

HEALTH AND STRESS

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HEALTH NEWS: ACCURATE OR ADVERTISING HYPE?

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Patients who are bombarded with TV ads for allegedly breakthrough drugs may think the message is educational when it is primarily promotional. Physicians who rely on scientific studies (often obtained from drug companies) are also apt to be confused by conflicting claims. These influences have recently been on a collision course with doctors, despite personal reservations, increasingly prescribing medications that their patients are clamoring for.

Only the United States and New Zealand allow the direct advertising of prescription drugs to the public. It has obviously been profitable for U.S. pharmaceutical companies since spending for TV and media advertisements directed to the public skyrocketed during the past decade to \$2.5 billion in 2001. A recent survey of primary care physicians confirmed that 12%

of patients had requested prescription drugs and that almost half were for directly advertised pharmaceuticals.

In most cases physicians prescribed the requested medicines even though they may have been ambivalent about the selection. While it might not have been their first choice, the drug had been approved as being effective and safe for that indication. It would also have been difficult to deny it when patients are repeatedly urged to "ask your doctor if Celebrex (Vioxx, Viagra, Lipitor) is right for you?" Many come armed with printouts from the drug's web site to which they have been referred. Some clamor for Celebrex while others vote for Vioxx, but is there any significant difference between the two? The same holds true for statins, another cash cow for companies who must continually compete for a larger share of this lucrative market.

There are fears that if doctors dole out drugs based on a more appealing TV ad the appropriateness of prescriptions could suffer. Medical journals are opposed to this practice because drug advertisements are a major source of revenue and the budget for this would surely shrink. Physicians are also concerned since it not only undermines their authority but also promises to reduce the lavish perks from drug companies that often influence their prescribing habits.

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A battle is shaping up between these and other interests competing for pharmaceutical company advertising and research dollars. However, since it is the bottom line that matters, direct consumer advertising looks like it will come out on top.

The Explosion Of Junk Science

Physicians may also have difficulty in evaluating the research results published in professional journals. This is especially true when they are released to wire services and the media by vested interests and deal with a promising new drug to cure cancer, prevent heart attacks or offer hope for some difficult to treat disorder. These are heralded as the latest medical breakthrough when in fact they are frequently reports of animal studies that have been hyped to imply benefits in patients that are purely speculative and not justified. While researchers may not make these claims, **companies are adept at crafting releases that send a powerful message designed to increase the price of their stock** with minimum mention about the clinical significance of the study.

There are often apparently reliable animal research or large population surveys showing that a disease can be caused by a lack of some nutritional supplement. In many instances, the administration of such substances seems to be effective in preventing or treating diseases. Such claims are often strongly disputed and later found to have been erroneous or exaggerated for commercial reasons especially with respect to vitamins and herbals

Many studies fall under the heading of "junk science", a term that refers to distorted analysis of the data or faulty experimental design in order to obtain results that would not be supported by qualified scientific studies. While not necessarily deliberate, these practices are often utilized to further a special agenda by certain groups, including:

- The **MEDIA** use junk science to create sensational headlines and programming. Some members of the media also use junk science to advance their own and their advertisers' social and political agendas.

- **PERSONAL INJURY LAWYERS** use junk science to bamboozle juries into awarding huge verdicts. Large verdicts may then be used to extort even greater sums from deep-pocket corporations who fear future jury verdicts will use this as a precedent.
- **SOCIAL ACTIVISTS** like the "food police", environmental extremists and gun control advocates often use junk science to achieve their own social and political goals.
- **GOVERNMENT REGULATORS** often use junk science to expand their authority and/or to increase their budgets.
- **BUSINESSES** use junk science to denigrate competitors or to make false claims about their own products and services.
- **POLITICIANS** frequently use junk science to curry favor with special interest groups or to appear as being "politically correct".
- **SCIENTISTS** usually use junk science for academic advancement, to obtain funding for research or to achieve fame and fortune through other pathways.
- **INDIVIDUALS** who are ill (real or imagined) tend to use junk science to blame others for causing their problems.

The situation is often worsened when several of the above combine to use a junk science report to further certain goals. Unfortunately, **prominent and trusted newscasters often use and emphasize such material for its sensational content in order to draw attention to their program, thus unwittingly increasing its credibility.**

Should You Take It Or Not?

Medical therapies and recommendations are constantly changing. Physicians who have been in practice for several decades inevitably discover that what was dogma when they started out is often not only discarded but replaced by practices that are the direct opposite of what they were taught.

During my internship and residency training, heart attack patients were routinely placed in an oxygen tent on complete bed

rest for a week. This was followed by a week of modified bed rest and sitting in a chair with another week or more of progressive ambulation. Hospitalization for a month was not unusual. Patients with uncomplicated infarcts are now urged to sit up the next day and are often home in a week or ten days.

Diverticulitis patients used to be warned to stick to a strict low residue diet and avoid any roughage to prevent particles from getting trapped in the gut and causing inflammation. For the past twenty years the advice has been to adhere to a high fiber diet, which is the exact opposite. The most recent recommendation is to go back on a low residue diet if there is a flare-up but resume the high fiber regimen after symptoms have subsided for a few days.

A chest X-ray used to be a routine part of every annual adult physical examination and was mandatory for all hospital admissions. Many authorities felt that this was not cost effective and resulted in unnecessary and possibly dangerous exposure to radiation for millions. The hospital requirement was removed in 1979 and most physicians no longer include chest X-rays in yearly physicals unless there is some specific indication. **According to the National Cancer Institute, chest X-ray screening is not indicated for smokers unless they have symptoms and may do more harm than good.** Their 20-year study found that frequent screening resulted in unnecessary surgery and an actual increase in lung cancer death rates.

Recommendations that women over 40 get mammograms every year or two have also been recently challenged by a large study showing no reduction in breast cancer deaths and an increase in unnecessary breast surgery.

The current constant barrage of medical research reports can also be contradictory. Taking a baby aspirin tablet of 81 mg. daily is widely recommended as a safe and effective way to prevent heart attacks. TV commercials urge people to chew a tablet immediately if they experience chest distress that might suggest an impending coronary. The fact is that all long term studies show that taking aspirin following a heart attack does not

reduce mortality rates and actually increases the incidence of sudden death.

Nor is prophylactic use of aspirin as safe as generally assumed. Low dose aspirin use may account for more than 30% of all major gastrointestinal hemorrhage in senior citizens and poses an increased risk of renal failure. One study showed that taking aspirin for ten or more years was associated with a 44% increase in disabling posterior subcapsular cataract formation. A recent review in the *British Medical Journal* concluded that **daily low dose aspirin to prevent heart attacks is no longer recommended for healthy people.**

The National Research Council recently raised daily calcium requirements 50 percent in children, teens and postmenopausal females as a safeguard to prevent osteoporosis and fractures. There is also evidence that calcium can prevent or reduce elevated blood pressure and cholesterol levels and reduces the risk of colon cancer. An article in the September 15 issue of *The Lancet* was entitled: "Cure of lifelong fatigue by calcium supplementation."

However, a study in the September issue of the *American Journal of Clinical Nutrition* that followed over 20,000 physicians for 11 years found that those with increased calcium intake, especially from dairy products, were 34 percent more likely to develop prostate cancer! People who form calcium stones were routinely told to avoid dairy products and high calcium foods but recent research reveals that **dairy products actually help to prevent calcium stones.** On the other hand, studies show that taking calcium supplements to prevent osteoporosis increases the likelihood of stone formation. So, are calcium supplements good for some people but bad for others?

The Pros And Cons Of Coffee And Tea

The risks and benefits of coffee, tea and caffeine consumption are even more controversial and confusing than calcium. The public has repeatedly been warned and most people believe that too much coffee and caffeine can cause cardiovascular problems like hypertension, rhythm disturbances and heart attacks. Pregnant women are told to limit coffee since it has been associated with low birth weight

However, most studies suggest that drinking up to 5 cups of coffee daily does not pose any health hazards and some suggest surprising benefits. One from the U.K. found that the more coffee subjects drank, up to about five cups a day, the higher their average scores on various tests of cognition, including a memory quiz that involved recalling items from a list of foods. Elderly subjects seemed to benefit the most. Those who drank four to six cups a day had scores about 8 percent higher than decaffeinated coffee controls.

Other studies show that regular coffee drinking reduces risk for gallstones and Parkinson's disease. It is not clear whether these effects are due to caffeine concentrations, which can vary considerably depending on source and preparation. Dark-roasted beans contain more caffeine than light-roasted varieties; caffeine in an eight-ounce cup of regular coffee can range from 150 to 263 mg. depending on whether it is percolated or drip, compared to 76 to 110 mg. for instant coffee and 30 to 50 mg. for a demi-tasse of espresso.

While coffee and caffeine are often perceived as potentially harmful, tea, which also contains caffeine, is promoted as providing varied health benefits. Starbucks patrons and other coffee drinkers are often surprised to learn that **next to water, tea is actually the most consumed beverage in the U.S.** Most people drink coffee because of its stimulating effects but tea seems to offer something for everybody. As William Gladstone, Queen Victoria's Prime Minister, wrote: **"If you are cold, tea will warm you; If you are too heated, it will cool you; If you are depressed, it will cheer you; If you are excited, it will calm you."**

Although tea contains more caffeine/oz. than coffee when in its dry form, it has only 1/2 to 1/3 as much compared to brewed coffee in the same size cup depending on the type of tea (black, green or oolong) and duration and manner of brewing. All teas come from the Camellia sinensis plant but black tea has the most caffeine and green tea the least. Herbal teas or infusions like chamomile and peppermint are made from other botanicals that do not contain any caffeine.

Over 90 percent of all tea consumed in the U.S. is black tea but green tea, which is a staple in the Orient, is gaining ground. It has long been used in Chinese medicine to treat headache, general body aches, poor digestion, depression, and to increase longevity. It is being promoted here because of studies linking green tea drinking with reduced risk of cancer and heart attacks and claims that, in addition to protective antioxidants, it contains chemicals with anti-inflammatory effects that could benefit patients with arthritis and colitis, prevent brain damage following stroke and even promote weight loss.

One study of 680 men and women who drank one or more cups of tea a day reported a 44% reduction in heart attacks compared to non-tea drinkers. Another study of 800 male senior citizens showed a 58% reduction in heart attacks in those who consumed over three cups of tea daily. In contrast, a seven-year study of 11,000 Scotch men and women aged 40-59 found that coffee drinkers were less likely to suffer heart disease than tea drinkers. **The greater the amount of coffee consumed (up to 21 cups/day) the lower the chances of coronary disease or death. Surprisingly, the results for tea drinkers, which topped out at 36 cups/day, proved to be just the opposite.**

The latest salvos in this debate were a September 4 news release stating that drinking one cup of coffee could increase arterial stiffness for at least two hours and increase risk for stroke. The very next day, another report claimed that coffee had a higher content of the antioxidants that prevent strokes and heart attacks than tea. What should you conclude?

Prosit! Nazdarovya! A Votre Santé?

Trying to balance the benefits and risks of alcohol consumption can also be confusing because of conflicting and contradictory claims. At one end of the scale some teetotalers are calling for a return to prohibition. At the other, wine manufacturers are petitioning regulatory agencies to allow them to advertise directly to consumers, as well as on labels, that their products promote cardiovascular health. The FDA

already allows certain cereal companies to make such statements and supportive evidence for moderate alcohol and especially wine intake is even more compelling.

Alcohol also has a much lengthier history since it is probably man's oldest medicine. Drinking alcohol was observed by the ancient Greeks to be safer than drinking water and alcohol was used as an antiseptic from the 5th century BC until antibiotics were discovered. The Bible refers to "*Wine that maketh glad the heart of man*" and over 2000 years ago, Pliny the Elder wrote "*In vino sanitas*" (in wine there is health). Louis Pasteur said "*Wine is the most healthful and most hygienic of beverages*", giving added meaning to toasting "To your health".

Studies show that moderate alcohol intake is associated with a decreased incidence of heart attacks and coronary events regardless of whether it is in the form of hard liquor, wine or beer. However, it is difficult to be precise about what constitutes "moderate alcohol intake" since a glass of wine or beer or a "shot" of distilled spirits can vary in size and concentration. A half-pint of beer in a glass is 284 ml. but bottles and cans can hold up to 500 ml. A small bottle of light beer contains 8 grams of alcohol but a slightly larger bottle of strong beer has well over four times as much.

A glass of wine in a pub holds 175 ml. but other popular wineglasses hold twice as much. Thus, a glass of thin Rhine wine at a restaurant might contain 8 grams of alcohol compared to the 40 grams in a generous glass of Pouilly Fuissé poured by your host at a party, a five-fold difference. In the U.S. standard drinks contain 12 ounces of beer, or 5 ounces of wine or 1.5 ounces of 80 proof distilled spirits, but this differs in other countries.

The concentration of alcohol can be confusing because it is expressed as percent ethanol by volume in Europe but as percent of proof in the United States, where 100% proof is 50% v/v (volume per volume). In England 100% proof is 57% v/v and concentrations can also differ widely among seemingly similar drinks. The strengths of beers range from 3.4% to 9% v/v; white wine from 8% to 13% v/v; and spirits from 37.5% v/v for mass market vodka compared to 57.3% v/v for cask strength.

Regardless of how much you drink, the relation between dose and resulting blood concentrations also differs. This depends on the rates of absorption and elimination and the volume of distribution or ratio between total amount in the body and blood concentration. While the volume of distribution can be estimated from age, sex, height, and weight, there are other influences that are more difficult to measure. As a result, it can be hard to predict the dose that is likely to raise blood alcohol concentrations above the statutory limit for driving, which ranges from 20 to 80 mg/100 ml in different countries.

To further complicate things, alcohol affects each of us differently. For some, it has a sedative effect. For others, modest amounts can suppress inhibitions that turn quiet introverts into loquacious exhibitionists. Higher concentrations impair cerebellar function causing slurred speech, poor hand-eye coordination and unsteadiness. These effects become progressively more pronounced as concentrations rise over 35 mg/100 ml and can be demonstrated in drivers who are intoxicated. At concentrations over 200 mg/100 ml there is progressive depression of sensation, consciousness and ultimately basic brainstem functions.

The apparent effects of identical blood levels also vary greatly and individuals who are legally drunk can act quite sober. In some cases 500 mg/100 ml can be lethal but higher concentrations may cause few signs in others. **One lady remained alert and responded to questions with a blood level of 1510 mg/100 ml (20 times the UK legal limit).** It is essential to consider all these variables when evaluating the benefits of "moderate" alcohol intake.

Should You Drink? How Much? What?

Considering the preceding, why do so many researchers and physicians extol the health benefits of regular alcohol consumption? Critics believe that personal bias may play a role, since it is often claimed that the doctor's definition of an alcoholic is "anyone who drinks more than I do". As for their colleagues who don't imbibe, they are apt to quote Ben Franklin's observation that "there are more old drunkards than old doctors."

Prohibitionists claim that every drink of alcohol kills off a few brain cells that will never be replaced. The mental status of some sots seems to support this and the adverse effects of excess alcohol are quite clear. In addition to destroying the liver there is often progressive damage to brain tissue and alcoholic dementia is an established medical diagnosis.

On the other hand, Franklin, Winston Churchill and others who sipped more than their share of brandies on a daily basis for decades seem to have thrived on booze. It all seems to depend on how long you have been drinking and how much you regularly consume. An 18-year study of Japanese-American men found a positive association between moderate intake among middle-aged men and subsequent cognitive performance in later life. Both nondrinkers and heavy drinkers scored much worse on mental function tests. A recent report in *The Lancet* (of more than 5000 people aged 55 and older without dementia who were followed for six years) also concluded that **those who regularly had one to three drinks daily were 42 percent less likely to develop Alzheimer's than nondrinkers.**

Although alcoholism has been linked to abuses and absenteeism, one study showed that employees who were moderate drinkers were better adjusted and less likely to miss work or to be late than nondrinkers. In another study, 10,000 men and women were examined and had psychological evaluations at age 23. When reevaluated at age 33, moderate drinkers had experienced much fewer emotional and general health complaints compared to nondrinkers. Periodic ten-year follow-ups are planned to see if this pattern persists.

Most recently alcohol has been reported to help prevent senile macular degeneration. However, the big push comes from numerous studies confirming that "moderate" consumption promotes cardiovascular health. Alcohol has now been found to be useful in treating heart failure even though excesses can cause cardiomyopathy and congestive failure. Similarly, while diabetics are routinely told to limit or avoid alcohol because it elevates blood sugar, a study in *The American Journal*

of Cardiology reported that men with Type 2 diabetes who consumed moderate amounts had a significantly reduced risk of both heart attacks and fatal coronary events. The authors also cited evidence that alcohol consumption may reverse reduced insulin sensitivity, an important contributor to Type 2 diabetes.

Possible explanations for the benefits of alcohol in cardiovascular disease include; preventing hypertension; inhibiting the formation of blood clots that can cause heart attacks and strokes; blocking free radical damage; boosting levels of HDL good cholesterol; and stimulating reverse cholesterol transport, the process by which cholesterol is removed from the walls of coronary and other arteries and carried to the liver for disposal.

While these effects can be demonstrated for any form of alcohol (as indicated in prior Newsletters) red wine has phenolic antioxidants that allegedly provide additional cardiac and other benefits. White wine makers say their products are just as good and grape juice manufacturers have also jumped on the bandwagon claiming the same and safer results. Other studies sponsored by breweries suggest that beer is not only superior to wine but is a much more cost effective way of getting alcohol as well as other nutrients

We are soon likely to be bombarded with conflicting claims about different heart healthy alcoholic products. However, **there is no solid evidence that any type of wine or beer is really superior.** In addition, what represents the optimal daily intake for each of us or how "moderate" should be defined may vary for each of us. It might be one or two drinks for some but several more for others.

The Vioxx-Celebrex Cox-2 Controversy

There is probably nothing that better illustrates the power as well as the problems associated with direct consumer advertising than the current Cox-2 commercial campaign being waged on television. It's hard to escape Olympic gold medallists Dorothy Hamill and Bruce Jenner praising the virtues of Vioxx or the clever Celebrex ads promising relief for all sorts of arthritic complaints. Prior to the Olympics, both

sports stars were featured on popular talk shows like CNN's Larry King Live, with Hamill telling the audience that Vioxx makes her feel "as if I've been given a new life it's — been amazing". This was followed up with a commercial featuring a female osteoarthritis patient telling her doctor that she had heard Vioxx mentioned on a television chat show and ending by urging that patients should ask their own doctor if they can take Vioxx.

The market for analgesics is estimated at ten billion dollars a year, which almost guarantees that there will inevitably be corruption, greed and underhanded practices to get a bigger piece of the pie. Vioxx (\$161 million) and Celebrex (\$79 million) were among the top six drugs advertised directly to the public in 2000, which may help to explain their hefty price of \$3.00/pill. The FDA has sent several official letters objecting to Celebrex promotional materials. One commercial that attracted their attention was entitled "City Park" and depicted people with arthritis in a park setting performing various activities — Tai Chi, rowing a small boat, riding on a scooter while a voice-over sang, "Celebrate, celebrate — do what you like to do."

The FDA said the 60-second advertisement was "misleading because the totality of the images, the music and the audio statements that you present overstate the efficacy for Celebrex". The images, the soundtrack, and both written and audio statements "collectively suggest that Celebrex is more effective than has been demonstrated by substantial evidence". The company has also been criticized for claims implying that Celebrex could be used with coumadin and aspirin and was superior to other NSAID's and Vioxx.

These issues were addressed in the February 14 issue of *The New England Journal of Medicine* with a review article showing that **television direct consumer advertising for prescription drugs increased more than 7-fold from \$.22 billion in 1996 to \$ \$1.57 billion in 2000. Although the tab for all direct advertising to consumers was \$2.47 billion in 2000, more than \$10 billion was spent on attracting physicians through journal advertising, free samples and possibly other perks provided by sales representatives.**

In his accompanying editorial, Jeffrey Drazen, editor-in-chief described the issue as "emotionally and economically charged". As a result, he had invited commentary from Sidney Wolfe, on behalf of consumers, and Alan Holmer, to represent drug companies, to answer the question, "Is this progress in empowering patients or just a way to make money?"

Wolfe complained that **"Confusion arises when commercially driven promotional information is represented as educational."** His main contention was that direct advertising attempts to evoke emotional responses and that any educational benefit is incidental to the main goal of increasing sales. He also criticized other practices, noting "The education of patients or physicians is too important to be left to the pharmaceutical industry."

Holmer argued that direct advertising bolstered the health system by promoting doctor-patient discussion and protected the patient from other financial incentives that might influence a physician's treatment decision. He cited surveys showing that if patients demand a given drug they receive something else about half the time and that over 80% of advertising dollars are targeted to physicians. He also believes that doctors underuse some drugs, like the statins, and that direct consumer advertising may correct this as well as remind patients to comply with prescriptions.

Direct advertising will undoubtedly increase and it is essential not to confuse this with medical advice that is in the best interests of patients. Unfortunately, our only safeguard is the already understaffed and underfunded FDA, which has other priorities.

Spin-Doctors' Strategies, Scams And Subverting The Statistics

Like other spin-doctors, those working for drug companies are successful primarily because they are able to persuade people that their message is truthful. There are several ways to accomplish this. A common ploy is to get audiences to accept what they say by

telling them what they already know, or want to hear. Another is to have some trusted celebrity provide a glowing testimonial allegedly based on personal experience. Once confidence has been gained, it is much easier to insert manipulated, dubious or downright misinformation. Public relations personnel have applied these principles and practices since the master of the art, Niccolo Machiavelli, invented them. The most convincing strategy is being able to provide supportive statistical data, especially in the form of double blind studies. Everyone knows that "figures don't lie."

On the other hand, it's equally true that liars can figure. The modern pharmaceutical industry was essentially established in 1899 when aspirin derived from willow tree bark was found to provide prompt pain relief. However, it also promoted ulcers, as did subsequent non-steroidal anti-inflammatory drugs (NSAID's) like Motrin and Naprosyn. All reduce pain and inflammation by inhibiting an enzyme called cyclooxygenase and researchers struggled for years to find a compound that could relieve pain without causing ulcers. In 1989, it was postulated there might be two forms of cyclooxygenase: one found mostly in the gut and a second primarily in the periphery where most pain originates, called cyclooxygenase-2, or Cox-2. The first drug that allegedly blocked only Cox-2 was Celebrex, approved in 1999, followed a few months later by Vioxx. These were marketed so successfully that

both outsold Viagra in the first 12 months after their introduction. Although gastroscopic studies showed fewer visible stomach lesions, this did not prove there would be fewer ulcers so the FDA mandated the same label warning that appeared on NSAID's with respect to this complication. In an attempt to have this label warning removed, a widely advertised Celebrex study was published in the *Journal of the American Medical Association* that provided strong support. Additional data on both drugs was also presented to the FDA.

The petition backfired when the reviewers realized that the company had only published the first six months of their yearlong study. **When all the data were reviewed, Cox-2 drugs were no better at avoiding ulcers than generic pills costing pennies! Worst of all, it appeared that they were associated with twice as many heart attacks and coronary events compared to other NSAID's.** Independent cardiologists who reviewed this described it as "a major health problem" and have asked the FDA to note this on the warning label. In addition, another study showed that when taken to relieve pain due to a sprain, Cox-2 drugs significantly delayed the ability of ligaments to heal, whereas older NSAID's actually speeded up the healing process.

All of this is likely to be forgotten in a future flurry of promotional advertising hype. In addition newer Cox-2 drugs are already available. To find out about their claims — stay tuned!

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