

## **Fraud in Drug Research**

Corporate Crime in the Pharmaceutical Industry is a book by Dr John Braithwaite where he describes many examples of corporate crime in the pharmaceutical industry. Dr Braithwaite's revealing study is based on extensive international research and includes interviews with 131 senior executives of pharmaceutical companies in the United States, the United Kingdom, Australia, Mexico and Guatemala. *"Data fabrication is so widespread", says Dr Braithwaite, "that it is called 'making' in the Japanese pharmaceutical industry, 'graphiting' or 'dry labelling' in the United States."* He further states: *"Pharmaceutical companies face great temptations to mislead health authorities about the safety of their products. It is a make or break industry - many companies get virtually all their profits from just two or three therapeutic winners. Most of the data that the Australian Drug Evaluation Committee relies upon in deciding questions of safety and efficacy is data from other countries, particularly the US. Inquiries into scientific fraud in the US have shown there is a substantial problem of fraud in safety testing of drugs in the US, just as has been documented in Japan."*

**In his book Dr. Braithwaite reports that between 1977 and 1980 the United States Food and Drug Administration Visits to "alternative" health care providers rise 47% in 7 years.**

In the November 11<sup>th</sup>, 1998 issue of the Journal of the American Medical Association, (JAMA), David Eisenberg, M.D. published his long awaited follow up study on the use of "Alternative Medicine" in the United States. Several years earlier, Dr. Eisenberg published his initial study that rocked the medical community with his findings of how many people were actually going to what he termed "Alternative Providers".

From inside the medical profession, any other health care profession was known as an alternative. However, the numbers from the Eisenberg study quickly showed that chiropractic and other non-medical forms of health care are not "alternative" in the public's eye.

This new study, conducted in 1997, illustrated some astounding facts and figures.

- Americans spent \$27 billion out-of-pocket for alternative therapies in 1997.
- Four out of 10 people used alternative healthcare in 1997.
- Visits to alternative health care providers (mostly chiropractors) increased by almost 50% from 1990.
- The number of visits to alternative health care providers (629 million) exceeded visits to medical providers (only 386 million) visits in 1997 alone.
- Less than 40% of patients tell their medical doctors that they seek alternative therapies.

Researchers also found that 42% of the alternative care was for existing illness while 58% was used for prevention and wellness. These numbers look good for the chiropractic profession, which has built its health care delivery future on wellness.

*"Many people initially enter the chiropractor's office for a health problem. But many then stay there for the wellness benefits chiropractic has to offer",* says Robert Braile, D.C. President of the International Chiropractor Association.

## Study shows more people using "alternative" health care.

According to an article in the May 20 issue of The Journal of the American Medical Association (JAMA), more people are turning toward what JAMA terms "Alternative Medicine". Traditionally, chiropractors do not use the term "Alternative Medicine" when referring to the profession of chiropractic, since chiropractic is a drugless natural approach to health. But it is interesting to note how the medical profession views chiropractic and other health approaches they term "alternative".

The article says, *"Research both in the United States and abroad suggests that significant numbers of people are involved with various forms of alternative medicine. However, the reasons for such use are, at present, poorly understood. Along with **being more educated** and reporting poorer health status, the majority of alternative medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine but largely because they find these health care alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life."* According to John A. Astin, Ph.D., a researcher at Stanford University's School of Medicine in Palo Alto, California who surveyed 1,035 randomly selected people, *"Alternative medicine users tend to hold a philosophical orientation toward health that can be described as holistic and are more likely to have had some type of transformational experience that changed their world view in a significant way."*

discovered 62 doctors who had submitted manipulated or downright falsified clinical data. A separate study conducted by the FDA has revealed that one in five doctors investigated, who carry out field research of new drugs, had invented the data they sent to the drug companies, and pocketed the fees.

## Hospital Admissions Due to Doctor Caused Diseases Still High

From the Archives of Internal Medicine January 11<sup>th</sup> 1999, comes the headline, *"Despite high-tech medicine, diseases from medical treatment still significant cause of Intensive Care Unit admissions."* Doctor caused diseases are referred to "iatrogenic" diseases, and according to the article are a major cause of ICU admissions. Surprisingly, the problem has not changed since 1980. This suggests that even with alleged advances in medical technology the results for the patient were just as risky.

In another study in 1994, French researchers reviewed 623 patients admitted to ICU. Of those 10.9% were determined to be iatrogenic disease admissions. A majority of those were drug related and next in incidence were medical acts. Of these 13 died and the costs for all were \$688,470.00 in the studied cases. This study concluded that 51% of these were preventable.

Groups outside medicine have claimed that the numbers are much higher than medically reported and that the costs of iatrogenic diseases overall run into the hundreds of billions.

### Medicines That Commonly Harm Children

According to a Canadian study reported at the annual meeting of the American Academy of Allergy Asthma and Immunology, antibiotics and vaccines are the medicines that

most often cause adverse reactions in children. "There is relatively little pediatric data on adverse reactions, which can range from rashes to potentially fatal hypersensitivity". More than 1,500 Canadian cases were reviewed between 1985 and 1995 by Sandra R. Knowles and her colleagues at the Sunnybrook Health Sciences Center in Toronto. In all, 1,800 drugs were implicated in this study.

The leading problems were caused from: Amoxicillin/Ampicillin with a 24% reaction rate, vaccines in general with a 19% reaction rate, Trimethoprim came in with 8%, Sulfamethoxazole (sulfa drug) at 8%, Erythromycin - was at 3%, and Penicillin also at 3% reaction rate.

### **Adverse Drug Reactions Kill Over 100,000 In Hospitals Annually.**

This statistic is according to a recent article appearing in The Journal of American Medical Association. The author, Bruce Pomeranz, M.D., Ph.D., reviewed 39 different studies of adverse drug reactions in hospitals, and came up with some alarming conclusions. According to Pomeranz's research, he estimates that 2,216,000 hospital patients experienced serious adverse drug reactions (side effects) and 106,000 died from these reactions in 1994 alone. This astounding number accounted for 4.6% of *all* recorded deaths in the U.S. in that year. This makes drug reaction deaths the fourth leading cause of death in the country.

Adverse drug reactions as defined in this study were not small problems. These reactions were only included in the study if they required hospitalization, prolonged hospitalization, caused permanent disability or resulted in death.

Probably the most surprising finding of the study is that the rate of adverse drug reactions has not changed over the last 32 years. This suggests that despite an increase in cost and technology, the drug related care given in hospitals has not improved its safety level or its death rate in over three decades.

### **Prescription Drug Use On Rise**

In a related story, it seems that the threat of serious adverse drug reactions has not decreased the usage. In an article in the January 7, 1999 New England Journal of Medicine, it was reported that, "*Prescription drugs are the fastest-growing component of personal health expenditures amounting to \$78.9 billion in 1997.*" This rate of consumption is growing at an ever-increasing rate. In 1995 spending for prescriptions grew by 10.6 percent, in 1996 it grew by 13.2 percent and in 1997 it continued the climb growing by 14.1 percent.

The Federal Office of Personnel Management blames the increase on several factors. They cite broader insurance coverage of prescription drugs, growth in the number of drugs dispensed, more approvals of more expensive drugs by the Food and Drug Administration, and direct advertising of pharmaceutical products to consumers.

It wasn't too many years ago that they government forced the removal of cigarette advertising off television because of the health hazard. Considering the numbers, maybe its time to take a long hard look at the drug ads.

## **Over 106,000 Drug Related Deaths per Year**

The USA Today, Wednesday, April 15, 1998, page 1 finds a report on a recent article in the Journal of the American Medical Association addressing the subject of unintended side-effects of properly prescribed, properly administered medications. The authors estimate deaths from such events to exceed 106,000 deaths per year. To offer some perspective on this number--57,000 US soldiers died in the Vietnam War! Keep in mind, this number represents a completely different data set than Lucian Leape's estimate of 180,000 hospital based iatrogenic deaths per year. Those deaths are associated with errors, not side effects of properly prescribed and administered medications.

## **Over-the-counter ulcer medications linked to 16,500 deaths last year.**

In a December 1, 1998 story in the USA Today comes a story whose first sentence reads, *"About 16,500 Americans died last year from bleeding stomach ulcers brought on by common medications known as non-steroidal anti-inflammatory drugs, (NSAIDs)".* For a comparison this was close to the number of deaths resulting from AIDS. Unfortunately for the victims bleeding stomach ulcers have no warning symptoms in 80% of the people who have them. Only 20% experience some symptoms such as abdominal pain or heartburn.

Some of the more common drugs that fit into this category are Motrin and Aleve as well as the prescription drug Relafen. While these drugs are some of the most common of their type on the market it seems the public does not recognize the danger. A recent national poll done by Roper Starch Worldwide showed that 75% of the people taking NSAIDs were either unaware, or unconcerned about the possible deadly effects. Unfortunately, those most at risk are those most likely to use the drug, including people with severe arthritis and those over 65 years of age.

What this article doesn't mention is that a growing number of these individuals are seeking non-drug solutions such as chiropractic. This approach eliminates the chance of serious complications and adverse effects from these drugs.

## **Drugs not answer for Health & Wellness**

In a feature article in the November 16, 1998 issue of the U.S. News & World Report, it was noted that drug usage is actually going up in the US. Drug companies are certainly not crying the blues because of the trend toward health and wellness. In fact they have shifted their emphasis in sales. More and more drug companies are pushing drug usage not only for treatment but for usage before any problems arise as a preventative. This mass marketing shift has paid off as prescriptions for drugs went up 400 million from 1993 to 1997, up to an astounding 2.4 billion prescriptions being dispensed in 1997!

This new approach markets drugs with the promise to prevent such things as heart attacks, cancer, osteoporosis, diabetes and impotence. Unfortunately, many of the drugs being marketed for healthy people to take as a preventative, were only tested on sick people. The article in U.S. News & World Report used the example of two drugs called Tambocor and Enkaid. These two drugs were routinely prescribed for years as a preventative of sudden heart attacks. Only after some time did a study of these drugs on healthy people reveal that the drug greatly increased the chance of sudden heart attacks when taken by healthy people. It is estimated that 50,000 people as a result of

these drugs may have died before a halt was instituted. The bottom line is that "better living through chemistry" may exact a terrible price.

### **Annual Death Rate Due to Medications Continues to Rise!**

The following is reprinted from a recent article in the Boston Globe entitled, "Medication-Error Deaths Soar in U.S.," by Richard A. Knox,

*"The incidence of death due to medication errors increased dramatically between 1983 and 1993 and shows no signs of abating, new research on the subject shows. Over the ten-year period in question, patient deaths due to medication leaped 260 percent overall, and 850 percent among persons receiving outpatient care. And these figures may represent "only the tip of the iceberg," according to David Phillips of U.C. at San Diego, who points out that many prescription error deaths aren't listed as such on death certificates. Death certificates from the ten-year period provided the raw data on which the findings are based.*

*Researchers involved in the study say that the increase in medication fatalities cannot be attributed simply to patients taking larger-than-prescribed doses of medication. Their comments are borne out by the fact that the sharpest increase in such deaths among outpatients occurred with the use of anesthetics. Anesthesia drugs are not self-administered, suggesting that the increase in outpatient care as part of overall cost-cutting measures among hospitals may be part of the problem. The study found that deaths due to anesthetics among outpatients increased 400 percent compared to anesthesia deaths occurring in hospitals. Surprisingly, the steep rise in medication deaths is not due to an increase in prescriptions, which during the ten-year period rose 39 percent, compared to the 260 percent increase in medication error deaths.*

*Compounding the problem, according to research conducted by Harvard University, is the fact that medication errors commonly occur even in the nation's highest-ranking teaching hospitals. The findings clearly indicate the need for a close reexamination of modern medicine's over-reliance on drug use and symptom care as primary approaches for treating illness."*

### **Drug Companies Marketing Aimed Directly At Consumers**

A revolution in drug marketing and sales has occurred. In the early 1990's a little known drug was introduced to doctors for blood pressure. The drug's name was minoxidil. This drug, as all others before it, was only advertised in professional journals to medical doctors. Then, when someone noticed that this drug actually stimulated some hair growth, things changed. This little known drug was soon known as Rogaine. And the marketing was not aimed solely at doctors, but directly to the consumer. This changed the prescription drug game totally. Prior to that most consumers only saw over-the-counter drug advertisements. Now, the drug companies are advertising the prescription products right to the consumer.

The results are predictable. An article in the January 7, 1999, New England Journal of Medicine reports, "Prescription drugs are the fastest-growing component of personal health expenditures amounting to \$78.9 billion in 1997". This rate of consumption is growing at an ever-increasing rate. In 1995, spending for prescriptions grew by 10.6 percent. In 1996, it grew by 13.2 percent, and in 1997, it continued the climb growing by 14.1 percent."

Based on the drug industries own figures, the top ten drug makers have spent 44% more money to advertise prescription drugs to consumers than to doctors. Claritin, a well advertised drug is one example where the makers spent over \$70 million in 1998 advertising to doctors, while spending \$183 million advertising to consumers.

The government, seeing the potential for abuse, has started to create guidelines for prescription drug advertisements. These guidelines are designed to inform consumers of major side effects of the advertised drugs, and give ways to get further information on their various reactions. Considering that children learn a lot about our world from television, we must consider if the drug companies message of "better living through drugs" is one we want our future generations to repeatedly see.

(Fortunately Chiropractic is a drugless health profession that deals with correcting causes and not just treating effects.)

Routine Use of Antibiotics for Otitis Media (Earaches) Unproven

### **"No Compelling Evidence"**

"After addressing these four questions, we conclude that existing research offers no compelling evidence that children with acute otitis media routinely given antimicrobials have a shorter duration of symptoms, fewer recurrences, or better long-term outcomes than those who do not receive them."

## **Chiropractic and Bedwetting**

Several recent studies have shown the benefits of chiropractic care for children suffering from "Nocturnal Enuresis" more commonly known as bedwetting. Several studies published in the Journal of Manipulative and Physiological Therapeutics showed marked improvement in children with this problem over children who did not receive chiropractic care.

In one study 171 children suffering with enuresis averaged 7 nights of bed wetting per week prior to the study. After the children were given some initial chiropractic care the average child reduced the number of "wet" nights to 4 nights per week. A full 25% of the children receiving chiropractic showed a 50% reduction in wet nights. In addition, only 1% of the children were considered "dry" prior to the study and prior to receiving chiropractic care. After the study 15% of the children were then considered "dry".

In another study, 46 primary enuretic children were studied. Of this group 31 were placed under chiropractic care while 15 were in the control group and did not receive any chiropractic care. The results of this study showed a 17.9% decrease in wet nights for the chiropractic group. Over the same period of time no change was noted for the control group who did not receive any chiropractic care.

**Amazingly, improvement in some of the studies was shown to be immediate after the first adjustment and remain stable thereafter****Childhood Asthma and Chiropractic**

It is estimated that up to 15 million people suffer from asthma. Of those, 14.8 million are children under the age of 18. In 1993 alone, there were 198,000 hospitalizations for asthma. In that same sample year, 342 people under the age of 25 died due to this

problem. In money terms, the direct cost of managing a patient with severe asthma has been estimated at more than \$18,000 per year.

The following statistics about asthma come from the Better Health & Medical Network.

- Asthma has increased 46% from 1982-1993 with an 80% growth in children under 18.
- In the 5-17 age group, asthma causes an annual loss of more than 10 million school days per year.
- Asthma accounts for more childhood hospitalizations than any other childhood disease.
- Children with asthma spend approximately 7.3 million days per year restricted to bed rest.
- In 1990, there were 7.1 million physician visits for asthma.
- Health care costs for asthma were estimated to be \$6.2 billion, which is almost 1% of the total US health care costs.
- More than 5,200 Americans died from asthma in 1991.

Recent articles in publications such as "The American Chiropractor", and "Today's Chiropractic" describe strong links between people who suffer from these conditions and nerve interference from subluxation. Subluxations are when bones in the spine pressure or irritate nerves causing abnormal nerve function. An article appearing in the Journal of Vertebral Subluxation Research Vol. 1 No. 4, also demonstrated the positive effects of chiropractic care on 81 children with asthma.

According to Richard Pistolese, research assistant for the International Chiropractic Pediatric Association, *"Based upon information currently available, chiropractic care represents a safe non-pharmacological health care approach, that may be associated with a decrease in asthma-related impairment, reduced respiratory effort, and a decrease incidence of asthma attacks."* Pistolese goes further to say, *"The correction of vertebral subluxation is a non-invasive procedure, which could reduce or eliminate the need for medication, and potentially ease the severity of the asthmatic condition."*

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### **Chiropractic Helps in Prevention of Recurring Ear Infections.**

In the October 1998 issue of the Ladies Home Journal appeared an article entitled, *"Chiropractic Adjustments for Chronic Ear Infections."* This article reviewed several studies showing the effectiveness of chiropractic care for preventing re-occurring ear infections known as Otitis Media or OM.

According to the article, reoccurring ear infections account for over 35% of all pediatrician visits in the United States. Sometimes these infections are due to bacteria and sometimes these are due to a virus. The most common medical care for this situation has been antibiotics, even though antibiotics have no effect on viruses. While the article mentions that the antibiotic may be effective in an acute bacterial infection, they do nothing to stop repeat infections. Research and statistics is now showing that repeated use of antibiotics is contributing to future infections by creating drug-resistant infections. The surgical approach has met with little long term results as the "tubes" placed in children's ears often come out and usually require a child to be put under general anesthesia to do the surgery.

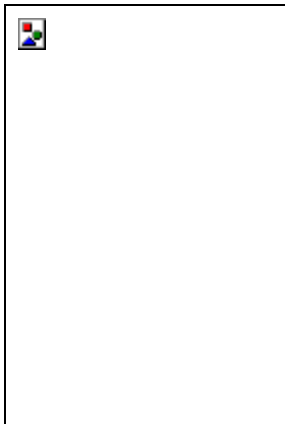
The article in the Ladies Home Journal states, "*Chiropractic care is thought to prevent recurrent infections by correcting misalignments (called subluxations) and allowing normal fluid drainage from the middle ear.*" What the article took special note of was that 6 months after the chiropractic care was given to the children in the study, 80 percent had not suffered a recurrence of ear infections.

In closing the article did make a profound statement. They made a recommendation to parents on this subject. "*If your child is between ear infections and his doctor suggests ear-tube surgery, ask if you can try chiropractic treatment first.*" While we agree with that sentiment, we suggest you not wait for a period between episodes, and you don't have to "ask" permission from any other doctor to seek chiropractic care. As the sneaker company said, "just do it!"

### **"Chiropractic Care of 401 Children with Otitis Media: A Pilot Study"**

*Found in the March 1998 edition of Alternative Therapies and authored by Fallon and Edelman.*

(Conclusion) "There is a strong correlation between chiropractic adjustment and the resolution of otitis media for the children in this study, which can serve as a starting point from which those in the chiropractic profession can examine their role."



### **Scientific Medical Journal Reports on Nerve Pressure**

Spine magazine, a well-respected medical journal, published a study from Texas Woman's University in their January 15, 1999, issue. The report appears to verify what chiropractors have been saying for over 100 years. Although the study was complex, researchers tested something known as the "H-Reflex" to measure the effect of pressure on spinal nerves. What they found was that pressure on spinal nerves, (chiropractors have referred to this as **subluxation**), causes measurable changes in the H-reflex. This shows a change in nerve function due to pressure on nerves.

Although this study is good, it only serves to verify prior chiropractic research on **subluxation**. In two separate studies, it was shown that as little as 10 to 45 millimeters of mercury pressure, (the weight of a coin on your hand), placed on the nerve root was enough to change the nerve impulses by 40 to 60 percent in minutes. This kind of research is good, but it only serves to verify what chiropractic patients have known for over 100 years. Chiropractic Works!

