™, Baby Playzone™ Crawl & Slide Arcade™, Baby Gymnastics™ Play Wall, Ocean Wonders™ Kick & Crawl™ Aquarium, 1-2-3 Tetherball™, Bat & Score Goal™.** The valve of the inflatable ball on these toys can come off and pose a choking hazard to young children. Fisher-Price, Inc., (800) 432-5437 or [www.service.mattel.com](http://www.service.mattel.com).

**Fisher-Price Healthy Care, Easy Clean and Close to Me High Chairs.** Children can fall on or against the pegs on the rear legs of the high chair, resulting in injuries or lacerations. The pegs are used for high chair tray storage. Fisher-Price, Inc., (800) 432-5437 or [www.service.mattel.com](http://www.service.mattel.com).

**Fisher-Price Little People Wheelies Stand 'n Play Rampway.** The wheels on the purple and the green cars can come off, posing a choking hazard to young children. Fisher-Price, Inc., (800) 432-5437 or [www.service.mattel.com](http://www.service.mattel.com).

**Fisher-Price Trikes and Tough Trikes Toddler Tricycles.** A child can strike, sit or fall on the protruding plastic ignition key resulting in serious injury, including genital bleeding. Fisher-Price, Inc., (800) 432-5437 or [www.service.mattel.com](http://www.service.mattel.com).

**Frigidaire and Electrolux ICON Smoothtop Electric Cooktops and Frigidaire Slide-In Ranges with Rotary Knobs and Digital Displays.** Liquids can pool under the control knob and cause the surface heating element to turn on unexpectedly, heat to temperatures other than expected and then not turn off, posing a risk of fire and burn hazards to consumers. Electrolux Home Products, Inc., (888) 281-5310 or [www.smoothtoprangerecall.com](http://www.smoothtoprangerecall.com) (Frigidaire) or [www.cooktoprecall.com](http://www.cooktoprecall.com) (Electrolux).

**GE Profile™ and GE Monogram™ Dishwashers.** Water condensation can drip onto the electronic control board, causing a short circuit and resulting in an overheated connector. This poses a fire hazard to consumers. GE Appliances & Lighting, (877) 275-6840 or [www.geappliances.com/recall](http://www.geappliances.com/recall).

**Green Mountain Vista, Inc. Roman Shades.** Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the shade or when a child pulls the cord out and wraps it around his/her neck. Green Mountain Vista, Inc., (800) 639-1728 or [www.gmvista.com](http://www.gmvista.com).

**Heritage Collection 3-in-1 Drop-Side Cribs.** The crib's drop-side rail hardware can malfunction, detach or otherwise fail, causing part of the drop-side rail to detach from the crib. When the drop-side rail partially detaches, it creates a space between the drop side and the crib mattress. An infant or toddler's body can become entrapped in the space, which can lead to strangulation and/or suffocation. A child also can fall out of the crib. Drop-side incidents also may occur due to incorrect assembly and with age-related wear and tear. Victory Land Group, Inc., (866) 499-2099 or [www.victorylandgroup.com](http://www.victorylandgroup.com).

**Home Improvement Books.** The books contain errors in the technical diagrams and wiring instructions that could lead consumers to incorrectly install or repair electrical wiring, posing an electrical shock or fire hazard to consumers. Oxmoor House, (866) 696-7602 or [www.sunsetrecall.com](http://www.sunsetrecall.com).

**Iron Lovers Benches.** The bench can tip over when only one person is seated on it. This could pose a fall hazard to consumers. Ross Stores, Inc., (877) 455-7677 or [www.rossstores.com](http://www.rossstores.com).

**John Deere EZtrak Zero-Turn Lawn Mowers with Foot Lift and Zero-Turn Mowers with Premium Foot Lift Kit.** A bolt in the right-hand steering lever can catch on the tab of the foot lift, stop and lock in place, causing the steering lever to remain in the forward travel position, posing an injury hazard to the driver. Deere & Company, (800) 537-8233 or [www.johndeere.com](http://www.johndeere.com).

**Kohler and Sterling Frameless By-Pass Bath Doors.** The glass doors can shatter, posing a laceration hazard. Kohler Co., (866) 782-6329 or [www.kohler.com](http://www.kohler.com).

**PBteen Sleep and Study Loft Beds.** The side rail on the bed can crack allowing the mattress support to collapse, posing a fall and injury hazard to users. PBteen, (877) 494-9822 or [www.pbteen.com](http://www.pbteen.com).

**Pumpkin, Ghost and Skull Halloween Lanterns.** The bulb in the battery-operated lanterns can overheat, posing fire and burn hazards to consumers. Dollar Tree Stores, Inc., (800) 876-8077 or [www.dollartree.com](http://www.dollartree.com).

## CONSUMER PRODUCTS

**Revi Carbon Bicycle Brakes.** The cable clamping area of the bicycle brakes can crack over time, causing the brakes to fail. This could pose a fall or crash hazard to the cyclist. The Hive, (800) 801-9936 or [www.bythehive.com/recall](http://www.bythehive.com/recall).

**Ryobi Model HP 1802M Cordless Power Drills.** The switch on the cordless drill can overheat, posing a fire and burn hazard to consumers. Ryobi, (800) 597-9624 or [www.ryobitools.com](http://www.ryobitools.com).

**Tike Tech Single City X3 and X3 Sport Jogging Strollers.** The opening between the grab bar and seat bottom of the stroller can allow an infant's body to pass through and become entrapped at the neck by the grab bar, posing a strangulation hazard to young children when a child is not harnessed. When using a stroller, parents and caregivers are encouraged to always secure children by using the safety harness and to never leave them unattended. Tike Tech, Ltd., (800) 296-4602 or [www.tiketech.com](http://www.tiketech.com).

**Trisonic Compact Fluorescent Light Bulbs.** Light bulbs can overheat and catch fire. Eastern America Trio Products, Inc., (800) 661-7146 or [www.trisonic.com](http://www.trisonic.com).

**Valco Baby Tri Mode Single and Twin Jogging Strollers.** The opening between the grab bar and seat bottom of the stroller can allow an infant's body to pass through and become entrapped at the neck by the grab bar, posing a strangulation hazard to young children when a child is not harnessed. When using a stroller, parents and caregivers are encouraged to always secure children by using the safety harness and to never leave them unattended. Valco Baby, (800) 610-7850 or [www.valcobaby.com](http://www.valcobaby.com).

**White Ruffle Outdoor Vests for Girls.** Metal snaps may detach from garment causing a choking hazard. The Children's Place Services Company, LLC, (877) 752-2387 or [www.childrensplace.com](http://www.childrensplace.com).

**Wolverine, Spiderman and Iron Man 2 Projector Flashlights.** The flashlights can cause the batteries and/or bulb to overheat, posing fire and burn hazards to consumers. Dollar Tree Stores, Inc., (800) 876-8077 or [www.dollartree.com](http://www.dollartree.com).

### OUTRAGE from page 12

strokes or multiple deaths and spending years concealing "clear indications that Avandia increased heart risks"?

But what punishment was actually inflicted? "In July, GlaxoSmithKline took a \$2.3 billion liability charge related to legal cases involving Avandia and another medicine, Paxil," Harris wrote. "At the time, investors cheered

the news as the company's attempt to set a ceiling for its liability surrounding the medicine."

In the Supreme Court's *Citizens United* 5-to-4 decision, the majority — conservatives, they're called — held that the First Amendment cannot stop corporations, just as it cannot stop flesh-and-blood persons, from

spending money to support or denounce individual election candidates.

Would that same majority provide "Equal justice under law" (the phrase engraved on the front of the U.S. Supreme Court building) for corporate executives who knowingly assault and kill people?

I've got a bridge I'd like to sell you. ♦



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## Outrage! Holding Executives Accountable for Corporate Wrongdoing

*The following article is written by Morton Mintz, a frequent contributor to Health Letter, as part of a series published on Nieman Watchdog.org, concerned with questions the press should ask corporations and the Food and Drug Administration.*

If people, not guns, are responsible for killing people, then aren't executives, not corporations, responsible when their products kill people? Such as GlaxoSmithKline executives who concealed for years that the drug Avandia [rosiglitazone] increased heart risks, causing thousands of strokes, heart attacks and deaths? And isn't this an issue reporters should deal with?

The top story in the Sept. 24 *New York Times* begins, "In a highly unusual coordinated announcement, drug regulators in Europe and the United States said Thursday that Avandia, the controversial diabetes medicine, would no longer be widely available."

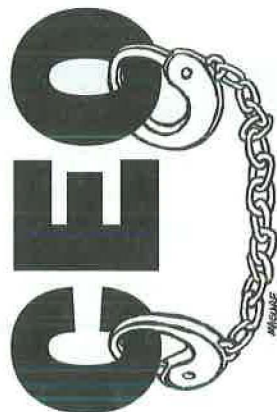
Gardiner Harris wrote:  
One study estimated that from 1999 to 2009, more than 47,000 people taking Avandia needlessly suffered a heart attack, stroke or heart failure, or died ...  
Senate investigators found that GlaxoSmithKline spent years hiding from regulatory authorities clear

indications that Avandia increased heart risks.

The foregoing two paragraphs, on page A15, abutted an Associated Press item about Teresa Lewis, who on the previous day became "[t]he first woman executed in the United States since 1905 ..." She had been convicted of conspiring to murder her son and stepson.

Putting aside the morality of the death penalty, let's assume that Ms. Lewis deserved to be lethally injected for causing the deaths of two people. And let's bear in mind that if guns don't kill people, people do, as gun advocates tirelessly assert, then corporations don't kill people, people do. So if Ms. Lewis deserves the death penalty, what punishment is deserved by the GlaxoSmithKline executives responsible for "needlessly" causing an estimated 47,000 or more heart attacks,

continued on page 11



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