

Cocaine, amphetamines cause brain changes

In the May, 1999 issue of the *European Journal of Neuroscience* reports that moderate, daily use of cocaine and speed cause changes in brain function.

Dr. Terry E. Robinson of the University of Michigan, one of the co-authors of the study, found that "repeated exposure to cocaine or amphetamine [for 30 days in this test] changes the structure of brain cells in two regions of the brain associated with memory and learning." The changes in brain cell structure were still evident one month after discontinuation of the drugs. The authors feel that these changes in structure may account for the strong, permanent changes in behavior that occur with long-term drug use and addiction.

By way of commentary, our concern lies in the fact that other drugs in the same category that have similar mechanisms of action will produce the same brain damage. In particular, we are concerned with Ritalin, the drug of choice for children diagnosed with Attention Deficit / Hyperactivity Disorder (ADHD). Ritalin is in exactly the same drug classification (Schedule II) as cocaine and amphetamines.

If Ritalin causes structural changes in the brain cells in areas that control memory and learning, it may not be the best approach to take with children who are having difficulty with memory and learning and ADHD children do. Chiropractic care removes interferences to the central nervous system which can also hinder memory and learning. ▲

■ FDA removes drug reviewer

In our September, 1998 issue we reported on the attempts of the consumer advocacy group *Public Citizen* to ban the use of the diabetes drug Rezulin. The *Associated Press* reports on December 10, 1998 that the U.S. Food and Drug Administration (FDA) has removed the chief medical reviewer of the Rezulin case who recommended removing the drug from the market after documenting liver damage and at least 33 deaths linked to use of the drug.

The reviewer, Dr. John Gueriguian had one meeting with the manufacturer, Warner-Lambert, in which it was reported that he used "intemperate language" as he laid out his case and documented the damage Rezulin can cause to the liver. Warner-Lambert complained to the FDA and Gueriguian was removed from that case and any other case involving Warner-Lambert drugs.

Gueriguian said he stands by his original review. "If (Rezulin) hadn't have been approved, at least 21 people would be alive now. In all probability, many more than that," he said. ▲

■ Magazine Drug Ads Too Vague

The October 6, 2001 issue of the British journal *The Lancet* finds that direct-to-consumer (DTC) magazine ads for prescription drugs may rely more on emotional appeal rather than supplying any substantive evidence that the drugs actually work.

The researchers, led by Dr. Steven Woloshin of Dartmouth Medical School in Hanover, New Hampshire, studied ads in 70 issues of 10 leading US consumer magazines. They found that 87% of the ads chose "vague, qualitative terms" such as "proven relief" to describe the drug's benefits instead of research evidence.

"This strategy," Woloshin says, "probably leaves many readers with the perception that the drug's benefit is large and that everyone who uses the drug will enjoy the benefit."

The authors go on to say that there is also a danger that the ads "medicalize" minor, run-of-the-mill problems. "A runny nose all of a sudden becomes allergic rhinitis."

The Pharmaceutical Research and Manufacturers of America, a drug industry trade group, says that DTC ads help educate the public about diseases and treatments they might otherwise be unaware of.

Woloshin disagrees, especially since his team found few hard facts in the ads they studied. Indeed, bold print lines like "Is it just forgetfulness...or Alzheimer's disease?" are more likely to increase reader's anxiety rather than their awareness.

While the FDA does require drug manufacturers to list drug's side effects in their advertisements, Woloshin suggests that the FDA also require them to list research data on benefits and side effects in easy-to-read information boxes similar to nutrition labels on food.

In 1999, drug companies spent \$1.8 Billion dollars on direct-to-consumer ads for prescription drugs.

■ One third of drug errors in elderly are preventable

A report given on March 24, 2002 at the annual meeting of the *American Society for Clinical Pharmacology and Therapeutics* in Atlanta, Georgia says that one third of all medication errors that happen with elderly patients are preventable.

The researchers collected data on 27,500 patients over the age of 65. They found an error rate of more than 4%, or 1,202 medication errors, by examining such things as doctor, clinic and emergency room notes.

Researchers found that the most errors occurred in emergency room situations. These errors primarily came from mixing blood-thinners such as warfarin with other drugs. Nonsteroidal anti-inflammatory drugs (commonly known as NSAIDS and available over-the-counter) were also identified as a major problem contributing to errors.

Commentary: Aside from recommending that patients simply ask their doctors whether their drugs have any dangerous side effects or interactions, the researchers suggest that the industry use . . . computers! Ever on the cutting edge, the \$1.3 trillion dollar a year medical industry is just now discovering that computerized warning systems should be able to keep track of dangerous drug side effects and interactions. Why, we will even bet that one day computers may replace typewriters and accounting ledgers. Just think!

■ Most drugs not tested for birth defect risk

The September 2002 issue of *Obstetrics & Gynecology* reports on the disturbing fact that more than 90% of new drugs on the market since 1980 are considered to have an “undetermined” risk of producing birth defects in the fetuses of pregnant women who take them.

All new drugs are tested on animals to see whether or not they produce birth defects. Drug companies then use that information to try and determine whether or not the drug will cause birth defects in humans.

One problem is that while animal testing may give some indications whether a drug is safe for humans, humans do not always respond the same way animals do.

Another problem occurs once a drug gets approval from the FDA. Drug companies then are not usually required to track what happens to humans after they have been taking a drug to check the long-term effects.

The researchers say they recognize that it is unethical to conduct studies in which pregnant women are given drugs to see if they cause birth defects in their children. They then go on to say, “however, almost all drugs are taken by some pregnant women.”

Commentary: The fact that drug companies are concerned about the ethics of drug testing on pregnant women is a good thing. However, once a drug gets FDA approval, turning around and telling pregnant women it’s now OK to take drugs that have not been proven safe is hypocritical at best and dangerous at worst.

■ Report: Drug ads continue deception after sanctions

A December 4, 2002 report by congressional investigators from the United States General Accounting Office (GAO) say that some drug companies continue to run deceptive ads and TV commercials, sometimes for years, after being cited for violations by the Food and Drug Administration (FDA).

Drug maker Pfizer, for example, continued to make deceptive claims about its cholesterol drug Lipitor over the last four years despite several letters from the FDA telling them to stop.

In 1997, the FDA revised its guidelines to allow drug companies to do more direct-to-consumer advertising. Since then, consumer advertising has increased almost 150 percent and the FDA issued 88 letters accusing drug companies of ad violations. Some companies, the report said, “have received multiple regulatory letters over time for new advertisements promoting the same drug.”

The drug companies may have found a convenient loophole. New FDA regulations have increased the amount of time it takes for letters to be sent to offending companies by anywhere from 2 to 11 weeks. By limiting their ad campaigns to short periods of time, drug companies can have deceptive ads complete their “broadcast life cycle” and be seen by millions of people before the agency can issue a regulatory sanctioning letter.

Commentary: This report estimates that each year, 8.5 million Americans request and receive prescriptions for specific (and we might add, expensive) drugs after seeing these direct-to-consumer ads. Here’s a tip. Assume the worst about any new drug. Because the FDA has decreased the amount of time for new drugs to be approved many new “miracle drugs” are, in effect, tested on the market. “Caveat emptor” is the Latin phrase for “let the buyer beware.”



More Than Half Of Americans At Risk Of Drug Interactions

The January 18, 2000 issue of the *Alternative Medicine Newsletter* tells us about a disturbing survey reported by the American Society of Health-System Pharmacists (ASHP) which found that more than half of all Americans are at risk of possible drug interactions.

The survey found that of 1000 American questioned, 46% of them take at least one prescription medicine every day. More than 25% take multiple prescription medicines daily. 56% said that they had taken two over-the-counter medications or supplements in the week before they were surveyed.

Mick Hunt, president of the ASHP says that "as you take more medications [the] opportunity for drug interactions grows."

The survey also found that only 39% of those surveyed tell their doctor or nurse about their drug use. 8% failed to tell them at all. According to Hunt, "healthcare providers need to do a little bit better job at pulling that information out," but ultimately the pharmacist is better qualified at helping patients be better informed on the dangers of the drugs they are taking and how they interact.

Seems to us the safest approach may be to rely less on dangerous drugs and more on a properly functioning body, maintained through Chiropractic Wellness Care.



The Drug Report

Various sources report that there's been lots of problems in the world of pharmaceuticals this month. Let's look at a few of the many reports.

The Associated Press reports on November 28, 2000 that the popular drug Lotronex, used for women with irritable bowel syndrome, has been pulled from the market after it was linked with severe side effects ranging from ischemic colitis (an irritable, life-threatening intestinal inflammation) and constipation so severe that many patients had to have portions of their intestines surgically removed. The FDA is aware of 8 deaths and 124 hospitalizations of patients who had been taking Lotronex.

Reuters Health reported on December 14, 2000 that an outbreak of polio, the first in the Western Hemisphere since 1991, appears to be a result of the polio virus used in the oral polio vaccine itself. The virus apparently mutated into a virulent form after it was given to people who had been vaccinated.

The following reports are from the *Alternative Medicine Newsletter*.

The December 7, 2000 issue reports that the acne drug Accutane will receive a special warning label outlining the side effects, including a possible link to suicide in people taking the drug. Soon, patients will be required to sign a waiver stating that they understand the risks.

The move is part of an attempt to counter another problem with Accutane: It causes severe birth defects in children whose mothers are taking the drug. This is not the best of news since Accutane users include teenagers, most of whom think they are invincible, will never die or get pregnant.

The December 12, 2000 issue reports that a study done at the Institute for the Health of the Elderly at Newcastle General Study in England finds that Alzheimer patients are being prescribed drugs that could be making their symptoms worse.

The study estimates that 30,000 people every year are being given the drugs inappropriately. The authors report that the drugs, major tranquilizers, are too often "used as a substitute for good, practical care management."

By way of commentary, we have a pharmacist friend who contends "drugs are for selling, not for taking."

FDA drug advisers and conflict of interest

According to a report in the September 25, 2000 *USA Today*, more than half of the experts hired by the U.S. Food and Drug Administration (FDA) to advise the agency on which medicines should be approved had direct financial interests in the drug they were asked to evaluate.

54% of the experts consulted had financial conflicts of interest in the drugs they were evaluating, a violation of federal law. However, since 1998, the FDA had waived the restrictions more than 800 times.

The conflicts involved included being employed by a drug company working on the development of a drug and then serving on an FDA committee to evaluate it, holding stock in the company involved, or receiving consulting fees or research grants from companies involved.

While the FDA does reveal when a conflict of interest exists, it keeps the details of the disclosure secret. As a result there is no way to determine which drug company is involved or the financial interest at stake.

With few exceptions, the FDA follows the advice of the committees that review drugs for approval.

By way of commentary, this article points out one of the reasons that taking drugs has become so dangerous. Patient safety concerns come into question when the people responsible for saying the drug is safe are the same ones who stand to gain financially from its approval. As previously reported in this publication, studies report that serious adverse drug reactions result in approximately 106,000 deaths every year. This figure accounted for nearly 5% of all causes of recorded death in 1994 making adverse drug reactions the fourth leading cause of death in the United States. These conflicts of interest are intolerable at best and deadly at worst.

Seniors Still Prescribed Dangerous Drugs

A study in the February 9, 2004 issue of the Archives of Internal Medicine highlights a report issued by the Centers for Disease Control and Prevention saying that dangerous and/or inappropriate drugs are still being prescribed to elderly Americans in about 1 out of every 12 visits to the doctor. This despite the fact that a similar study issued in 1995 reported similar findings.

“This is a sizable problem,” said CDC statistician Diane Makuc, “it hasn’t been getting better.”

Inappropriate prescriptions are those that specifically carry warnings against use with the elderly or those that interact negatively with medication the patient is already taking. Inappropriate medication use in people over 65 has been cited in numerous adverse drug reactions, excess utilization of the health care system and poor physical function.

The study points out that inappropriate prescriptions were found to have been given in nearly 8% of senior’s doctor visits. The most common inappropriate prescriptions have been for pain relievers and central nervous system drugs.

Commentary: 8% may not sound like much but this figure represents an astounding 16.7 million visits that resulted in patients receiving inappropriate and/or dangerous prescriptions. Even worse, the problem was identified five years ago and the situation hasn’t gotten better. And they call it health care.

■ Aspirin Anti-Clotting Effect Weakens Over Time

The March 17, 2004 Journal of the American College of Cardiology reports that over time, aspirin taken daily to prevent blood clotting loses its effectiveness.

Previous research has indicated that aspirin's clinical efficacy decreases over a two year period. This study, done at the University "La Sapienza" in Rome, Italy also found similar results after monitoring blood samples from 150 patients for two years after they started aspirin therapy.

At the beginning of treatment, a maximum of 88% of patient's platelets could be made to clump together. While aspirin therapy decreased that number to 38% after two months, the clumping gradually increased back up to 62% after 24 months.

Previous research has also shown that while people taking an aspirin a day do experience a lower incidence of heart episodes, they suffer from a higher incidence of stroke and kidney disease than those who don't take a daily aspirin.

■ Painkillers For Knee Pain No Better Than Placebo

The August 2004 issue of the *Annals of the Rheumatic Diseases* reports that common painkillers containing acetaminophen are no more effective at relieving symptoms of osteoarthritis of the knee than a sugar pill.

779 patients with knee pain of at least 30 on a 100 point scale during physical activity were observed in the study. The participants were randomly assigned to be given 4 grams per day of acetaminophen (Tylenol) for six weeks or an inactive placebo. The level of improvement the observers were aiming for was a 30% decrease in pain.

52.6% of the acetaminophen group reached this level of relief. 51.9% of the placebo group reached the same level taking the inactive placebo, with an insignificant difference of only .7%.



Merck Pulls Vioxx Off Market

Reuters reported on September 30, 2004 that Merck and Co, Inc. has pulled its arthritis drug Vioxx off the market after a study showed it doubled the risk of heart attack and stroke.

Vioxx (also sold as Ceoxx in some parts of the world) is in a class of drugs known as COX-2 inhibitors. The drugs Celebrex and Novartis are in the same class. The U.S. Food and Drug Administration (FDA) said it would watch other COX-2 inhibitors closely as a result of the Vioxx report.

Last year Vioxx had sales of \$2.55 billion, accounting for more than 10% of Merck's annual revenues. More than 91 million prescriptions for Vioxx have been written in the U.S. alone since the drug's introduction in 1999.

Analysts say that this could cost Merck more than the \$16 billion drug maker Wyeth has spent to cover damages to people who suffered heart damage as a result of taking the recalled diet drug combination fen-phen.

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■ Children's Cancer Treatments Increase Cancer Risk

The May 2004 International Journal of Cancer highlights a study that shows children with cancer who are treated with radiation and certain chemotherapy drugs stand a higher risk of developing soft tissue sarcomas later on in life.

The records of 4400 patients who survived childhood cancer were analyzed. Sixteen soft tissue sarcomas occurred at least three years after the first cancer was diagnosed. While this rate of occurrence is only 0.6%, it is 54 times higher than that seen in an average population.

Of the 16 sarcomas that developed, 14 of them occurred in or near the site where the radiation was given for the first cancer. It was also found that as the radiation dosages increased, so did the risk of soft tissue sarcoma later on.

Additionally, the researchers found that treatment with a drug called Procarbazine also seemed to increase the risk of sarcoma.

Commentary: In a surprisingly brilliant flash of genius, the researchers concluded that the risk of sarcoma could be decreased by limiting the exposure of healthy tissues to high doses of radiation.

■ Drug Exec Quote: Drugs Don't Work In Everybody

On December 8, 2003 BBC News Online interviewed Allen Roses, an expert in genetic and senior executive at the drug company giant GlaxoSmithKline. In the interview, Mr. Roses was quoted as saying “drugs on the market work, but they don't work in everybody.”

In fact, it is estimated that 90% of drugs only work in 30-50% of the population. Roses cited research published three years ago that found different drugs had significantly different success rates with different people. That study found that most drugs had an efficacy rate of 50% or less.

Richard Ley, a spokesman for the Association of the British Pharmaceutical Industry, said “It's not news to anyone that not all drugs work in all people all the time.” He says using one drug for any particular condition “is not a viable approach. A medicine might work well in one person, and not at all for another.”

■ Acid inhibiting drugs increase risk of pneumonia

A study in the January 3, 2005 issue of the *Journal of the American Medical Association* finds a 27% increased risk of pneumonia in patients who take the new classes of acid inhibiting drugs such as Prilosec, PepcidAC and Nexium.

364,000 people were studied for seven years. 477 people developed pneumonia during or after taking the drugs, an increased incidence of 27%. The increase in risk is thought to occur because of an increase in stomach bacteria, which is normally killed by the stomach acid.

The drugs are normally reserved for more serious conditions but more and more doctors are using them for simple indigestion. The researchers caution against this, suggesting simple antacids instead.

■ 20 Deaths Not Enough For Recall Of ADD/ADHD Drug

On February 10, 2005, the U.S. Food and Drug Administration (FDA) said that U.S. drug safety reports of 20 deaths linked to the attention deficit drug Adderall XR are not enough to remove the drug from the market.

Health Canada banned sales of the drug the previous day. Their decision was based on a review of adverse event reports released by the producer of the drug, Shire Pharmaceuticals Group of Basingstoke, England.

Robert Temple, director of medical policy for the FDA said “the cases are not convincing evidence the drug is clearly responsible for these deaths.” He went on to say that while the FDA is deciding whether to conduct its own study of Adderall XR, the drug will continue to be available in the U.S., its biggest market.

U.S. House and Senate committees have been studying drug safety since the painkiller Vioxx was removed from the market after it was tied to heart risks and antidepressants were linked to an increased risk of suicide in children.

In a letter to FDA chairman Lester Crawford, Iowa Senator Charles Grassley contends that the FDA may be slow to act on Adderall “because there was concern that FDA could not handle another ‘drug safety crisis.’” Calls to the FDA for comment were not immediately returned.

Adderall already carries a “black box warning”, the strongest the FDA requires. It warns that amphetamines “have a high potential for abuse” and they “should be prescribed or dispensed sparingly.”

Michigan Representative Bart Stupak questioned the FDA’s ability to inform people about drug dangers. “If you’re going to keep this thing on the market,” he said, “have a signed informed-consent for the patient, and make it mandatory.”

■ Drug Complaints Reach Record High

USA Today reports on March 13, 2005 that the number of adverse drug events (ADEs) reported to the U.S. Food and Drug Administration (FDA) reached an all-time high in 2004.

There were approximately 422,500 ADE reports received by the FDA from pharmaceutical companies, health professionals and patients. This is a 14% increase over the 370,887 reports in 2003.

While the FDA requires the manufacturer to file ADE reports, doctor's and nurse's reports are voluntary, leading government officials to believe that the reported events represent only a portion of the actual number.

Paul Seligman, director of the FDA's Office of Pharmacoepidemiology and Statistical Sciences blames the increase in ADEs on the fact that there are more drugs on the market and use has increased. "Clearly," he said, "when you have more products on the market, you're likely to have more side effects."

Prescription sales cost Americans more than \$235 billion in 2004, a record that beat the 1995 volume by more than 300%.

Ritalin Use Linked To Chromosomal Changes

On February 24, 2005, the editors of the journal *Cancer Letters* released an early, online version of their journal. It advises us of a study at the University of Texas Medical Branch at Galveston that found that every one of 12 children treated for ADD/ADHD with methylphenidate, the active ingredient in Ritalin, experienced a threefold increase in levels of chromosome abnormalities of the type typically associated with increased risks of cancer and other damaging health effects.

The researchers were startled to note that all of the children experienced the chromosome damage only three months after taking the drug.

The researchers went on to say that to their knowledge, this is the first study done examining the link between methylphenidate and its potential chromosome-damaging effects.

They decided to do the study because even though methylphenidate has been approved for use in humans for more than 50 years, “there are surprisingly few studies” in either humans or animals “on the potential for serious side effects,” such as chromosome damage and cancer.

In the new study, researchers drew blood from children diagnosed with ADD/ADHD before taking methylphenidate in order to get a baseline level of chromosomal structure. Three months after they began taking normal therapeutic doses of the drug, all 12 children in the study had blood taken again.

“It was pretty surprising that all of the children taking methylphenidate showed an increase in chromosome abnormalities in a relatively short period of time,” said lead researcher Randa El-Zein, M.D., Ph.D. Most of the damage found was chromosome breaks “and a higher frequency of [chromosome] aberrations is reported to be associated with an increased risk of cancer down the line.”

While this does not mean that the children will get cancer, it does expose them to an additional risk factor.

Methylphenidate is the most widely used class of amphetamine-like drugs used to treat ADD/ADHD. Methylphenidate use skyrocketed by more than 500% between 1991 and 1999.

■ Safety Of Over-The-Counter Drugs Questioned

The Associated Press reports on a study presented to the April 18, 2005 conference of the American Association for Cancer Research. The study found that people who take over-the-counter pain relievers such as Advil, Motrin and Aleve for at least six months had twice the risk of dying of a heart attack or stroke if they smoked as well.

The study adds to the growing body of information that shows heart problems can develop from use of the whole family of non-steroidal anti-inflammatory drugs known collectively as NSAIDs.

The recently banned cox-2 inhibitors Vioxx and Bextra belong to the same family of drugs and doctors have been switching patients over to the over-the-counter drugs in the belief that they were safer alternatives.

Researcher Dr. Andrew Dannenberg of Cornell University says, “to the best of our knowledge, these are the first data to support [the FDA requiring drug manufacturers to put] a box warning on NSAIDs, not just cox-2s.”

Lead researcher Dr. Jon Sudbo of the Norwegian Radium Hospital in Oslo advised smokers, “If you think you need them use them, but you have to be careful.”

Commentary: No specific mention was made of what he meant by “be careful.” We hope he was suggesting that they avoid both smoking and using NSAIDs.

■ Combining Medicines Makes It Difficult To Predict Adverse Drug Effects

The May 1, 2005 issue of the Journal of Psychiatric Practice reports that patients who take more than one medication rarely were taking the same combination of drugs as other people. Understandably, this makes it difficult for doctors to monitor and predict dangerous drug interactions.

The practice of mixing medicines increased with age, especially among patients taking anti-depressants. More than one-third of patients taking anti-depressants were taking at least 8 other medications.

In his assessment of the finding, Dr. Sheldon Preskorn, professor and chairman of the Department of Psychiatry at the University of Kansas School of Medicine warned that since doctors do not have a complete enough clinical knowledge of all the combined effects of the drugs they prescribe, the result is an increase in the number of adverse drug reactions.

■ AMA refuses to support ban on drug ads

The Associated Press reports on June 21, 2005 that at their annual meeting, the American Medical Association has refused to support a ban on “Ask your doctor about...” direct-to-consumer drug ads, despite the fact that some doctors have raised concerns about the heavy marketing of dangerous painkillers and antidepressants.

The concerned doctors worry that the ads encourage patients to seek expensive, risky drugs they may not need while those doctors who are against the ban feel it would violate the drug makers’ right to free speech.

Commentary: Given the fact that AMA policy makers also adopted a report supporting the use of antidepressants in children, despite the increase in associated suicidal tendencies, we are not optimistic that the concern for the welfare of patients will override the concern for the welfare of drug companies’ freedom of speech rights and resulting financial benefits.

■ Prescription drug prices increase by 5.5% in first half of 2005

The August 2, 2005 issue of the Wall Street Journal reports that prescription drug prices increased by 5.5% in the first half of 2005, similar to the price increases for the same period in 2004.

Some analysts have been predicting that drug manufacturers would increase prices at a higher pace before January 1, 2006 when Medicare prescription drug benefits begin.

The 5.5% increase more than doubled the 2.5% rate of general inflation for the first half of 2005.



NSAIDs More Dangerous Than Previously Thought

The September 1, 2005 issue of the American Heart Association journal Hypertension reports that regular use of the Non Steroidal Anti-Inflammatory Drugs (NSAIDs) acetaminophen (Tylenol) and ibuprofen (Advil) have been linked to an increase in blood pressure.

While high doses of both drugs have long been associated with liver and kidney damage, this study found double the risk of high blood pressure in women who regularly took as little as one extra-strength Tylenol or its equivalent a day. The researchers say this study raises new concerns about the dangers of the over-the-counter (OTC) painkillers.

The study was conducted at Brigham and Women's Hospital in Boston, MA. Painkiller use in 5123 women was tracked for three years through the use of detailed questionnaires. None of the women had high blood pressure when the study began.

Older women (51 to 77 years) who took 500 mg of acetaminophen every day had a 93 percent increased risk of developing hypertension compared to non-users. The younger group of women (34 to 53 years) had a 99 percent increased risk.

The researchers also went so far as to say that regular use of NSAIDs could be a contributing factor in the increase in hypertension in the U.S.

Lead researcher Dr. John Forman, of the Harvard Medical School said that if the study had lasted longer, they may have found that even lower doses of acetaminophen may be associated with high blood pressure. "We should avoid the belief that all OTC medications are safe, when, in fact, they are not."