PUBLICCITIZEN Health Letter

SIDNEY M. WOLFE, M.D., EDITOR DECEMBER 2010 – VOL. 26, No. 12

Treating the Common Cold (Without Making Yourself Sicker)

The following article originally appeared on www.marlothomas.aol.com. It is a conversation between actress and activist Marlo Thomas and Dr. Sidney Wolfe about treating the common cold.

Marlo Thomas: I pride myself on not getting many colds — I don't have time to be sick! But hey, I'm human, and occasionally I come down with a doozy. And I just can't stand it! A head cold may be a minor illness, but it causes such misery! I'm always tempted to reach for something...anything to make those sniffles stop. But I don't, and here's why: There's no one I trust more when it comes to health than Sidney Wolfe. And Dr. Wolfe — a physician who is coauthor of "Worst Pills, Best Pills: A Consumer's Guide to Avoiding Drug-Induced Death or Illness," as well as being the editor of WorstPills.org — has some strong opinions on cold medicines! I asked him what to do, and what not to do, when a cold strikes. Here's his advice.

Dr. Sidney Wolfe: Hi Marlo — thanks for inviting me to participate in this important conversation. As you know, I've spent years spreading the word that people are taking too many unnecessary or unnecessarily dangerous drugs, exposing themselves to more ailments than they realize every time they take a pill. Over-the-counter medicines for the common cold are one of my pet peeves — they're mostly unnecessary, and people often take even more medicine than they need (or realize) when they choose a "combination" formula.

Here's the background: The illness we call the common cold is caused by a virus that infects the upper respiratory tract (nose, throat and upper airway). This creates the inflammation of the mucous membranes that leads to the miserable stuffy head, runny nose, sneezing, and, sometimes, sore throat or cough. There are no drugs available to kill that virus. A cold can't be "cured" by anything except time, so the safest, cheapest approach is to let it run its course while you get lots of rest and drink plenty of fluids. If you need more relief than that, there are some single-ingredient, over-the-counter medications that may help lessen symptoms while you wait it out — but you need to choose wisely and select only the medicines you need for your most troublesome symptoms.

And that's the real issue: So many of the cold medicines on drugstore shelves now have far more ingredients than anyone needs, and most of the combinations don't even make sense. For example, why would anyone need something that combines an expectorant (which thins out secretions and makes your coughs more productive, ridding your lungs of mucus) with a cough suppressant (which stops you from coughing in the first place)? That's just one example of the shotgun approach taken by those "multi-symptom" formulas containing multiple drugs. It's a big problem, because every medicine ingredient you take, whether or not it has any benefit for you, has some risk of side effects (which can be either sudden or cumulative). The more ingredients, the greater your risk. Your goal should always be to take the minimum number of medicines, at the lowest doses, to have the safest and most effective treatment.

So here's what to do if you have a cold:

- Drink eight to 10 full glasses of (nonalcoholic) liquids a day, preferably hot or warm. Warm liquids are the best expectorants, so if you're coughing up mucus, lots of soup and tea will help clear your airways. Coughing is a protective mechanism.
- Get plenty of rest, as much as you think you need. Your body is telling you something when you're sick — give yourself a break, and don't push yourself. You'll recover faster.
- If you have a runny nose, remember that your body is draining itself of

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mucus, and don't take anything to stop it.

- If you have a stuffy nose, try nose drops or sprays, not oral decongestants. (Try a simple sterile-saline nasal solution first before you use medicated drops or sprays.) The reason to choose medicated sprays and drops over oral medications is that they provide a much smaller dose of medicine, in exactly the right place (your nose). Oral formulas contain 25 times as much medicine, and they circulate that medicine throughout your entire body for no reason. Instead, look for these safe, effective ingredients:
  - oxymetazoline hydrochloride (found in Afrin)
  - xylometazoline hydrochloride (found in Otrivin)
  - phenylephrine hydrochloride (found in Neo-Synephrine)

Get the store brand or generic versions of these three to save money; the store brands and generics are equally effective as long as the ingredients are the same. Don't use drops or sprays for more than three days, though, since overuse can actually cause irritation and more congestion.

- If you have a headache or body ache, take simple aspirin (unless you are under 40 — due to the risk of Reye's syndrome, a rare but potentially fatal disease) or acetaminophen in the smallest amount that affords relief.

What NOT to do when you have a cold:

- Don't take an antihistamine, or any medicine that contains one, for treating a cold. Although antihistamines are appropriate and effective for some allergies, since they combat histamines (which your body releases during an allergic reaction), they make no sense for a cold at all!
- Don't take oral decongestants such as pseudoephedrine (found in Sudafed, Contac and many other products). They're no more effective than nasal sprays or drops, and because of the higher dose they can have significantly more side effects and risks.
- Don't take the expectorant guaifenesin (found in Robitussin preparations and Mucinex). There are serious doubts about its effectiveness, so why take it?
- Don't take the cough suppressant dextromethorphan, found in many preparations such as Delsym and Robitussin DM (for DextroMethorphan); it is not effective in either children or adults and has some side effects.
- Don't take combination formulas of any kind — treat only the symptom you have.
- If you are under 40, do not use aspirin because you may have influenza rather than a cold. There is strong evidence that young people who take aspirin when they have the flu (or chicken pox) have a greatly increased risk of later getting Reye's syndrome.

Call your doctor if a fever climbs above 103°F (39.4°C), or if a fever at or above 100°F (38°C) lasts for more than four days. Under either of these circumstances, you probably do not have a cold.

Other signs that you may have something more serious than a cold: chills and coughing up thick phlegm (especially if greenish or foul-smelling), sharp chest pain when taking a deep breath, rapid breathing, or an extremely severe and persistent sore throat.

Otherwise, remember the old saying: If you don't treat a cold, it will last seven days. If you treat it, it will be gone in a week. It may be uncomfortable, but it's not serious — don't take medicine that has the potential to make it worse than it is!

If you go to WorstPills.org, you can find out more about colds as well as information about more than 200 other drugs listed as DO NOT USE, mainly because they are more dangerous than the equally effective safer alternatives we list. ✦

Skin Cancer Doesn't Discriminate (Suggestions to Prevent Skin Cancer)

The following article by Erin N. Marcus, M.D., was posted on the Huffington Post *website on September 23, 2010. It has been reprinted with permission.*

The mole on Ivis Febus-Sampayo's face looked odd. But it wasn't until her son needed treatment for acne that she went to a dermatologist.

"As mothers, we're working, we're busy," she said. "I forgot about me and called the dermatologist to make sure my son was getting taken care of."

The doctor removed a sliver of the mole, and reassured Ivis that it was probably nothing to worry about. Two weeks later, she received a diagnosis she never imagined possible: melanoma.

"I'm of olive complexion, I'm not a sun worshiper, I never baked in the sun, and I don't like the beach," said Ivis, a Latina who was born in Spanish Harlem and grew up in Philadelphia and New York. "At no time did I ever think I could have skin cancer."

But anyone can get skin cancer, and over the past few decades, melanoma — the most aggressive form of the disease — has become far more common. Its incidence has increased faster than that of any other cancer, and it's now the fifth most common cancer diagnosis in men and the seventh most common cancer diagnosis in women. Even though African Americans and Hispanic Americans are less likely to develop melanoma, they are more likely than white non-Hispanics to be diagnosed after the disease has spread, when it's at a stage that's tougher to treat.

"There's a misconception that if you have darker skin, you will not get melanoma," said Dr. Claudio Dansky Ullmann, a researcher at the National Cancer Institute. "It may be that you are less sensitive or less likely to develop it, but that doesn't mean you aren't going to develop it."

Exposure to ultraviolet radiation from the sun is the biggest risk factor for melanoma and skin cancers generally, and the one that people can do the most to avoid. (Genetics and some skin and immune conditions can increase risk, and some studies suggest that workers exposed to polychlorinated biphenyls (PCB's) may be at increased risk, too.) Cancer specialists stress that it's important for everyone to protect their skin, regardless of their pigmentation. The American Cancer Society (ACS) promotes a "Slip, Slop, Slap, Wrap" approach — meaning slip on protective clothing (the tighter weave, the better), slop on sunscreen (and re-slather every two hours), slap on a hat (with a two to three inch brim all around), and use wrap-around sunglasses that block ultraviolet light (melanoma can start inside the eye, too). The ACS and other groups also recommend minimizing outdoor activities between 10 a.m. and 4 p.m., when the sun's rays are strongest.

There's been some controversy about the safety of sunscreens, and the Food and Drug Administration plans to issue new guidelines on sunscreens this year. Dermatologists have traditionally recommended using sunscreen with an SPF ("sun protection factor") of 30 or greater. My colleague Dr. Robert Kirsner, a professor of dermatology at the University of Miami Miller School of Medicine, says it's more important to make sure the sunscreen protects against UVA (ultraviolet A) as well as UVB (ultraviolet B) rays. The Environmental Working Group, a research and advocacy organization, has raised questions about the safety of many sunscreens, and characterizes the SPF label as misleading. It posts its own rating system for sunscreens.

Of course, the best protection is to limit time spent in the sun, and avoid tanning salons. If your job requires you to be outdoors, try to cover up with a hat, long sleeves and pants, and try to work under an awning or in the shade.

Another key part of preventing deaths from skin cancer is early detection, since the prognosis is better when the disease is caught early, before it penetrates the layers of skin and spreads to other organs. The American Academy of Dermatology (AAD) urges everyone get regular skin exams by a medical professional, and the ACS also recommends everyone examine their own skin monthly. (Of note, the United States Preventive Services Task Force gives routine physician skin screening exams an "insufficient" rating — because there isn't enough research to recommend them one way or the other.) If you don't have health insurance, the AAD organizes free skin screenings, as does the Skin Cancer Foundation.

Many dermatologists recommend using an "ABCDEF" approach to look at your skin, and seeking attention if you notice anything that has one or more of the following characteristics:

- **A**ssymetrical
- Irregular **B**orders
- More than one **C**olor
- **D**iameter more than 5 millimeters (i.e., about the width of a typical pencil eraser)
- **E**volving, meaning it's changing
- **F**unny looking (also known as the "ugly duckling" sign, meaning a growth on the skin that looks different from its neighbors)

It's also important to inspect your finger and toe nails, the soles of the foot, and covered areas, such as the groin. Some studies indicate that African Americans in particular often develop melanomas on the bottom of the feet.

There are many new techniques for diagnosing melanoma, but only one in four primary care doctors get any training in this area during their residencies. If you feel your primary care physician isn't taking your

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Lesbian, Gay and Bisexual Teens Singled Out For Punishment: Study in Leading Pediatric Journal Finds Unfair Treatment Nationwide

Lesbian, gay and bisexual (LGB) adolescents are about 40 percent more likely than other teens to receive punishment at the hands of school authorities, police and the courts, according to research published in the January 2011 issue of Pediatrics and released online.*

The analysis, conducted at Yale University, found that the disparities in punishments are not explained by differences in misbehavior. Youth who identified themselves as LGB actually engaged in less violence than their peers, for example. Nonetheless, virtually all types of punishments — including school expulsions, arrests, juvenile convictions, adult convictions and especially police stops — were more frequently meted out to LGB youth.

For instance, adolescents who self-identified as LGB were about 50 percent more likely to be stopped by the police than other teenagers. Teens who reported feelings of attraction to members of the same sex, regardless of their self-identification, were more likely than other teens to be expelled from school or convicted of crimes as adults.

Girls who labeled themselves as lesbian or bisexual were especially at risk for unequal treatment: they experienced 50 percent more police stops and reported about twice as many arrests and convictions as other girls who had engaged in similar behavior.

Although the study did not explore the experiences of transgender youth, anecdotal reports suggest that they are similarly at risk for excessive punishment.

The study is the first to document excessive punishment of LGB youth nationwide. It was based on the National Longitudinal Study of Adolescent Health (Add Health) and included approximately 15,000 middle and high school students who were followed for seven years into early adulthood. Add Health utilized special techniques to ensure participants' privacy: for questions on more sensitive topics, respondents listened to questions through headphones and entered their responses directly onto laptop computers. The study collected details on subjects' sexuality, including feelings of sexual attraction, sexual relationships and self-labeling as LGB. Add Health also surveyed participants regarding how frequently they engaged in a variety of misbehaviors ranging in severity from "lying to parents" to using a weapon.

The study authors hypothesize that the excessive punishments of LGB youth may reflect authorities' reluctance to consider mitigating factors such as young age or self-defense in determining punishment for LGB youth. Moreover, they note that LGB youth frequently encounter homophobia in the education, healthcare and child welfare systems, and may therefore fail to receive services offered to other young people.

"The painful, even lethal bullying that LGB youth suffer at the hands of their peers has been highlighted by recent tragic episodes. Our numbers indicate that school officials, police and judges, who should be protecting LGB young people, are instead contributing to their victimization," said Kathryn Himmelstein, the study's lead author. She continued, "LGB teens can't thrive if adults single them out for punishment because of their sexual orientation." Himmelstein, who initiated the study while a Yale undergraduate, currently teaches mathematics at a public high school in New York City.

The research was supervised by Dr. Hannah Brückner, a Yale sociologist and nationally recognized expert on adolescent sexuality. Pediatrics is the world's leading journal of pediatric medicine.

** "Criminal Justice and School Sanctions against Nonheterosexual Youth: A National Longitudinal Study," Kathryn E.W. Himmelstein, B.A., and Hannah Brückner, Ph.D.* Pediatrics, *January 2011. http://pediatrics.aappublications.org/cgi/reprint/peds.2009-2306v1?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=himmelstein&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT* ✦

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concerns about a skin lesion seriously, push to see a dermatologist. Published research suggests that the specialists are generally better at telling apart a benign skin lesion from a cancer. (And as a primary care physician myself, this isn't a recommendation I make lightly.)

In Ivis' case, the melanoma was caught at an early stage. A few days after her cancer surgery, she returned to her job as the director of Latina Share, a New York-based support and advocacy group for women with breast and ovarian cancer. She now wears a hat and applies sun screen every day. "I think it's really important that people understand you don't have to be fair skinned, with blue eyes and blonde hair to get skin cancer," she said. "We need to become advocates for our own health, especially in the Latino community, where it's always family first. I always tell women, you need to take care of yourself — if you're not here, you can't take care of them."

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

Early Stage Breast Cancer: More or Fewer Psychological Problems after More or Less Surgery

The following article originally appeared in Health Letter *25 years ago, in the July/August 1985 issue. It is about a study conducted in 1985 regarding the psychological problems that can result from different breast cancer treatment options.*

Dr. Wendy Schain, a Washington, D.C. psychologist, seems to have confirmed what many people already suspect: that early breast cancer patients have fewer emotional problems if treatment conserves the breast than if it removes the breast.

Schain [was] a consultant to a National Cancer Institute (NCI) study at the National Institutes of Health's Clinical Center (hospital) in which women with small early-stage breast cancers agree to let a computer decide whether they will be treated by a) mastectomy, loss of the entire breast, or b) surgical removal of the lump and a small rim of surrounding normal tissue followed by a series of radiation treatments [in 1985].

All patients — in both groups — with positive lymph nodes found at surgery received chemotherapy in addition to mastectomy or lumpectomy. The choice of therapy was made by computer because the NCI medical team did not yet know for sure which of the two strategies would produce longer survival rates or if they would be equivalent; it was thus important that no bias creep in that might distort the results.

Before knowing which of the two kinds of treatment they would receive, patients in the NCI study took a standard psychological test and answer a detailed questionnaire. At this point, according to Schain, their fears about the disease, their feelings about the two treatment approaches and other matters — sexual concerns, for instance — were the same. But she found that clear differences emerged when they answered a second questionnaire six months after they started treatment.

To be said for mastectomy, Schain told a scientific meeting, is that, to date [in 1985], study patients treated with it report less pain, less soreness in the treated breast area and less restricted arm movement than the comparable patients treated with lumpectomy and radiation.

On other counts, however, mastectomy has been coming out second best. For instance, the mastectomy patients who needed chemotherapy in addition to other treatment — because cancer was found in their underarm lymph nodes as well as in the breast — reported more nausea and vomiting from the drugs than the lumpectomy-radiation patients also requiring chemotherapy.

What's more, despite the fact that 83 percent of both groups in the study had been confident of the effectiveness of their treatment, women receiving lumpectomy and radiation felt far better about themselves and about the quality of their lives.

In other words, whether the problem was anxiety, sadness, frustration, worries about appearance, lack of sexual interest or not being able to control events in one's own life, it was as much as seven times less common among the study women whose breasts had been spared. And on one count — feeling that life was not worthwhile — no women who still had her breast reported this emotion, whereas 12 percent of the breast amputees admitted to being this seriously depressed.

Unlike early breast cancer patients who undergo mastectomy and are then discharged, lumpectomy patients in the study then face seven to nine weeks of outpatient radiation therapy several times a week. Schain believes that the social support from other patients and staff that are a byproduct of this protracted treatment is one reason the lumpectomy women are less psychologically upset.

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In addition, she [said], "Lumpectomy patients do not have to deal with a radically altered body image. Mastectomy patients, on the other hand, must constantly confront their physical disfigurement and related feelings of sadness and loss. This may trigger a fear of underlying cancer, which could contribute to their continued emotional distress."

There are, of course, some early-stage breast cancer patients for whom lumpectomy is not appropriate. Sometimes, for example, the tumor is too large relative to the size of the woman's breast to make possible a satisfactory cosmetic result. For such patients or patients who, for any reason, have undergone mastectomy, there is almost always, fortunately, an alternative: breast reconstruction. This can be done either immediately after the loss of the breast, so that the patient wakes up from surgery and still has two breasts, or later.

All of the women in the NCI study who had a mastectomy were offered reconstruction. ✦

Thirteen Dirty Big Pharma Tricks That Rip You Off and Risk Your Health for Profit

The following is excerpted from an article by Martha Rosenberg, which originally appeared on www.alternet.org on December 22, 2010.

Even during a two-year recession with people losing their homes and jobs, pharma is still the nation's third most profitable sector. How does it do that? In part by cheating the government, misrepresenting science, bribing doctors, patients and pharmacies and squeezing the FDA. Other than that, the industry plays completely fair. Pharma has often been criticized for lack of creativity in developing new drugs. But these dirty tricks show its creativity is alive and well when it comes to putting the public at risk just to turn a profit.

1. Astroturf Patients?

Pharma promotes fake patient advocacy groups to lobby for its interests. These front groups often push the FDA to approve an expensive drug that has acceptable, cheaper alternatives. Or, they'll try to prevent Medicaid from switching to the less pricey drug. One of the largest faux groups, the "grassroots" National Alliance on Mental Illness (NAMI), was investigated by Sen. Charles Grassley for undisclosed pharma links. He found the 10 top NAMI state chapters received $3.84 million from pharma in less than five years, the biggest largesse from Eli Lilly, AstraZeneca and Bristol-Myers Squibb.

2. Cheating the Government

Pharma is now a top defrauder of the federal government. "Desperate to maintain their high margin of profit in the face of a dwindling number of important new drugs," pharma illegally promotes unapproved uses of drugs and deliberately overcharges Medicare and Medicaid, says Dr. Sidney Wolfe, director of Public Citizen's Health Research Group. Pharmaceutical companies have been hit with $14.8 billion in wrongdoing settlements in the last five years. But that's still cheaper for Big Pharma than going about things the old-fashioned, legal way. So the fraud continues.

3. Trials and Fibulations

Presiding over clinical trials can make a doctor thousands [of dollars] per patient. But they wouldn't compromise patient safety just to make a buck, would they? Medical College of Georgia psychiatrist Richard Borison and his colleague Bruce Diamond did 13 years ago when they tested Zyprexa, Risperdal and 20 other drugs and ended up in jail. So did Baystate Medical Center's Scott Reuben, who went to prison earlier this year for fraudulent Celebrex, Neurontin and Lyrica trials. And a Tucson facility testing asthma drugs Symbicort, Advair and Singulair doctored data and risked patients' health to net as much as $10,000 per patient, according to a whistleblower and government and court documents. How many other drugs were tested for such fiscal outcomes? Not counting recalled ones, of course.

4. More Trials and Fibulations

Even without fraud, pharma-sponsored studies can deceive. Trials that only determine that a drug is "not worse" than another one or impute safety before real data are available — as in the case of Vioxx and Avandia's threat of heart attacks — can skew results. And some research is not meant to be accurate to begin with. The Johnson & Johnson Center for Pediatric Psychopathology Research at Massachusetts General Hospital was founded to "move forward the commercial goals of J.& J." according to unsealed court documents. Its head, Harvard's Joseph Biederman, promised J.& J. a proposed drug trial "will support the safety and effectiveness of risperidone [Risperdal] in this age group," before it was ever conducted. Why leave things up to science?

5. Overseas Adventurism

As pharma increasingly eyes poorer countries for new markets and cheaper manufacturing it also eyes them for cheaper clinical trials. In 1996, 11 Nigerian children died in trials testing Pfizer's not-yet-approved antibiotic Trovan. While Pfizer paid the Nigerian government and state of Kano millions in a settlement, documents released by Wikileaks show that Pfizer tried to extort Nigeria's former attorney general to drop the lawsuits. Trovan was withdrawn from U.S. markets in 2001 for liver toxicity, though "safety signals" may have appeared sooner.

6. Clueless Institutional Review Boards

Institutional review boards, charged with overseeing clinical trials, should catch the unsafe drugs and shady trials. But a Congress and General Accountability Office sting conducted last year on a Colorado review board raises serious doubts. When asked to oversee a study of Adhesiabloc, a product designed to reduce scar tissue after surgery, Coast Independent Review Board said, "When do we start?" Even though the product did not exist — nor did its developer or lead researcher!

7. Double Dealing at the Pharmacy

The best thing that ever happened to pharma (after direct-to-consumer advertising) is Pharmacy Benefit Managers (PBMs). Their job is to negotiate the best drugs for their clients, which are heath and pension plans. But they

seem far more adept at taking money to push pharma's top branded drugs, regardless of the cost. Recently CVS' pharmacy benefit manager, AdvancePCS, sent letters to doctors extolling the benefits of the expensive drug Zyprexa on behalf of drug giant Eli Lilly. Had a generic drug been prescribed over Zyprexa, savings would have been huge.

8. FDA Foreplay

A sneaky way pharma tries to get FDA to approve a drug — even when the science isn't there — is to float the drug to the public. That's where directed marketing comes in. When "patients" (these are often astroturf groups), really want a drug approved, it puts huge pressure on the FDA to be sensitive to the public's wishes. This tactic famously flopped for Boehringer-Ingelheim this year when it tried to sell a medication for "hypoactive sexual desire disorder" (HSDD) in women (first it had to sell the disease itself). Even though BI debuted its pink Viagra at a medical conference last year and rolled out its elaborate "Sex Brain Body: Make the Connection" Web site with TV personality Lisa Rinna soon after, FDA said no. Seems even though Boehringer-Ingelheim was effective in "raising awareness" about female sexual dysfunction, something else wasn't effective: the drug. And when it came to foreplay, the FDA had a headache.

9. Pharma Service Announcements

Public service announcements are messages for your own good, like, "Do You Know the Seven Warning Signs of Cancer?" But a lot of the awareness messages and warning signs you hear now are not from the government or medical groups, but pharma.

"Voices of Meningitis" ads on mom sites and online TV, for example, look like they are raising awareness of meningitis, but they were actually funded by maker Sanofi Pasteur, which makes a meningitis vaccine.

"Unbranded" advertising appears to have legit origins, like the National Association of School Nurses, which sponsors the Sanofi Pasteur's meningitis ads. But when TV, radio and web messages push "awareness" of diseases like ADHD, irritable bowel syndrome (IBS), restless legs syndrome (RLS) or excessive sleepiness (ES), be suspicious. Real diseases aren't given initials for quick recall and easy reference. Nor do they come with snappy self-quizzes and pretty patient models. Unbranded messages also pimp the PSA (public service announcement) money that media outlets have for actual public issues.

10. National 'Interests' of Health

The National Institutes of Health are supposed to fund research for the public health with the public's tax dollars. But recently, a researcher who was stripped of his own NIH grant because of his huge financial links to pharma, is ruling on other researchers' grants on NIH committees, reports the *Chronicle of Higher Education.* The researcher, psychiatrist Charles Nemeroff, was also allowed to keep NIH funds when he moved to the University of Miami after being disqualified from them at Emory University. Clearly, when it comes to conflicts of interest at the top of level of government research, the fox is guarding the henhouse (or pork house).

11. Big Pharma Sends Schools Doctors

Continuing Medical Education (CME) are courses that doctors are required to take to keep their state licenses and stay up-to-date with current practice and treatment guidelines. But many are created by pharma, which covers the cost of the course for the doctor in exchange for unvarnished sales pitches. Worse, many are embarrassingly dumbed down.

A recent "course" offered by Medscape was titled "Quadrivalent HPV Vaccine May Be Effective in Women 24 to 45 Years Old." Participants were told that after taking the course, they would be able to "specify the currently recommended age range" for the vaccine (especially if they could read the title!). Another course manipulates participants to "lobby your legislators" for pharma-related Medicare funding. Congress recently investigated the billion-dollar continuing education industry for illegal marketing -- too bad Congress couldn't investigate for stupidity.

12. Ghostwriting

Ghostwriting — the act of medical marketing writers writing a paper, with doctors only posing as the authors — was rampant until 2008 Congressional investigations. But even though it's now prohibited, few journals have retracted ghostwritten articles that sold Vioxx, Fen Phen, Prempro and probably Avandia. Asked about the papers ghostwritten "by" Lila Nachtigall, a professor in the Department of Obstetrics and Gynecology, Deborah Bohren, vice president for public affairs at New York University's Langone Medical Center said, "If we had received a complaint, we would have investigated."

A Congressional investigation doesn't qualify as a complaint?

13. Crooked Books and Slanted Messages

Pharma is often accused of ghostwriting articles that end up in medical journals under doctors' names who had nothing to do with the writing or research. But this month an entire textbook was accused of being funded and approved by pharma. The 1999 textbook, written to help primary care doctors diagnose psychiatric conditions, was funded entirely by GlaxoSmithKline (GSK) — which makes pills for... psychiatric conditions! Nor were its authors, two prominent psychiatrists, strangers to GSK. Alan Schatzberg is on GSK's speakers bureau and Charles Nemeroff was investigated by Congress for undeclared GSK income. Did the authors write the book themselves or was it ghostwritten by pharma or its marketing company? Does it matter? ✦

Product Recalls

November 4, 2010 – December 15, 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

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

Solo Slim, All Natural Dietary Supplement Capsules, 470 mg, 30-count bottles. Volume of product in commerce: 227,505 bottles (since August 2007). Marketed without an approved new drug application: Solo Slim dietary supplement product was found to contain undeclared didesmethyl sibutramine, an analogue of sibutramine, based on FDA's sampling and analysis. Sibutramine is an FDA-banned drug used as an appetite suppressant for weight loss. Recall includes all lots currently on the market with expiration dates including and prior to August 2013. Changsha Foreign Economic Relations and Trade Corp.

Solo Slim Extra Strength, All Natural, Caffeine & Ephedra Free Dietary Supplement Capsules, 775 mg, 30 capsules. Volume of product in commerce: 268,705 (since August 2007). Marketed without an approved new drug application: Solo Slim dietary supplement product was found to contain undeclared didesmethyl sibutramine, an analogue of sibutramine, based on FDA's sampling and analysis. Sibutramine is an FDA-banned drug used as an appetite suppressant for weight loss. Recall includes all lots currently on the market with expiration dates including and prior to August 2013. Velocity Pharma, 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

Aceon (Perindopril Erbumine) Tablets, 2 mg, 100-count bottles, Rx only. Volume of product in commerce: 3,771 bottles. Impurities/degradation: A known degradation product (RWJ-4191) was found to be above specification at the 16 month/25 C/60% RH stability interval. Lot #: 3073841, exp. date 05/2011. Patheon Pharmaceuticals, Inc.

Avalide Tablets, 300/25 mg, 2-, 7- and 14-count blister packs and 30- and 90-count bottles. Volume of product in commerce: 2,222,828. GMP deviation: During manufacturing, the granulation time for the finished drug product was extended, which resulted in varying levels of Polymorph Form B. Polymorph Form A is the intended form. Polymorphism is the existence of different kinds/forms of crystal of the same chemical compound. In this case the extended granulation time changed Polymorph Form A to varying levels of Polymorphic Form B. Multiple lots. Bristol Myers Squibb Manufacturing Co.

Lipitor (Atorvastatin Calcium) Tablets, 40 mg, 90-count bottle, Rx only. Volume of product in commerce: 230,267 bottles. Chemical contamination: Firm received complaints of an uncharacteristic odor, which was subsequently attributed to contamination by 2,4,6 tribromoanisole. Lot #s: 0628040, 0672040, 0673040, 0754040, 0755040, 0763040, 0764040, 0765040, 0788040, exp. date 03/2013; 0540050, exp. date 04/2013; 0660060, 0682060, exp. date 05/2013. Pfizer, Inc.

Medrol, Methylprednisolone Tablets, 16 mg, Rx only. Volume of product in commerce: 5,821. Subpotent (single-ingredient drug): The firm voluntarily initiated this recall when it was determined that this lot did not meet assay specifications on stability. Lot #: 0AUCX, exp. date 07/2012. Pfizer Italia.

Nimodipine Capsules, 30 mg, blister packs of 30 and 100. Volume of product in commerce: 14,824 cartons. CGMP deviations; leaking capsules. Lot #s: 3305.013A, 3305.014A, 3305.014B, exp. date 10/2010; 3305.015A, exp. date 12/2010; 3305.016A, 3305.016B, exp. date 01/2011. Pharmaceutics International, Inc.

Prednisone Tablets, 10 mg, 21 tablets, Rx only. Volume of product in commerce: 36,168 units. Superpotent (single-ingredient drug): A tablet was found to be 129.5 percent of the label claim. Lot# L091D10A, exp. date 04/2013. Qualitest Pharmaceuticals.

Tamoxifen Citrate Tablets, 10 mg, 180-count bottle, Rx only. Volume of product in commerce: 4,124 bottles. Tablet thickness: Some tablets may not meet weight requirements. Lot # 394204. Teva Pharmaceutical Industries, Ltd.

CONSUMER PRODUCTS

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

Name of Product; Problem; Recall Information

2011 Model Year Anthem Giant Bicycles. The frame can crack at the junction of the seat post and top tube, posing a fall hazard to riders. Giant Bicycle, (866) 458-2555 or www.giant-bicycles.com.

Bassettbaby Drop-Side Cribs with External Plastic Hardware. The cribs' drop-side rail can malfunction, detach or otherwise fail, causing part of the drop side to detach from the crib. When a 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 can occur due to incorrect assembly and age-related wear and tear. Bassett Furniture Industries, Inc., (800) 308-7485 or www.bassettbaby.com.

Beman Bone Collector Arrows. The recalled arrows can break when launched and hit unintended targets, posing a puncture hazard to the user and bystanders. Beman, (888) 380-6234 or www.beman.com/recall.

Bosch Hammer Drills. The models have a grounding system and trigger switch that could cause ground wire abrasion and/or ground connector failure posing a shock hazard. In addition, the switch trigger could become stuck in the "on" position posing an injury hazard to the user. Robert Bosch Tool Corp., (866) 244-2110 or www.boschtools.com.

Camping Stoves and Equipment. Damaged fuel lines and/or O-rings may cause fuel leakage, posing a fire hazard to consumers. Katadyn North America, Inc., (800) 755-6701 or www.optimusstoves.com/usen/.

Chaperone Infant Car Seats. The harness chest clip can break and pose a laceration hazard. Due to its small size it also poses a choking hazard. Britax, (888) 427-4829 or www.britax.com.

Circo Children's Space Camp Combo Pack. The floor of the tent failed a flammability test and poses a fire hazard. Target Corp., (800) 440-0680 or www.target.com.

Classic Sport Super Bounce Pogo Sticks. The aluminum rivets on the pogo stick's frame tubes can break and cause the support clamp to detach and release the spring, posing fall and laceration hazards to consumers. Sportcraft, (800) 526-0244 or www.sportcraft.com.

Cub Cadet Volunteer Utility Vehicles. The front lower ball joint can detach and cause a loss of steering control. This poses a crash hazard for consumers. Cub Cadet, (888) 848-6038 or www.cubcadet.com.

Desk and Table Lamps. Substandard electrical wiring, connections and plugs in these lamps pose a fire and shock risk to consumers. CDX Group, Inc., (877) 253-4599 or www.picture2009.com.

Digital Clamp Meters and Multimeters. When the battery runs low, the meters can fail to give an accurate voltage reading, resulting in the operator falsely believing the electrical power is off or low. This poses an electrocution hazard. Extech Instruments, (855) 239-8324 or www.extech.com/recall.

Enamel-Coated 8-inch Cast Iron Skillets. Small pieces of the enamel coating can pop off when the skillet is heated, posing a burn hazard to consumers. QVC, (800) 367-9444 or www.qvc.com.

Folding Camp Rockers. The plastic anchors attaching the fabric seat back to the frame can break, posing a fall hazard to consumers. L.L.Bean, (800) 555-9717 or www.llbean.com/recall.

Forever-Glo® Cylinder Nite Lites. An electrical short circuit in the night light can cause it to overheat and smolder or melt which can burn consumers or result in a fire. American Tack & Hardware Co., Inc., (800) 420-7511 or www.amertac.com.

Full Speed Ahead BB30 Gossamer Crank Sets. If the fixing bolt is over-tightened on the non-drive crank arm, the bolt shoulder can crack or break. If this occurs, the non-drive arm can fall off the bicycle causing the rider to crash and suffer injuries. Full Speed Ahead, (877) 743-3372 or www.fullspeedahead.com.

Golf Cars and Hospitality, Utility and Transport Vehicles. The brake pedal can crack and separate, resulting in a loss of braking ability. This can result in a crash. Club Car, (800) 227-0739, ext. 3580 or www.clubcar.com.

Honda and Mantis Mini Tillers. A rubber grommet that is part of the engine's fuel tank can crack and leak fuel, posing a fire hazard. Honda, (888) 888-3139 or www.hondapowerequipment.com.

CONSUMER PRODUCTS

Hooded Jackets and Sweatshirts. The children's hooded sweatshirts have a drawstring through the hood and/or waist that can pose a strangulation or entrapment hazard to children. In February 1996, CPSC issued guidelines, which were incorporated into an industry voluntary standard in 1997, to help prevent children from strangling or getting entangled on neck and waist drawstrings in upper garments, such as jackets or sweatshirts. VOS Sports, Inc., (888) 268-6867 or www.vossports.com.

Horse-on-a-Stick Toys. The reins on horse-on-a-stick toy's bridle are long enough to form a loop around a child's head and neck, posing a strangulation hazard to young children. Big Ideas Marketing, (888) 908-8697 or www.bigideasmarketing.com.

Kitchentrend Stainless Steel Carafe. The handle can come loose from the body of the carafe and cause liquid to spill, posing a burn hazard to consumers. J & H International, (800) 770-3214.

Lowe's Home Roman Shades and Roll-Up Blinds. Roman Shades: Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Roll-Up Blinds: Strangulations can occur if the lifting loop slides off the side of the blind and a child's neck becomes entangled on the free-standing loop or if a child places his/her neck between the lifting loop and the roll-up blind material. Lowe's Home Centers, Inc., (800) 445-6937 or www.lowes.com.

Motorized Awnings. The awning motor's power cable can be severed while the awning is opened or closed manually, posing a risk of electrical shock to the user. Somfy Systems, (800) 637-6639 or www.somfysystems.com.

Pottery Barn Lamps. The electrical wire that runs through the lamps can be pinched or severed at the lamp's adjustable joint, posing a risk of electric shock to consumers. Pottery Barn, (877) 851-7890 or www.potterybarn.com.

Rachael Ray™ Brand Two Quart Teakettle. Water heated in the teakettles can spill and spray while being poured, posing a burn hazard. Meyer Corp. U.S., (877) 782-8242 or www.meyer.com/rrteakettlerecall.

Rocking Horses. The reins on the rocking horse bridle are long enough to form a loop around a child's head and neck, posing a strangulation hazard to young children. Rocking Horse Depot, (623) 302-6313 or www.rockinghorsedepot.com.

Roman Shades, Roll-up Blinds and Roller Blinds. Roman Shades: Strangulations can occur when a child places his/her neck between the exposed inner cord and the fabric on the backside of the blind or when a child pulls the cord out and wraps it around his/her neck. Roll-up Blinds: Strangulations can occur if the lifting loops slide off the side of the blind and a child's neck becomes entangled on the free-standing loop or if a child places his/her neck between the lifting loop and the roll-up blind material. Roller Blinds: Strangulations can occur if the blind's continuous loop bead chain or continuous loop pull cord is not attached to the wall or the floor with the tension device provided and a child's neck becomes entangled in the free-standing loop. Domestications or Hanover, (800) 453-1106 or www.domestications.com or www.hanoverdirect.com.

Ryobi RTS20 Portable Table-Saws. The saw blade on the motor carriage could be misaligned, posing a laceration hazard. Ryobi, (800) 597-9624 or www.ryobitools.com.

Silver and Gold Metallic Taper Candles. The metallic paint can ignite on the candles, posing a risk of fire. General Wax and Candle Co., (800) 543-0642 or www.generalwaxrefund.com.

Silver Metallic Pillar Candles. The metallic paint on the candles can ignite, posing a risk of fire. General Wax & Candle Co., (800) 543-0642 or www.generalwaxbbbrefund.com.

Ski-Doo® Snowmobiles. Electrostatic changes can accumulate and spark in the fuel tank when the engine is left idling, posing an explosion hazard that could result in serious injuries or death. BRP U.S. Inc., (888) 638-5397 or www.ski-doo.com.

Spark, Spitfire Inline Skates. The frame mounting bolts and wheel axle bolts can be loose on new skates. Loose wheels or frames on the skates can cause the rider to fall, posing a risk of injury. Rollerblade USA, (800) 232-7655 or www.rollerblade.com.

The First Years American Red Cross Cabinet Swing Locks. The installed latches can break and children could gain access to contents of a cabinet, posing the risk of exposure to hazardous items. The First Years, (866) 725-4407 or www.recalls.thefirstyears.com.

Toddler Girl Pants and Shorts. The metal clasp at the waistband can detach from the garment, posing a choking hazard to young children. American Eagle Outfitters, Inc., (888) 307-3672 or www.77kids.com.

Touch Point Oscillating Ceramic Heaters. The oscillating mechanism in the heaters can short out, posing a fire hazard to consumers. Meijer, (800) 927-8699 or www.meijer.com.

OUTRAGE from page 12

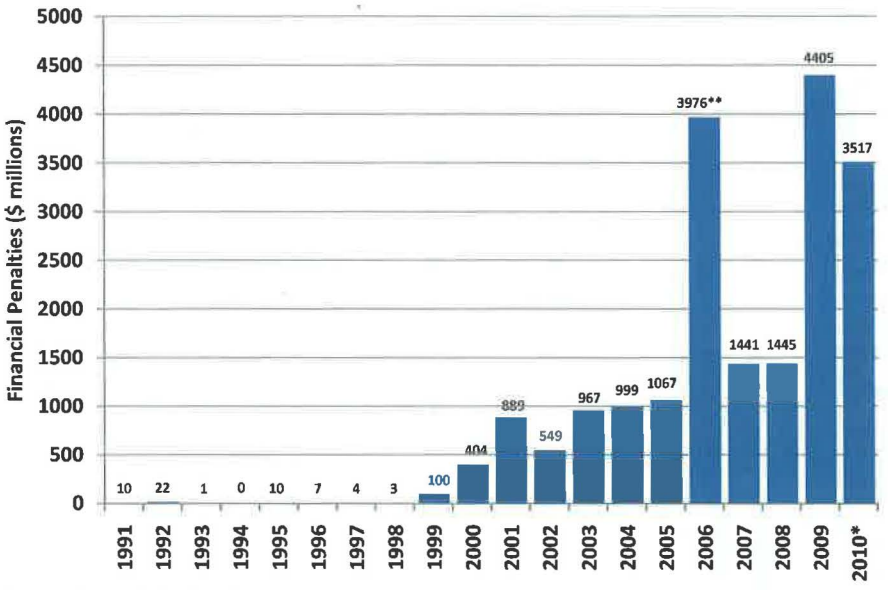
The increase in payments for fraud is likely attributable to drug companies engaging in more wrongdoing and better enforcement at the state and federal level, said Dr. Sidney Wolfe, director of the Health Research Group at Public Citizen.

"Desperate to maintain their high margin of profit in the face of a dwindling number of important new drugs, these figures show that the industry has engaged in such activities as dangerous, illegal promotion for unapproved uses of drugs and deliberately overcharging vital government health programs, such as Medicare and Medicaid," said Wolfe. Wolfe compiled and analyzed the data with physicians from the Johns Hopkins General Preventive Medicine program, Drs. Sammy Almashat and Charles Preston, as well as Columbia University public health student Timothy Waterman, all of whom worked at Public Citizen.

Public Citizen's study also found that more than one-half of the industry's fines were paid by just a few companies — GlaxoSmithKline, Pfizer, Eli Lilly and Schering-Plough. These four companies accounted for more than half of all financial penalties over the past two decades, paying $10.5 billion in fines collectively. These pharmaceutical companies were among the largest in the world. The two largest criminal penalties ever assessed by the U.S. government against any companies were against Lilly ($515 million) and Pfizer ($1.2 billion), both in 2009.

To conduct the study, Public Citizen created a database of information about pharmaceutical companies' civil and criminal settlements, including information about the type of alleged violation and the amount of money paid in settlements. This study is the first to attempt to document and analyze all major pharmaceutical company settlements with both federal and state governments, the authors said.

PHARMACEUTICAL INDUSTRY FINANCIAL PENALTIES, 1991-2010



*2010 data include only the first 10 months of the calendar year (through Nov. 1, 2010)

**One settlement with GlaxoSmithKline for $3.4 billion accounts for the spike in financial penalties in 2006.

Nationally, former pharmaceutical company employees and other whistleblowers have been instrumental in bringing to light the most egregious violations; they have initiated the largest number of federal settlements in the past decade. The number of federal settlements arising from whistleblower cases has more than doubled over the past five years, yielding total payouts more than two and a half times higher than in the previous 15 years combined.

Needed remedies include imposing steeper financial penalties and criminally prosecuting company leadership, including jail sentences, if merited.

"The danger to public safety and loss of state and federal dollars that comes with these violations require a more robust response," Wolfe said. ✦

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

PUBLICCITIZEN Health Letter

Outrage! Pharmaceutical Industry Is Biggest Defrauder of the Federal Government under the False Claims Act, New Public Citizen Study Finds

The drug industry has now become the biggest defrauder of the federal government, as determined by payments it has made for violations of the False Claims Act (FCA), surpassing the defense industry, which had long been the leader, according to a new Public Citizen study.

The study found that pharmaceutical cases accounted for at least 25 percent of all federal FCA payouts over the past decade, compared with 11 percent by the defense industry.

The fraud results were a key finding from a Public Citizen analysis of all major pharmaceutical company civil and criminal settlements on the state and federal levels since 1991 and found that the frequency with which the pharmaceutical industry has allegedly violated federal and state laws has increased at an alarming rate. Of the 165 pharmaceutical industry settlements comprising $19.8 billion in penalties during the past 20 years, 73 percent of the settlements (121) and 75 percent of the dollar amount ($14.8 billion) have occurred during the past five years. (See Table on page 11.)

Civil, Criminal Settlements Have Increased Dramatically; Off-Label Promotion Largely Responsible

Many of the infractions, and the single largest category of financial penalties, stemmed from the practice of off-label promotion of pharmaceuticals — the illegal promotion of a drug for uses not approved by the Food and Drug Administration (FDA). Off-label promotion can be prosecuted as a criminal offense because of the potential for serious adverse health consequences to patients from such promotional activities. Another major category of federal financial penalties was purposely overcharging for drugs under various federal programs, which constitutes a violation of the FCA.

On the state level, the largest category of financial penalties has come from companies deliberately overcharging state health programs, such as Medicaid. Public Citizen's study found this to be the most common category of violation among state settlements.

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