THE PHARMACEUTICAL DRUG RACKET
The Pharmaceutical Drug Racket - Part One

THE ROCKETING COST OF HEALTH CARE

“Medical ‘ignorance’ is costing us billions” reads a heading in the Daily Telegraph Mirror of February 24, 1991, over an article:

“Poor funding and a lack of knowledge about preventive medicine has led to a $2 billion blow-out in public health spending, experts say.

“These costs rose nationally from $26 billion to $28 billion [in one year] - an average of $1700 per person - according to figures to be released by the Australian Institute of Health.”

Writing in an article in the Sunday Telegraph on October 27, 1991, the Federal Minister for Community Services and Health, Brian Howe, expresses his concern:

“Health care costs a huge amount of money: $1796 for every man, woman and child....

“The trouble is that if Medicare becomes too costly, this country can’t afford to keep footing the bill: which means that individual Australians will have to foot the bill instead or go without the necessary health care.

“I believe the Federal Government should continue to pay much of the health care cost, but my concern has been that one day the Government will have to say it can no longer afford Medicare.

“Medicare is getting increasingly costly. Total government expenditure on Medicare benefits rose by 70 per cent between 1984-85 and 1989-90, and by another 11.2 per cent in 1990-91.

“Before the changes in the Budget were announced, Medicare benefits were expected to rise by another 28 per cent in real terms over the three years to 1994-95: that’s approximately $1.3 billion....” (1)

The rocketing cost of health care in Australia is not unique to this country, but is typical of all industrial nations. In his book Limits to Medicine (1979), prominent medical historian, Ivan Illich, writes:

“During the past twenty years, while the price index in the United States has risen by about 74 per cent, the cost of medical care has escalated by 330 per cent. Between 1950 and 1971 public expenditure for health insurance increased tenfold, private insurance benefits increased eightfold, [2a] and direct out-of-pocket payments about threefold. [2b] In overall expenditures other countries such as France [2c] and Germany [2d] kept abreast of the United States. In all industrial nations - Atlantic, Scandinavian, or East European - the growth rate of the health sector has advanced faster than that of the GNP [gross national product]. [2e] Even discounting inflation, federal health outlays increased by more than 40 per cent between 1969 and 1974 [2f].” (2)

ARE WE CONSUMING TOO MANY DRUGS?

As was reported in the Bulletin, March 24, 1992, one of the fastest-growing components of Australia’s costly health bill is the pharmaceutical drug trade, which accounts for $2 billion a year for prescription drugs. The Bulletin article reveals that “Australians are on a drug binge, consuming twice as many antibiotics per capita as Sweden and far more than the US and Britain”. (3) The situation in the United States and Britain sixteen years ago was bad enough for Illich to write:

“In the United States, the volume of the drug business has grown by a factor of 100 during the current century: [4a] 20,000 tons of aspirin are consumed per year, almost 225 tablets per person. [4b] In England, every tenth night of sleep is induced by a hypnotic drug and 19 per cent of women and 9 per cent of men take a prescribed tranquillizer during any one year. [4c] In the United States, central-nervous-system agents are the fastest-growing sector of the pharmaceutical market, now making up 31 per cent of total sales. [4d] Dependence on prescribed tranquillizers has risen by 290 per cent since 1962, a period during which the per capita consumption of liquor rose by only 23 per cent and the estimated consumption of illegal opiates by about 50 per cent [4e].” (4)

At the time of Illich writing this (1976), it is estimated that 50 to 80 per cent of adults in the United States and
In his book Confessions of a Medical Heretic (1980), famed medical writer and paediatrician, Dr Robert Mendelsohn, accused doctors of having “seeded the entire population with these powerful drugs”. Mendelsohn further states that “Every year, from 8 to 10 million Americans go to the doctor when they have a cold. About ninety-five percent of them come away with a prescription - half of which are for antibiotics.”

A recent report by the National Health Strategy (1992) has pointed out that 160 million prescriptions are being dispensed from Australian pharmacies every year, and an estimated further 20 million from hospital pharmacies. This figure represents a 640 per cent increase since 1949, during which 280,719 prescriptions were dispensed.

As reported in Clinical Pharmacology and Therapeutics (1976), a study in a large country town in Australia has revealed that people who reported no illness took as many drugs as those who reported a chronic and acute illness. The authors noted that “the rate of increase in drug usage at around 25 per cent per year can only be explained by increased drug usage of both prescription and OTC [over-the-counter] drugs by the majority of the population”. At the time of the report Australians were consuming half the number of prescription drugs compared to today.

Recent figures of how many OTC or non-prescription drugs consumed by Australians are difficult to obtain. Industry sources are reluctant to divulge this information. However, a study by the Health Commission of NSW in 1979 that stated that “at present Australia has one of the leading rates of per capita consumption of analgesics in the world”, quoted 1973 figures for sales of OTC medications at $166 million.

It is estimated that in 1991 $1.4 billion was spent on OTC medications, which when added to the $2 billion spent on prescription drugs, totals a staggering $3.4 billion.

DRUGS IN THE FOOD WE EAT

Apart from the vast number of drugs taken directly, people are also unknowingly consuming large amounts of drugs and other chemical substances indirectly from the food they eat. Most food industries rely on chemical substances from soil to supermarket and the animal products industries are by far the most excessive users of these substances. The avalanche of drug and chemical usage by these industries occurred with the shift in production methods from free-range farming to factory and feedlot farming in the last 20 to 30 years.

Over 15 years ago, there were more than 1,000 drug products and as many chemicals in use by the livestock and poultry producers in the United States. Also, more than 40 per cent of the antibiotics and other antibacterials produced every year in the US were used as animal feed additives and for other animal purposes. Almost 100 per cent of poultry, 90 per cent of pigs and veal calves, and 60 per cent of cattle have regular amounts of antibacterials added to their feed. Seventy-five per cent of hogs have their feed supplemented with sulphur drugs and almost 70 per cent of US beef is from cattle fed on hormones to promote growth.

The amount of drugs and chemical substances used on farm animals in the industrialised nations is enormous.

THE CONSEQUENCES

As could be expected, one result of the vast over-consumption of drugs is the astronomical profits generated by the drug industry. Since the beginning of the sixties, drug industry profits (as a percentage of sales and company net worth) have surpassed all other manufacturing industries listed on the Stock Exchange.

Another result is the inevitable deterioration of public health. According to the Food and Drug Administration (FDA), 1.5 million Americans were hospitalised in 1978 as a consequence of taking drugs and some 30 per cent of all hospitalised people are further damaged by their treatments. Every year, an estimated 140,000 Americans are killed because of drug taking and one in seven hospital beds is taken up by patients suffering from adverse drug reactions.

A report by the General Accounting Office in the United States revealed that 51.5 per cent of all drugs introduced between 1976 and 1985 had to be relabelled because of serious adverse reactions found after the marketing of these drugs. These included heart, liver and kidney failure, foetal toxicity and birth defects, severe
blood disorders, respiratory arrest, seizures and blindness. The changes to the labelling either restricted a drug’s use or added major warnings. (23)

**HOW COMMON ARE DRUG ADVERSE REACTIONS?**

According to the Adverse Drug Reactions Advisory Committee (ADRAC), the official federal government body responsible for monitoring the safety of drugs already in use: “There is a dearth [scarcity] of published information on the medical and economic importance of adverse drug reactions in Australia.” (24) However, a recent study (1991), cited by the National Health Strategy report on drug use, claims that in 1987-88 there were between 30,000 and 40,000 hospital admissions in Australia because of drug taking and also that adverse drug reactions (ADRs) would have been a major factor for between 700 to 900 deaths a year. (25)

There are some who are highly critical of the official estimation of the extent of drug reactions within communities. Dr Julian Gold, head of the National Health Surveillance Unit of the Commonwealth Institute of Health, whose job as a medical epidemiologist is to collate information on the total health environment, estimates that up to 40 per cent of all patients in Australia may actually be victims of doctor induced (iatrogenic) illnesses. (26) A 40 per cent figure has also been estimated for the United Kingdom. (27) Generally of this amount, half are from drug reactions. (28)

**UNDER-REPORTING OF DRUG REACTIONS**

Many drug reactions go unnoticed. In Controversies in Therapeutics (1980), Dr Leighton Cluff comments:

“National Health statistics do not reflect the magnitude of the problem of drug-induced diseases. A death certificate may indicate that a person died of renal failure, but it may not state that the disease was caused by a drug.” (29)

According to a US Senate Select Committee, hundreds of victims of the drug chloramphenicol died undiagnosed in the United States. (30)

Dr Leighton Cluff further states: “Physicians are currently not required to report observed cases of drug-induced diseases to a centralized registry.” (31)

In Australia, the reporting by doctors of adverse reactions is voluntary. Postage-paid forms are provided to doctors who are asked to report adverse reactions to ADRAC. Due to complacency, ignorance, and perhaps guilt that their prescribed treatment has caused harm, most doctors fail to fill in these forms.

Even when doctors are willing to report ADRs, there are significant problems that add to the under-reporting of drug reactions. ADRs can sometimes be difficult to identify and Dr Judith Jones, Director of the Division of Drug Experience at the FDA in the United States, has listed three factors that inhibit detection:

1. Difficulty in distinguishing the reaction from underlying diseases, or negative placebo effects.
2. Many ADRs have a silent nature and if not specifically looked for, they may not be found. For example, kidney and liver damage.
3. In multi-drug regimes it is difficult to identify the particular drug which is causing the suspected reaction. (32)

Only 5 to 10 per cent of actual cases are believed to be reported to ADRAC. (33) In the United Kingdom, which has a similar reporting system to ours, only 1 to 10 per cent of cases are revealed. (34) The inadequacy of the reporting system in the UK was demonstrated by the fact that only about a dozen of the 3,500 deaths, later linked with isoprenaline aerosol inhalers during the 1960’s, were actually reported by doctors at the time. (35)

Because most adverse reactions to drugs go unreported, the official estimates must be only the tip of the iceberg.

**WHO IS TO BLAME FOR DRUG DAMAGES?**

Not only do health officials grossly underestimate the extent of drug reactions, they also try to convince the unwary public that drug-related illnesses are largely due to inappropriate drug usage. Officials try to place the
onus on consumers and prescribing doctors, and reassure the public that problems rarely occur if drugs are used as prescribed. To protect the drug industry from blame, officials purposely ignore the fact that most drugs are harmful; even if used “appropriately”.

**EPIDEMIC IATROGENESIS**

On doctor or hospital induced illnesses, a once active member of the Doctors’ Reform Society and author of the book Medicine Out Of Control (1979), Dr Richard Taylor, writes:

“In fact, because of the increasing complexity of medical technology and the increase in the variety of chemicals available for treatment, iatrogenic disease is on the increase....

“Unfortunately iatrogenic diseases may be self-perpetuating. Many iatrogenic complications require specific treatment, thus exposing the patient to the possibility of yet another iatrogenic disease. A patient may even experience an iatrogenic complication from a diagnostic test which was required to diagnose the initial iatrogenic disease. The situation in which an iatrogenic disease provokes a second iatrogenic complication could be termed second level iatrogenesis. In a hospital setting these situations are not uncommon. It is even possible for third and fourth level iatrogenesis to occur.” (36)

Dr Beaty and Dr Petersdorf write in the Annals of Internal Medicine (1966):

“...it should be pointed out that iatrogenic problems are cumulative, and in an effort to extricate himself from complications of diagnosis and therapy, the physician may compound the problem by having to employ manoeuvres that are in themselves risky.” (37)

Dr Taylor further explains:

“Every drug administered, every diagnostic test performed, every operative procedure entered into, carries with it the risk of iatrogenic complications. The more medication, tests and operations a patient experiences, the more likely he or she is to develop an iatrogenic disease. Because of the present fragmentation of medical care with each sub-specialist looking after his own particular organ system, the total risk to which the patient is exposed is often forgotten.” (38)

Taylor, Beaty and Petersdorf are not alone in their criticisms of allopathic medicine, also known as “modern medicine”. More and more physicians and other medical professionals are becoming increasingly disillusioned with their own profession. Allopathic medicine has become more of a band-aid treatment. In their attempts to “patch-up” symptoms of illnesses, doctors are known to use poisonous chemical-based drugs, radical surgical operations and dangerous radiation, which often cause more harm than the original problem.

Apart from introducing more illnesses, allopathic “treatments” mask symptoms of the underlying causes of the illness, which inevitably make it more difficult to detect and treat, and thereby causing it to become more chronic.

Allopathic medicine can be useful and sometimes life-saving for emergency situations (for example, car accidents), yet its harmfulness and ineffectiveness cannot be over-stated.

A prominent critic of allopathic medicine has been the late Dr Robert Mendelsohn, who exposed much corruption in American medicine. Dr Mendelsohn published the following best-selling books: Confessions of a Medical Heretic (39) (1980), Mal(e) Practice: How Doctors Manipulate Women (40) (1982), and How to Raise a Healthy Child...In Spite of Your Doctor (41) (1987). These books are highly recommended.

In Limits to Medicine, Ivan Illich warns:

“The pain, dysfunction, disability, and anguish resulting from technical medical intervention now rival the morbidity due to traffic and industrial accidents and even war-related activities, and make the impact of medicine one of the most rapidly spreading epidemics of our time.” (42)

**DOCTORS STRIKE: DEATH-RATE DROPS**

With the above in mind, it is not surprising that during a one month physicians’ strike in Israel in 1973, the national death-rate reached the lowest ever. According to statistics by the Jerusalem Burial Society, the number
of funerals dropped by almost half. (43)

Identical circumstances occurred in 1976 in Bogota, the capital city of Columbia; where there, the doctors went on strike for 52 days and as pointed out by the National Catholic Reporter; during that time the death rate fell by 35 per cent. This was confirmed by the National Morticians Association of Columbia. (44)

Again in California a few years later, and in the United Kingdom in 1978 identical events have occurred. (45)

THE SMALL ROLE OF MEDICINE IN MORTALITY

It is important to understand that the vast majority of people are born healthy and, if not tampered with, are “equipped” to remain healthy throughout life. We seldom require intervention with illnesses because the body, as well as the mind, is usually able to defend and heal itself against disease and injury. Only infrequently do we require assistance.

Medical intervention is the least important of the four factors that determine the state of health. The Centers for Disease Control analysed data on the ten leading causes of death in the United States, and determined that lifestyle was by far the most important factor (51%), followed by environment (20%), biologic inheritance (19%), and lastly medical intervention (10%). (46)

According to a classic analysis by Professor Thomas McKeown of Birmingham University, medicine played a very small role in extending the average lifespan in Britain over the past few centuries, the major benefit to people having been improvements in nutrition and public sanitation. (47,48)

Researchers, John McKinlay and Sonja McKinlay came to similar conclusions. They showed that medical intervention only accounted for between 1 and 3.5 per cent of the increase in the average lifespan in the United States since 1900. (49)

The above statistics prove that health depends primarily on prevention, through hygiene and proper nutrition.

In the few instances, when therapy of any sort is warranted, it must deal with the whole person (the holistic approach), treating the actual cause rather than attempting to isolate and suppress symptoms. Allopathic medicine fails in comparison to the holistic approach, and in many instances damages the patient even more than the illness it intends to treat.

Natural medicines and therapies, such as herbalism, homoeopathy, naturopathy, osteopathy and acupuncture, to name a few, work on the holistic approach, and are generally far superior in safety and efficacy than allopathic “treatments”.

DRUG COMPANIES BRIBING DOCTORS

A major reason why health care is in such a shambles is that the medical establishment has allowed itself to be bought off by the pharmaceutical industry, whose prime motive is profit. In the book Dissent in Medicine - Nine Doctors Speak Out (1985), Dr Alan Levin writes:

“Health care in the United States has become a megabillion-dollar business. It is responsible for over 12 percent of the gross national product. Revenues from the health industry, which currently exceed $360 billion a year, are second only to those of the defense industry. True profits are much higher. [In 1991 the US had spent $750 billion on health care. It has been estimated that by the year 2000, annual health care costs in the US will have increased to at least 1.5 trillion dollars. (50)] It is not difficult, then, to see why this industry is so appealing to corporate investors. Many industrialists determined to profit from health-care products have encountered one major obstacle: Practicing physicians remain the primary distributors of health care products. Physicians, who have traditionally existed as independent entrepreneurs do not fit easily into the corporate mind-set. If corporations did not have control over their distributors (the physicians) they would not be able to guarantee profits to their stockholders.... Thus, we need not wonder why senior executives of major health care-oriented corporations have decided to woo physicians into their camps.

“Pharmaceutical companies have curried the favor of practicing physicians for many years... As the cost of development and marketing of pharmaceuticals increased [during the 1960’s], the drug companies efforts to attract the allegiance of practicing physicians intensified.
“Not only did drug company operation costs increase markedly, but the rewards of the marketplace rose tremendously.... The increase in revenues brought competition which led to a nationwide increase in drug advertising. Advertisements in medical journals and public magazines were popularized by carefully controlled news releases associated with ‘medical breakthroughs.’

“These advertising efforts, which began with gifts to practicing doctors and medical students, have become a massive campaign to mold the attitudes, thoughts, and policies of practicing physicians. Drug companies hire detail men to visit physicians’ offices and to distribute drug samples. They describe the indications for these drugs and attempt to persuade physicians to use their products. Like any other salesman, they denigrate the products of their competitors while glossing over the shortcomings of their own.

Detail men have no formal medical or pharmacological training and are not regulated by any state or federal agencies. Despite their lack of training, these salesmen have been very effective. Their sales campaigns have been so successful within the United States that the average physician today has virtually been trained by the drug detail man. This practice has led to widespread overuse of drugs by both physicians in their everyday practice and the lay public.... With the exception of heroin and cocaine, 85 percent of all drugs currently abused in the streets are manufactured by ‘ethical’ drug companies.... Gross sales forecasts from these ‘ethical’ drug companies deliberately include profits made from illicit sales to drug peddlers.

“The drug industry woos young medical students by offering them gifts, free trips to ‘conferences’, and free ‘educational material.’ [Emphasis added.] (51)

A double page article titled “$200m ‘bribe’ to lure our doctors”, appearing in the Sun Herald (August 18, 1992), reported that:

“Drug companies spend a massive $200 million every year in Australia on marketing their products... That represents almost $10,000 a year spent attempting to woo each of Australia’s 21,000 ‘actively prescribing’ GPs, according to Dr Ken Harvey from La Trobe University.”

The article cited Theo van Lieshout, secretary of the NSW Doctors’ Reform Society as saying that 50 per cent of drugs on the market did not exist 10 years ago - and doctors had not learned about them in medical school. Busy physicians therefore rely mainly on drug company sales staff to tell them about new medications.

As reported in the Bulletin (March 24, 1991), Dr Ken Harvey stated: “The students concede concern. The problem is, after five years out in practice, with six drug reps a week coming in, they have gone away from prescribing sensibly and by scientific name to prescribing the brand promoted by the last rep who walked in.”

(52)

UNIVERSITY SCIENTISTS - THE WILLING PAWNS

Drug companies employ many means in bribing doctors and medical institutions. Dr Levin writes:

“Young physicians are offered research grants by drug companies. Medical schools are given large sums of money for clinical trials and basic pharmaceutical research. Drug companies regularly host lavish dinner and cocktail parties for groups of physicians. They provide funding for the establishment of hospital buildings, medical school buildings, and ‘independent’ research institutes.

“The pharmaceutical industry has purposefully moved to develop an enormous amount of influence within medical teaching institutions. This move was greatly facilitated by several factors. The first was the economic recession, which caused a marked constriction in federal funding for research programs. Academic scientists lacked funding for pet research projects. The second was the tremendous interest that academic scientists held in biotechnology, the stock market, and the possibility of becoming millionaires overnight. The third is the fact that academic physicians tend to lack real clinical experience. In the university, the physician is an expert in esoteric disease, end-stage disease, and animal models of human disease. He or she has little or no experience with the day-to-day needs of the chronically ill patient or the patient with very early symptoms of serious illness. As the academic physician does not depend upon the good will of the patient for his or her livelihood, the patient’s well-being becomes of minor consideration to him or her. All these factors make the academic physician a very poor judge of treatment efficacy and a willing pawn of health industrialists.
“Pharmaceutical companies, by enlisting the aid of influential academic physicians, have gained control of the practice of medicine in the United States. They now set the standards of practice by hiring investigators to perform studies which establish the efficacy of their products or impugn that of their competitors....

“Practicing physicians are intimidated into using treatment regimes which they know do not work. One glaring example is cancer chemotherapy....

“Your family doctor is no longer free to choose the treatment modality he or she feels is best for you, but must follow the dictates established by physicians whose motives and alliances are such that their decisions may not be in your best interests. [Emphasis added.]” (53)

Dr Alan Levin is an Adjunct Associate Professor of Immunology and Dermatology at the University of California. He is a Fellow of the American College of Emergency Physicians, the College of American Pathologists, and the American Society of Clinical Pathologists. Dr Levin is also a recipient of fellowships and awards from Harvard Medical School and other medical institutions, and was Director of various research laboratories.

Ivan Illich echoes Levin’s last comment: “The medical establishment has become a major threat to health. The disabling impact of professional control over medicine has reached the proportions of an epidemic.” (54)

THE DRUG STORY

How the pharmaceutical industry took control of the hospitals, universities, research and other institutions in the early part of this century is amply demonstrated by world-famous medical historian and author, Hans Ruesch, in his devastating expose: Naked Empress or The Great Medical Fraud (55) (1992). The book is an absolute must to read. Naked Empress exposes massive corruption and fraud in medicine, science, industries, governments, media, and various organisations. The importance of this book cannot be overstated.

In Naked Empress, Ruesch cited another important expose titled The Drug Story (56) (1949), by American investigative reporter, Morris A. Bealle. According to Bealle: “America’s largest and most ruthless industrial combine, the Rockefeller Empire” (which was built on Standard Oil Company) in the early part of this century became interested in the drug trade after making breath-taking profits from palming off bottled petroleum called Nujol as a supposed cure for cancer and later constipation.

In 1939 the Drug Trust was formed by an alliance of the world’s two greatest cartels in world history - the Rockefeller Empire and the German chemical company, I.G. Farbenindustrie (I.G. Farben). Drug profits from that time onwards curved upwards into gigantic proportions and by 1948 it became a 10 billion dollar a year industry. (57)

I.G. Farben’s unsavoury past is highlighted by the fact that during the Second World War it built and operated a massive chemical plant at Auschwitz using slave labour. Approximately 300,000 concentration-camp workers passed through I.G. Farben’s facilities at Auschwitz and at least 25,000 of them were worked to death. (58) Also, others were brutally killed in I.G. Farben’s drug testing programs. (59) Twelve of I.G. Farben’s top executives were sentenced to terms of imprisonment for slavery and mistreatment offences at the Nuremberg war crime trials. (60)

Hoechst and Bayer, the largest and third largest companies in world pharmaceutical sales respectively, are descended from I.G. Farben. In September 1955, Hoechst appointed Friedrich Jaehne, a convicted war criminal from the Nuremberg trials, as Chairman of its supervisory board. Also, a year later, Bayer appointed Fitz ter Meer, another convicted war criminal, as Chairman of its board. (61)

On the Rockefellers’ moves towards “influencing” medical colleges and public agencies in the United States, Bealle writes:

“The last annual report of the Rockefeller Foundation itemizes the gifts it has made to colleges and public agencies in the past 44 years [from 1948], and they total somewhat over half a billion dollars. These colleges, of course, teach their students all the drug lore the Rockefeller pharmaceutical houses want taught. Otherwise there would be no more gifts, just as there are no gifts to any of the 30 odd drugless colleges in the United States.” (62)
The Rockefellers did not restrict their “educational” activities to the US alone. In 1927 they formed the International Education Board which “donated” millions of dollars to foreign universities and politicos, with all the usual strings attached. (63)

As these huge amounts of money were being “donated” to drug-propagandising colleges, the Rockefeller interests were expanding world-wide. It was large enough 40 years ago for Bealle to state:

“It has long been demonstrated that the Rockefeller interests have created, built up and developed the most far reaching industrial empire ever conceived in the mind of man. Standard Oil is of course the foundation industry upon which all of the other industries have been built....

“The keystone of this mammoth industrial empire is the Chase National Bank with 27 branches in New York City and 21 in foreign countries [now renamed the Chase Manhattan Bank with over 200 branches in the US and abroad]. Not the least of its holdings are in the drug business. The Rockefellers own the largest drug manufacturing combine in the world, and use all of their other interests to bring pressure to increase the sale of drugs.” (64)

THE NOT-SO-INDEPENDENT MEDIA

Instrumental in Rockefellers’ moves towards making the world drug-dependent is their enormous influence on the media. Commenting on this, Ruesch explains:

“So the stage was set for the ‘education’ of the American public, with a view to turning them into a population of drug dependents, with the early help of the schools, then with direct advertising and, last but not least, the influence the advertising revenues had on the media.

“A compilation of the magazine Advertising Age showed that as far back as 1948 the larger companies spent for newspapers, radio and magazine advertising the sum total of $1,104,224,374, when the dollar was still worth a dollar. Of this staggering sum the interlocking Rockefeller-Morgan interests (gone over entirely to Rockefeller after Morgan’s death) controlled about 80 percent, and utilized it to manipulate public information on health and drug matters - then as now.

“Anybody who tries to get into the mass media independent news, contrary to the interests of the Drug Trust, will sooner or later run into an unbreakable wall....

“For big advertisers it is easy not only to plant into the media any news they wish to disseminate, but also to keep out the news they don’t want to get around. A survey in 1978 by the Columbia Journalism Review failed to find a single comprehensive article about the dangers of smoking in the previous seven years in any major magazine accepting cigarette advertising....

“Even the most independent newspapers are dependent on their press associations for their national news. And there is no reason for a news editor to suspect that a story coming over the wires of the Associated Press, the United Press or the International News Services is censored when it concerns health matters.

“Yet this is what happens constantly.” [Emphasis added.] (65)

Ruesch showed how the above-mentioned international media were taken over by the Drug Trust and he further explains:

“So this sews up the press associations of the Rockefeller Drug Trust, and accounts for the many fake stories of serums and medical cures and just-around-the-corner-breakthrough-to-cancer, which go out brazenly over its wires to all daily newspapers in America and abroad....

“Thus newspapers continue to be fed constantly with propaganda about drugs and their alleged value, although 1.5 million people landed in hospitals in 1978 because of medication side effects in the U.S. alone, and despite recurrent statements by intelligent and courageous medical men that most pharmaceutical items on sale are useless and/or harmful.” (66)

Among the many publications owned by the Rockefeller Drug Trust, there are: Fortune, Life, Time, Readers Digest and Newsweek magazines, and the Encyclopedia Britannica. These publications are constantly pushing
FOOD AND DRUG ADMINISTRATION - SERVING WHOM?

Leaving no stone unturned, Ruesch shows how the Drug Trust, in securing their drug interests, planted stooges into senior positions of colleges, universities, and government bodies. About the Food and Drug Administration, Ruesch charges:

“When a good law was enacted many years ago for protecting the American public from spoiled food and poisonous drugs, the Drug Trust lost little time to get its hooks into the government bureau that was charged with enforcing the law.” (67)

Ruesch cited Morris Bealle who wrote that the FDA “is used primarily for the perversion of justice by cracking down on all who endanger the profits of the Drug Trust”. (68) Ruesch further states:

“Apparently, the FDA doesn’t only wink at the violations of the Drug Trust whose servant it is (such as the mass deaths in the ginger jake and sulfathiozole cases), but it is particularly assiduous in putting out of business all competitors of the Drug Trust, like the vendors of natural therapeutic devices that improve the health of the public and thus decrease the profits of the Drug Trust....

“And the situation is practically identical in all the other industrialized countries, notably Great Britain, France and West Germany.” (69)

THE UNDECLARED WAR ON NATURAL MEDICINE

The Civil Abolitionist carried an article rightly titled “FDA: The American Gestapo Prosecutor or Persecutor?”, which reported that on May 6, 1992, the clinic of Jonathan Wright MD, a highly regarded nutrition specialist, was assailed by 22 armed men because the doctor had been treating his patients with safe natural substances that didn’t meet the FDA's approval. During the SWAT type attack the front door was kicked open, guns were pointed directly at staff and the shocked patients were herded into a room. Also patient records, equipment, business records and vitamin supplies were confiscated. At the time of the article, the FDA had not as yet filed charges against Dr Wright. (70)

During last year, similar actions have taken place against three manufacturers of vitamin supplements (Allergy Research, Thorne Research and Highland Laboratories). (71)

The Nexus magazine, reporting in their Aug.-Sept. 1992 issue, writes: “This undeclared war on ‘unconventional’ medicines has been followed up with the introduction of bills in Congress which are making it difficult, if not impossible, to obtain vitamins, minerals and herbs, and which legalise their search-and-seizure techniques.” It revealed that:

“There is a bill currently pending in the House called H.R. 3642 (written and sponsored by FDA allies Representative Henry A. Waxman, and Representative John Dingell) that would:

* Make vitamins, minerals and herbs unavailable except through prescription from Medical Doctors.
* Prevent food supplements from entering the country.
* Make it illegal for anyone to sell vitamins, mineral and herbs, with a fine of up to US$1 million for each violation, plus a $250,000 against the store.
* Permit the IRS to make collections.
* Permit the FDA not only to seize but to also destroy all vitamins, minerals and herbs found on the premises.
* Permit the FDA to inspect records, embargo and recall products, and assess civil penalties for ‘serious’ violations with any judicial review.

Nexus was recently contacted by an international businessman who mentioned that a bill identical in nature to the one above has been passed in the UK, that one similar was on the table in several European countries and Canada, and that one was being discussed for Australia.” (72)
In Australia, a repeal of Schedule 1, Exemptions of the Therapeutic Goods Act, scheduled for January 1994, would minimize access to natural therapy remedies by natural therapists and would threaten the existence of the natural therapy profession and manufacturers of natural therapy remedies. (73)

CORRUPT FDA OFFICIALS

Nexus reported that it is a matter of public record that the FDA indulges in the following practices:

* Many of the so-called “research grants” that the FDA receives are “donated” by the very drug companies they were supposed to be regulating.

* Mid- and upper-level FDA officials enjoy “revolving door” status when they leave the FDA, wherein they go to cushy, well-paying jobs in those very same drug companies they were supposed to have been regulating.

* Currently, 150 top FDA officials hold significant amounts of stock in the pharmaceutical companies they were supposed to be regulating. (74)

AMERICAN ‘MURDER’ ASSOCIATION

The AMA, once openly declared by Dr Richard Kunnes at an AMA convention that it shouldn’t be the acronym for American Medical Association but for American “Murder” Association, is, according to Morris Bealle, the front for the Drug Trust. (75) When the FDA has to put an independent operator out of business, they get the AMA to furnish quack doctors to testify that while often knowing nothing about the product involved, it is their considered opinion that it has no therapeutic value.

Bealle cited an example in which the AMA furnished ten medicos to testify in court that “vitamins are not necessary to the human body”, in order to close down an independent distributor of natural vitamins. (76)

J.W. Hodge, MD, of Niagara Falls, New York, writes about the AMA:

“The medical monopoly or medical trust, euphemistically called the American Medical Association, is not merely the meanest monopoly ever organized, but the most arrogant, dangerous and despotic organization which ever managed a free people in this or any other age. Any and all methods of healing the sick by means of safe, simple and natural remedies are sure to be assailed and denounced by the arrogant leaders of the AMA doctors’ trust as ‘fakes, frauds and humbugs.’ Every practitioner of the healing art who does not ally himself with the medical trust is denounced as a ‘dangerous quack’ and impostor by the predatory trust doctors. Every sanitarian who attempts to restore the sick to a state of health by natural means without resort to the knife or poisonous drugs, disease imparting serums, deadly toxins or vaccines, is at once pounced upon by these medical tyrants and fanatics, bitterly denounced, vilified and persecuted to the fullest extent.” (77)

It comes as no surprise that the Australian counterpart, the Australian Medical Association, in conjunction with the Royal College of General Practitioners, as reported in the Australian (July 21, 1992) are pushing for legislation that would cause medical doctors using natural therapies to lose Medicare status. This would mean that their patients would not be able to have bills rebated by Medicare. (78)

THE MASTERS OF GOVERNMENT

If to you it seems inconceivable that governments have allowed a ruthless industry to dictate health matters, consider what Woodrow Wilson stated during his first presidential campaign in 1912:

“The masters of the government of the United States are the combined capitalists and manufacturers of the United States. It is written over every intimate page of the record of Congress, it is written all through the history of conferences at the White House, that the suggestions of economic policy in this country have come from one source, not from many sources. The benevolent guardians, the kind-hearted trustees who have taken the troubles of government off our hands have become so conspicuous that almost anybody can write out a list of them... The big bankers, the big manufacturers, the big masters of commerce, the heads of railroad corporations... The government of the United States at present is a foster child of the special interests.” (79)
Writes Ruesch:

“Woodrow Wilson’s words have remained as true today as they were when he pronounced them from his campaign train. The American Presidents, unless they want to end up like John Kennedy, do not rule their country anymore than the official governments of the other so-called democracies, for the big boys in industry and finance have long since taken over that task.” (80)

Morris H. Rubin, Editor and Publisher of The Progressive, writes in an article in January 1977:

“Corporate power has become the dominant force in our society... All attempts to check the mounting power of the corporate giants have failed. Consider the two most important instruments forged by the progressive forces of the country in their crusade to curb the march of monopoly: the regulatory system and the antitrust program...

“The regulatory system lies in shambles, and the corporations which were intended to be regulated in the public interest now dominate these regulatory agencies. The betrayal of the public trust is virtually complete... The antitrust laws are virtually dead letters. It is clear from recent disclosures that the Antitrust Division of the Justice Department is almost immobilized because of deals made over its head and behind its back in the White House and other corridors of power...” (81)

“The oil lobby, perhaps the most powerful lobby on earth, is almost matched by hospital owners and doctors.” - President Carter, 1979. (82)

Incidently, in 1980, Exxon became America’s largest corporation. Exxon is the new name for the old Rockefeller Standard Oil Trust.

For a further insight on how the cartels have turned democracies into private oligarchies, the books Naked Empress by Hans Ruesch and None Dare Call It Conspiracy (83) (1971) by investigative journalist, Gary Allen, are highly recommended.

AUSTRALIA’S HEALTH SYSTEM UNDER THREAT FROM US CORPORATIONS

Because the Australian Government can no longer afford to fund our ailing public health care system, privatisation is inevitable. A major concern is that the ruthless US corporations will be the principal buyers. An article appearing in the Daily Telegraph Mirror (October 1, 1992), titled “U.S. Giants ‘Threat To Hospitals’”, reports:

“Huge American corporations soon will control Australia’s public hospitals forcing health care costs to double, a leading health expert claims.

“Dr Ron Williams says the public health care system is facing a bleak future because governments can no longer afford to fund it.

“And as they are forced to sell off hospitals to private interests, American corporations will step in and take over, leaving ordinary Australians unable to afford skyrocketing health care costs.

“'I see little but doom and gloom,’ says Dr Williams, who has spent 11 years researching the Australian and American health care systems.

“'I wish I could say that if we all pulled together we could avert the coming brutality... but today’s reality is that for the health industry, compassion will give way at an increasing rate to profit....

“'As public hospitals are sold to privates, and as nursing homes join national chains, as nurses move out of government employment on to contract, as individual doctors lose ever more control over their practices; no government will say that the processes it is promoting might lead to disaster.’” [Emphasis added.]


Disclaimer: This article is presented for educational purposes only and is not intended as a substitute for professional or medical advice. CAFMR disclaims all liability to any person arising directly or indirectly from the use of the information provided.
REFERENCES AND NOTES

16. Illich, op. cit., p. 36.
21. Calculated by comparing statistics provided in refs 7 & 8.
23. In 1973, $166 million was spent on OTC drugs (see ref. 11) and $240 million was spent on prescription drugs (Pharmacy Guild of Australia, Guild Digest, 1991, tables 27 & 31). From this it was calculated that in 1973 the cost of OTC was 69% of the cost of prescription drugs. If the rate of increase of OTC drugs is proportional to the rate of increase of prescription drugs, then it could be estimated that OTC drugs in 1991 would amount to 69% of $2 billion (cost of prescription drugs in 1991. See ref. 3), which equals to $1.4 billion.
24. In 1973, $240 million was spent on prescription drugs. If the rate of increase of OTC drugs is proportional to the rate of increase of prescription drugs, then it could be estimated that $1.4 billion.
25. See ref. 3.
26. Illich, op. cit., p. 79.
27. Hans Ruesch, Naked Empress or The Great Medical Fraud, CIVIS (Latin acronym for International Center of Scientific Information on Vivisection) Publications, POB 152, Via Motta 51, CH-6900 Massagno/Lugano, Switzerland, 1992, p. 12.
42. Illich, op. cit., p. 35.
44. ibid.
45. ibid.
52. See ref. 3.
54. Illich, op. cit., p. 11.
55. Hans Ruesch, Naked Empress or The Great Medical Fraud, CIVIS Publications, Massagno/Lugano, Switzerland, 1992.
57. ibid.
60. Borkin, op. cit.
61. ibid.
64. Bealle, op. cit. repr. in ref. 55, pp. 100-1.
66. ibid., pp. 103-4.
67. ibid., p. 105.
68. Bealle, op. cit., repr. in ref. 67.
73. See ref. 72.
75. ibid., p. 106.
76. J.W. Hodge quoted in ref. 75.
82. Cary Allen, None Dare Call It Conspiracy, Concord Press - P.O. Box 2686, Seal Beach, California 90740, 1971.
The sordid behaviour of today’s pharmaceutical corporations has been further demonstrated by Dr John Braithwaite, now a Trade Practices Commissioner, in his devastating expose, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY (1) (1984).

International bribery and corruption, fraud in the testing of drugs, criminal negligence in the unsafe manufacture of drugs - the pharmaceutical industry has a worse record of law-breaking than any other industry. Describing many examples of corporate crime, which shows the depth and seriousness of the crime problem in the pharmaceutical industry, Dr Braithwaite’s revealing study is based on extensive international research, including interviews of 131 senior executives of pharmaceutical companies in the United States, the United Kingdom, Australia, Mexico and Guatemala.

The book shows how pharmaceutical multinationals defy the intent of laws regulating safety of drugs by bribery, false advertising, fraud in the safety testing of drugs, unsafe manufacturing processes, smuggling and international law evasion strategies.

At the time of researching the subject, Braithwaite was a Research Criminologist at the Australian Institute of Criminology and a Fulbright Fellow affiliated to the University of California, Irvine and the United Nations Center on Transnational Corporations.

FRAUD IN DRUG TESTING

“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.” [Emphasis added.] (2)

In his book Braithwaite cited former FDA Commissioner Goddard expressing his concerns over research dishonesty at a Pharmaceutical Manufacturers Association Meeting in 1966:

“I have been shocked at the materials that come in. In addition to the problem of quality, there is the problem of dishonesty in the investigational new drug usage. I will admit there are grey areas in the IND situation, but the conscious withholding of unfavourable animal clinical data is not a grey matter. The deliberate choice of clinical investigators known to be more concerned about industry friendships than in developing good data is not a grey matter. The planting in journals of articles that begin to commercialize what is still an investigational new drug is not a grey matter area. These actions run counter to the law and the efforts governing drug industry [sic!] .” (3)

Goddard’s immediate successor at the FDA, Dr Ley, spoke before the US Senate hearings of a spot check that showed up the case of an assistant professor of medicine who had reputedly tested 24 drugs for 9 different companies. “Patients who died while on clinical trials were not reported to the sponsor”, an audit revealed. “Dead people were listed as subjects of testing. People reported as subjects of testing were not in the hospital at the time of tests. Patient consent forms bore dates indicating they were signed by the subjects after the subjects died.” (4)

Another audit looked at a commercial drug-testing firm that had apparently worked on 82 drugs and 28 sponsors:

“Patients who died, left the hospital or dropped out of the study were replaced by other patients in the tests
without notification in the records. Forty-one patients reported as participating in studies were dead or not in the hospital during the studies. Record-keeping, supervision and observation of patients in general were grossly inadequate.” (5)

Between 1977 and 1980 the FDA have discovered 62 doctors who had submitted manipulated or downright falsified clinical data. (6) A 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. (7)

Citing case examples, Dr Braithwaite states:

“The problem is that most fraud in clinical trials is unlikely to even be detected. Most cases which do come to public attention only do so because of extraordinary carelessness by the criminal physician...” (8)

According to Dr Judith Jones, Director of the Division of Drug Experience at the FDA, if the data obtained by a clinician proves unsatisfactory towards the drug being investigated, it is quite in order for the company to continue trials elsewhere until satisfactory results and testimonials are achieved. Unfavourable results are very rarely published and clinicians are pressured into keeping quiet about such data. (9)

It is very easy for the drug company to arrange appropriate clinical trials by approaching a sympathetic clinician to produce the desired results that would assist the intended application of the drug. (10) The incentive for clinical investigators to fabricate data is enormous. As much as $1000 per subject is paid by American companies, which enables some doctors to earn up to $1 million a year from drug research, (11) and investigating clinicians know all too well that if they don’t produce the desired data, the loss of future work is inevitable.

UNIVERSITY SCIENTISTS - THE MORE THAN WILLING PAWNS

Braithwaite cited an FDA survey of safety testing violations that have shown that university laboratories had the worst record for violations than all other laboratories in the survey. (12) Braithwaite writes:

“As one would predict from the foregoing discussion of how contract labs can be used by sponsors to abrogate responsibility for quality research, contract labs were found to have a worse record of GLP [Good Laboratory Practices] violations than sponsor labs. The worst record of all, however, was with university laboratories. One must be extremely cautious about this finding since there were only five university laboratories in the study. Nevertheless, it must undermine any automatic assumption that university researchers, with their supposed detachment from the profit motive, are unlikely to cut corners on research standards.” (13)

INAPPROPRIATE CLINICAL TRIALS

Even if data obtained from clinical trials is not falsified, it is of little worth, because they are not performed appropriately. Trials involve relatively small numbers of people; so many harmful effects of a new drug appear only when it has been marketed and widely used.

Furthermore, the subjects taking part in the trial usually do not represent those who will use the drug after its approval. Very young or elderly people, women of child-bearing age and people with liver or kidney disease are usually not included in clinical trials, although such people may be given the drug after it is marketed. Also, optimal dosages for adults are calculated on the basis of what is most effective for an average size adult. Many adults differ from this average, and about 45 per cent of ordinary adults are probably going to respond atypically to some classes of drugs. (14)

DRUG COMPANIES CONCEALING AND MISREPRESENTING DANGEROUS DRUG EFFECTS

Dr Braithwaite cited a number of cases where drug companies concealed and misrepresented dangerous effects of drugs noted by their own investigators. Braithwaite writes:

“In 1959 Wallace and Tiernan put a new tranquilliser, Dornwal, on the market despite the strenuous objections of its own medical director. Other company experts warned that Dornwal could cause serious and possibly fatal blood damage. They were right. Wallace and Tiernan failed to send to the FDA reports of side-effects which induced nine cases of bone marrow disease and three deaths from using the drug (Johnson, 1976) [15a] ....
“One could list a number of similar types of cases. Johnson and Johnson’s subsidiary, McNeil Laboratories, was denounced by the FDA for concealing information on side-effects of Flexin which according to Johnson (1976) included the drug being associated with 15 deaths from liver damage. Such more blatant cases are merely the tip of an iceberg of selective misinformation.

“The most dramatic recent case has been the disclosures in the British Parliament and US Congress that Eli Lilly and Co. knew of the dangers of Opren, an anti-arthritis drug associated with 74 deaths in Britain alone, 15 months before the drug was withdrawn (Sunday Times, 27 February 1983)....

“The problem is not restricted to Anglo-Saxon countries. In November 1982, a Japanese company, Nippon Chemipharm, admitted to presenting bogus data to the Japanese Government with its application to market a pain-killer and anti-inflammation drug under the brand name of Norvedan. The company submitted cooked up data to the Government in the name of Dr Harcio Sampei, chief of plastic surgery at Nippon University. The good doctor had accepted 2.4 million Yen in cash from the company in return for permission to use his name. More disturbing are similar allegations on another Nippon Chemipharm product. The company denies cooking data on this second product. But the worrying aspect of the second scandal is that a former company researcher claims to have submitted a written report alleging fraud in drug testing by Nippon Chemipharm to the Japanese Health and Welfare Ministry; Ministry officials, he alleges, chose to ignore the report (Japan Times, 23, 24, 25 November 1982).” [Emphasis added.] (15)

IN WHOSE INTERESTS ARE DRUGS TESTED?

The testing procedures of drugs are primarily performed to ensure the approval and marketing of these substances; despite the fact they are usually unsafe and ineffective. If drug companies were truly ethical and responsible, the vast majority of drugs would not have been allowed on the market in the first place.

West Germany’s prestigious weekly, Der Spiegel (June 24, 1985), carried a most revealing article titled, “How The Pharmaceutical Industry Bought Bonn”. The article, which featured on the front page and covered several pages, contributes to the real motives behind drug testing. In essence, the article could just as well apply to the United States, Britain and most other industrial nations. The following is a brief excerpt:

“As a rule, the drug companies didn’t pour millions into the coffers of the political parties, but gave money to individual politicians and public officials selected among those that determine the health policy. With the help of congressmen in their employ, they acquired uniquely favorable marketing conditions that would insure them durable profits. The pharmaceutical industry, which is worth billions, has bought up, as it were, the legislature, as the uncovered documents reveal...

“The approval of drugs should henceforth depend on two conditions: evidence of their ‘efficacity’ and of their ‘innocuity’. provided by chemo-physical tests, animal experiments, and clinical assays and opinions.” [Emphasis added.]

Many of the politicians and public officials who contributed to the acceptance of these guidelines were named in the article, and the bribes they pocketed were itemised.

FRAUDULENT ANIMAL TESTING

The most blatantly fraudulent procedure of drug testing is the testing of these substances using animal models; a practice often termed “vivisection”. To begin with, many of the most common or life-threatening side-effects cannot be predicted by animal tests. For instance, animals cannot let the experimenter know if they are suffering from headache, amnesia, nausea, depression and other psychological disturbances. Allergic reactions, some blood disorders, skin lesions and many central nervous system effects are even more serious examples that cannot be demonstrated by animal models. (16)

According to one of the world’s best known toxicologists, Professor Gerhardt Zbinden, from Zurich’s Institute of Toxicology; “Most adverse reactions that occur in man cannot be demonstrated, anticipated or avoided by the routine subacute and chronic toxicity experiment.” (17) Professor Zbinden has shown that of the 45 most common adverse reactions only 3 may possibly be predicted, and of the remaining 42, “only in exceptional cases can they be predicted from routine toxicologic tests”. (18)
SPECIES DIFFERENCES

Apart from the effects that cannot be demonstrated in animals, another very fundamental problem exists with testing substances using animals. Each individual species of animal has a unique genetic make-up. Any genetic differences predetermine massive variations in histology (structure, composition and function of tissues), biochemistry (chemistry of living organisms), morphology (structure of organisms), physiology (function of living organisms), and other species characteristics.

Because each animal species is different, substances that are tested on them for “safety” and “effectiveness” will have a different effect on each individual species. This has been amply demonstrated by Professor Pietro Croce, former animal experimenter, and world renowned author and medical researcher, in his revealing treatise, VIVISECTION OR SCIENCE - A CHOICE TO MAKE (19) (1991).

Morphine sends cats into a frenzy of excitement yet it calms and anaesthetises humans. The amount of opium that can be eaten without discomfort by the hedgehog would keep the most hardened addict happy for a fortnight. Arsenic kills humans but is harmless to guinea-pigs, chickens and monkeys. Chloroform, used successfully for decades in human surgery, is poisonous for dogs. Digitalis, which dangerously raises the blood pressure of dogs, is used to lower blood pressure for humans. (20) The list can be lengthened at will, but these few examples should be sufficient to demonstrate that there could not be a more unreliable test for new drugs than animal experimentation.

There are five basic stages in which a drug has an effect when taken internally. These are: absorption into the bloodstream, distribution to the site of action, mechanism of action, metabolism, and excretion. Considering that people of different sexes, ages, health and genetic make-up may react quite differently; it is obvious that other species often react very differently. Even a minor change, repeated at each stage, can accumulate, resulting in a major change of effect. One of the most important factors is the speed and pattern of metabolism, or the way in which a drug is broken down by the body. (21) Scientific reports show that variation in drug metabolism between species is the rule rather than the exception. (22,23)

Toxic drug effects not predicted by animal testing may be seen in people if their metabolism is slower, with the potentially dangerous result from longer exposure. The anti-inflammatory drugs phenylbutazone and oxyphenbutazone, which have been responsible for an estimated 10,000 deaths worldwide, (24) takes 72 hours for people to metabolise. However, phenylbutazone is metabolised by rhesus monkeys, dogs, rats and rabbits in eight, six, six, and three hours, respectively. (25) Oxyphenbutazone takes only half an hour for dogs to metabolise. (26)

Another fundamental problem that makes animal testing a flawed process concerns the etiology (cause) of the disease that the drug under test is supposed to treat. Because animals don’t suffer the same diseases as humans, experimenters attempt to artificially re-create spontaneous human diseases (naturally occurring diseases that arise from within) in healthy animals, and then they use these “models” to attempt to determine the efficacy (effectiveness) of the drug in question. This is totally illogical because the artificially re-created animal disease can in no way approximate a naturally occurring human disease (nor of the same animal species for that matter). Once a disease is “re-created”, it is artificial and is no longer the original, natural disease. Sometimes it is possible to re-create some of the symptoms of the disease but never the disease itself. (27,28) The only exception to this rule is in the case of infectious diseases, but animal infectious diseases are not the same as human infectious diseases. (28)

As well as the routine subacute and chronic toxicity tests (which involve poisoning by a substance being taken in normal quantities over a long period of time), drugs are also tested on animals for acute toxicity (poisoning due to a large amount of substance taken in a short period of time) and teratogenicity (ability to cause fetal malformations).

FRAUDULENT ACUTE TOXICITY TESTS

The LD50 is an acute toxicity test designed to indicate the human lethal dose that results from accidental or intentional overdose. The standard LD50 tests consist of forcing massive amounts of the test substance down the throat of a large number of animals to discover at what dosage-level about 50 per cent of them will die. Even if the substance is not poisonous to the animal, it will cause damaging effects by overpowering the
Most toxicologists and clinicians agree that these tests are scientifically indefensible. Professor Zbinden writes: “For the recognition of the symptomatology of acute poisoning in man, and for the determination of the human lethal dose, the LD50 in animals is of very little value.” (30) D. Lorke, from the Institute of Toxicology, Bayer AG, Germany, states that “even if the LD50 could be measured exactly and reproducibly, the knowledge of its precise numerical value would barely be of practical importance, because an extrapolation from the experimental animals to man is hardly possible”. (31)

Despite the fact that these tests have no scientific validity, they are used as a crude index of acute toxicity, demanded by government regulations. According to one of Britain’s largest contract laboratories, Huntingdon Research Centre; “Approximately 90 per cent of LD50 tests which are performed by this Contract Research Centre, and probably by others also, are purely to obtain a value for various legislative needs.” (32)

**FRAUDULENT TERATOGENIC TESTS**

Supposedly to safeguard pregnant women from the exposure of potentially teratogenic drugs, these substances are tested on various species of pregnant animals before being marketed. However, these tests are also worthless, because as Dr Robert Sharpe explains in his book, THE CRUEL DECEPTION (1988):

“In pregnant animals, differences in the physiological structure, function and biochemistry of the placenta aggravate the usual differences in metabolism, excretion, distribution and absorption that exists between species and make reliable predictions impossible.” (33)

The ineffectiveness of the teratogenic tests is demonstrated by the fact that the malformations caused by thalidomide (a drug prescribed to pregnant women for morning sickness that caused over 10,000 grotesque birth deformities) proved very difficult to duplicate on animals, despite being tested on a large range of species. Writing in his book DRUGS AS TERATOGENS, J.L. Schardein comments:

“In approximately 10 strains of rats, 15 strains of mice, eleven breeds of rabbit, two breeds of dogs, three strains of hamsters, eight species of primates and in other such varied species as cats, armadillos, guinea pigs, swine and ferrets in which thalidomide has been tested teratogenic effects have been induced only occasionally.” (34)


“Only when the white New Zealand rabbit was tested, a few malformed rabbit babies were obtained, and subsequently also some malformed monkeys - after years of tests [where researchers were constantly increasing the doses that were force-fed], hundreds of different strains and millions of animals used. But researchers immediately pointed out that malformations, like cancer, could be obtained by administration of practically any substance in high concentration, including sugar and salt, which will eventually upset the organism, causing trouble.” (35)

**BIRTH DEFORMITIES ON THE INCREASE**

As a result of the thalidomide tragedy, there has been a massive increase in the use of test animals but this has failed to prevent further deformities. On the contrary, the malformations have increased, and more than twenty years later, on July 19, 1983, a headline in the New York Times revealed: “Physical and Mental Disabilities in Newborns Doubled in 25 Years.” Furthermore, it has recently been uncovered that every year more than a quarter of a million babies (1 in 12) are born with birth defects in the United States. (36)

**CRITICISMS FROM WITHIN**

Because animal testing gives false and misleading data on the “safety” and “efficacy” of dangerous drug substances, many toxicologists and clinicians have expressed much criticism. To quote some of them:

“Even when a drug has been subjected to a complete and adequate pharmacologic investigation on several species of animals and found to be relatively non-toxic it is frequently found that such a drug may show unexpected toxic reactions in diseased human beings. This has been known almost since the birth of scientific pharmacology.” (37)
“...most experts considered the modern toxicological routine procedure a wasteful endeavour in which scientific inventiveness and common sense have been replaced by a thoughtless completion of standard protocols.” (38)

(Professor G. Zbinden, World Health Organisation toxicologist.)

“Normally, animal experiments not only fail to contribute to the safety of medications, but they even have the opposite effect.” (39)

(Professor Kurt Fickentscher, 1980, of the Pharmacological Institute of the University of Bonn, Germany.)

ANIMAL TESTING GIVES HINTS, INDICATIONS?

In support of animal testing vivisectionists say: “We don’t expect final answers from animal experiments, but just hints, indications, which encourage us to continue in a particular direction.” This is, of course, sheer nonsense; Professor Pietro Croce explains:

“But what’s an indication? An approximate information, merely orientative. And as the compass card shows, an orientation can point in the right direction, of which there is only one, or to one of the many wrong directions. And an animal experiment only very rarely points to the right direction, and when it does, it is due to coincidence, and at any rate verifiable only after the fact. Experimenting on animals to do medical research is like playing roulette.” (40)

HOW SHOULD DRUGS BE TESTED?

Vivisectionists would have the public believe that animal testing is an essential part of drug testing and evaluation, and that these tests cannot be dispensed with. This is also nonsense, as true scientific methods that are accurate and reliable are available and in current use.

Drug testing and evaluation should include: the use of human tissues, cells and organs (In vitro cultures); (41) chromatography and mass spectrometry (which separate drug substances at their molecular level to identify their properties); (42) quantum pharmacology (using quantum mechanics to understand the molecular structure of chemicals); (43) properly carried out human clinical trials; (44) and thorough reporting of drug side-effects by post-market surveillance. (45) The Ames test used in conjunction with in vitro tests is very effective in determining teratogenic and carcinogenic (cancer causing) properties of substances. (46)

WHY DO DRUG COMPANIES USE ANIMAL TESTS?

Although the previous methods have a demonstrated proven worth, drug companies still insist on using misleading animal tests, because they argue that government regulations demand them. But why would they?

Bearing in mind the drug companies’ criminal reputation in fraudulent drug testing and other illegal activities, with the collaboration of corrupt government and medical officials (as demonstrated by Ruesch and Braithwaite, among others), the following analysis by Hans Ruesch comes as no surprise:

“It is not only scandalous but also tragic that the Drug Trust is permitted to flood the market with its products on the grounds that they have been thoroughly tested for effectiveness and safety on animals, and that the Health Authorities, meaning the Government, abet this deception, which is nothing but confirmed fraud. For both sides are well aware that animal tests are fallacious and merely serve as an alibi - an insurance against the day when it is no longer possible to conceal the disastrous side effects of a drug. Then they can say that ‘all the required tests have been made’ - that they have obeyed the Law.

“But they don’t say that they themselves have imposed those laws, because the Lawmaker has no choice in all medical questions but to submit to the dictates of the ‘medical experts’. And who are they? Agents of the Chemo-Medical Syndicate, whose links to the Health Authorities are so close that they usually overlap. So they, and no one else, impart binding orders to that mysterious and omnipotent individual, identified anonymously as ‘The Lawmaker’.” [Emphasis added.] (47)

To back his conclusions, Hans Ruesch has assembled massive damning evidence against the perpetrators of the
phony drug testing fraud. This has been well documented in his book SLAUGHTER OF THE INNOCENT, and its sequel, NAKED EMPRESS OR THE GREAT MEDICAL FRAUD (1992). The documentary film, HIDDEN CRIMES (48) (1986), which is based on Hans Ruesch’s books and is produced by Javier Burgos, gives a visual account of the vivisection fraud.

Ruesch cited a criminal trial involving Chemie Grunenthal, the German manufacturer of Thalidomide. They were incriminated for having marketed a harmful drug. Writes Ruesch:

“In December 1970, the longest criminal trial in Germany’s judicial history - two and a half years, 283 days in court - ended with the acquittal of Chemie Grunenthal, after a long line of medical authorities had testified that the generally accepted animal tests could never be conclusive for human beings. This was unprecedented, for the testimonies came from an impressive array of individuals whose careers and reputations were practically built on animal experimentation...” (49)

Another example to illustrate the above point; Ruesch cites the case of Opren (the arthritis drug responsible for a number of deaths), as reported in the February 12, 1983 issue of Britain’s Economist:

“The Labour member of parliament, Mr Jack Ashley, is campaigning against the refusal of Eli Lilly [drug company] to pay compensation to the families of Opren’s victims. Eli Lilly says that it complied with all pre-marketing testing requirements and cannot therefore be held liable through negligence.” [Emphasis added.] (50)

**DOCTORS AGREE: VIVISECTION IS SCIENTIFIC FRAUD**

The following statements from doctors, not bound to commercial interests, contribute to the real motives behind the vivisectionists’ methods of drug testing:

“Results from animal tests are not transferable between species, and therefore cannot guarantee product safety for humans... In reality these tests do not provide protection for consumers from unsafe products but rather are used to protect corporations from legal liability.” (51)

(Dr Herhert Gundersheimer, 1988, Baltimore, Maryland.)

“ Toxicologists are...pursuing an illusion of safety using animals to fulfil political and legal obligations. As if to confirm our suspicions, some drugs are marketed and clinical procedures undertaken despite ‘failing’ animal tests!...

“But if animal tests are sometimes ignored, they can also be used to imply certain advantages of a company’s new product over existing drugs....

“On the other hand the fact that animal tests are misleading can form the basis of a company’s defence against claims about one of its products....

“ So, if animal experiments are misleading, they are at least flexible: they can be deemed inapplicable when necessary, ignored when convenient and used to imply important advantages over competing products.”  
[Emphasis added.] (52)

(Dr Robert Sharpe, in THE CRUEL DECEPTION, 1988.)

“Another basic problem which we share as a result of the regulations and the things that prompted them is an unscientific preoccupation with animal studies. Animal studies are done for legal reasons and not for scientific reasons. The predictive value of such studies for man is often meaningless - which means our research may be meaningless.” (53)

(Dr James Gallagher, 1964, Director of Medical Research, Lederle Laboratories, US.)

“There are many ways of producing ‘irrefutable’ facts in support of any argument, using different kinds of animals: one just has to choose the right one. For example:

“ Do we want to show that Amanita phalloides is an excellent edible toadstool? Then we have only to feed it to the rabbit....

“Do we want to discourage people from eating parsley? Let us give it to the parrot which will probably be
found lying stone-dead under its perch the next morning.

“Should we wish to rule out penicillin as a therapeutic drug, we have only to give it to the guinea-pig which will be dead in a couple of days....

“If we wish to convince the consumers of tinned food that botulin poison is harmless let us give it to the cat and it will lick its lips. Let us give it instead to the cat’s traditional prey, the mouse, and it will die as if struck by lightning....

“If we need to show that Vitamin C is useless we withhold it from the diet of the most readily available animal: the dog, the rat, the mouse, the hamster...they will continue to thrive because their bodies produce Vitamin C of their own accord. But let us not eliminate it from the diet of guinea-pigs, primates, or humans or they will die of scurvy....

“To sum up, one has only to know how to choose the proper animal species to obtain the desired results... This is a kind of science which one can knead like dough. The trouble comes in believing that with dough one can produce health for human beings.” [Emphasis added.] (54)

(Professor Pietro Croce in VIVISECTION OR SCIENCE - A CHOICE TO MAKE, 1991. From 1952 to 1982 Croce was head of the laboratory of microbiological, pathological anatomy and chemical analysis at the research Hospital L. Sacco of Milan, Italy.)

“Relying on animal tests means that new products which are thought to be safe are mass-market far too quickly and are prescribed by general practitioners and hospital doctors for thousands or even millions of patients without ever being properly assessed. It is hardly surprising that when problems occur - as they do all too frequently these days - they occur on a massive scale. Animal experiments allow drug companies to mass-market new drugs without testing them to see if they are safe and they encourage complacency among prescribing doctors who are not as alert for side effects as they should be because they have been told that the drugs they are prescribing are safe.

“The consequence of our reliance on animal testing is that new and untried drugs and procedures are being tested on vast numbers of people simply so that those making those drugs or pieces of equipment can make massive profits as quickly as possible.” (55)

(Dr Vernon Coleman, 1991, author of a number of books on health and medicine. UK.)

“The great majority of perinatal toxicological studies seem to be intended to convey medico-legal protection to the pharmaceutical houses and political protection to the official regulatory bodies, rather than produce information that might be of value in human therapeutics.” (56)

(Professor D. Hawkins, 1983. Prof. of Obstetric Therapeutics at the Institute of Obstetrics and Gynaecology and Consultant Obstetrician and Gynaecologist at Hammersmith Hospital, UK.)

“The extensive animal reproduction studies to which all new drugs are now subjected are more in the nature of a public relations exercise than a serious contribution to drug safety... The illogicality of the situation is demonstrated by the continued use of well-established drugs which are known to be teratogenic in some mammalian species (e.g. aspirin, penicillin/streptomycin, cortisone). Conversely a new drug which comes through its animal reproductive studies with flying colours may nevertheless be teratogenic in man.” (57)

(Professor R.W. Smithells, 1980. Prof. of Paediatrics and Child Health at the University of Leeds and a former member of the Committee on Safety of Medicines.)

“The virtue of animal model systems to those in hot pursuit of the federal dollars is that they can be used to prove anything - no matter how foolish, or false, or dangerous this might be. There is such a wide variation in the results of animal model systems that there is always some system which will ‘prove’ a point. Fraudulent methods of argument never die and rarely fade away. They are too useful to promoters...” (58)

(Dr Irwin Bross, 1982, former Director of the largest cancer research institute in the world, the Sloan-Kettering Institute, then Director of Biostatics, Roswell Park Memorial Institute, Buffalo, New York.)

“The richest earnings occur when a new variety of a drug is marketed before competing drugs can be
discovered. Under this system it is impracticable to do tests extending over a long period to establish the range of usefulness and potential dangers from toxicity... Thus after extensive laboratory tests on toxicity and pharmacological properties, but sometimes with a minimum of clinical trial, a drug may be marketed.” (59)

(Dr William Bean, 1957, of the Iowa State University in his testimony to the Kefauver Committee.)

**CONCLUSION ON DRUG TESTING**

The inescapable conclusion is that drug companies choose animal tests over scientific methods because of the utter unreliability of animal tests. Because each animal species is unique in its physiological, biochemical, histological, morphological and other characteristics, and consequently reacts differently to substances, drug companies can produce results favourable to their interests by simply choosing the appropriate species.

If their product is harmless, fine, money rolls in. If it’s harmful, no problem, accusations are disposed of on the grounds that it was tested and found to be “safe” on animals.

If drugs were tested properly using true scientific methods, the vast majority of them would not be allowed onto the market because their harmfulness and ineffectiveness would be all too apparent. The constant stream of new drugs would slow to a trickle and within a few years most drug companies would go bankrupt.

**DRUGS ARE POISONS**

The problem is that virtually all drugs are toxic to some degree, and as Eli Lilly once said, “a drug without side effects is no drug at all”. (60) No drug can be pinpointed to affect only the organ it is designed to treat, and most drugs have broad effects and some affect virtually every organ system in the body. (61)

Drugs are toxic because they are generally composed of artificial chemical compounds that have been synthesised in the laboratory. (62) In the past, before drugs became big business, nearly all medicines were composed of natural plant-derived ingredients that were far safer than today’s drugs. Unfortunately, the drug companies today choose to chemically synthesise the ingredients instead, because they are cheaper to produce and can be patented, giving the companies monopoly rights on their sales. (63)

For some insight into the toxic nature of the next drug your doctor tries to prescribe for you, the authors recommend that you ask him or her to look up the drug for you in their copy of MIMS ANNUAL or MIMS bi-monthly (64). These books, which doctors have at their disposal, give disturbing details on the toxic effects of individual drugs. You will discover that your doctor would more than likely be reluctant, because he or she knows that after seeing the details for yourself you would most probably refuse the drug. However, be warned, the information in MIMS is only what the drug companies supply and is not a true account of how dangerous these chemical substances really are.

**HOW MANY DRUGS DO WE NEED?**

Already over 30 years ago, Dr Walter Modell of Cornell University’s Medical College, whom Time had described as “one of America’s foremost drug experts”, wrote in CLINICAL PHARMACOLOGY AND THERAPEUTICS:

“When will they realize that there are too many drugs? No fewer than 150,000 preparations are now in use. About 15,000 new mixtures and dosages hit the market each year, while about 12,000 die off... We simply don’t have enough diseases to go around. At the moment the most helpful contribution is the new drug to counteract the untoward effects of other new drugs.” (65)

Since 1961, the number of drug preparations marketed world-wide has increased to 205,000 with a proportional rise in new maladies.

Further, Ruesch reveals:

“In 1980, the Geneva based World Health Organisation (WHO) published a list of 240 drugs that were considered ‘essential’ or sufficient for Third World needs. Since the Third World’s health has been touted as being very much in need of Western help, the 240 drugs should more than suffice for Western populations as well.
“Considering WHO’s report, how come have an estimated 205,000 drugs and combinations thereof been produced - most of which have long since been withdrawn?...

“On October 14, 1981 the Swiss weekly Weltwoche reported that UNIDO (United Nations Industrial Development Organisation) had set up in collaboration with WHO a list of merely 26 drugs that were considered indispensable for the Third World....

“The UNIDO report emphasized that of the 26 ‘indispensables’, 9 should have special priority.

“And which drug topped the list of these 9 that were considered even more indispensable than all the other indispensables? Acetylsalicylic acid, meaning our good old Aspirin, which was discovered almost 100 years ago and has proved itself less harmful than most other drugs. Perhaps because it is one of the few still in use today that had not been developed by animal tests?

“Some people think that even the list of 9 more indispensable than others is too long.” (66)

**SOME FRAUDULENTLY TESTED DRUGS THAT INJURED AND KILLED**

**Paracetamol (painkiller)** - 1,500 people had to be hospitalised in Great Britain in 1971.

**Orabilex** - caused kidney damages with fatal outcome.

**MEL/29 (anti-hypertensive)** - caused cataracts.

**Methaqualone (hypnotic)** - caused severe psychic disturbances leading to at least 366 deaths, mainly through murder or suicide.

**Thalidomide (tranquilliser)** - caused 10,000 malformed children.

**Isoproterenol (asthma)** - caused 3,500 deaths in the sixties.

**Stilboestrol (prostate cancer)** - caused cancer in young women.

**Trilergan (anti-allergic)** - caused viral hepatitis.

**Flamamil (rheumatism)** - caused loss of consciousness.

**Eraldin (heart medication)** - caused severe eye and digestive tract damage, and many deaths.

**Phenformin (diabetes)** - caused 1,000 deaths annually until withdrawn.

**Atromid S (cholesterol)** - caused deaths from cancer, liver, gall bladder and intestinal disease.

**Valium (tranquilliser)** - addictive in moderate doses.

**Preludin & Maxiton (diet pills)** - caused serious damage to the heart and the nervous system.

**Nembutal (insomnia)** - caused insomnia.

**Pronap & Plaxin (tranquillisers)** - killed many babies.

**Phenacetin (painkiller)** - caused severe damages to kidneys and red blood corpuscles.

**Amydopyrine (pain killer)** - caused blood disease.

**Marzine (nausea)** - damaged children.

**Reserpine (anti-hypertensive)** - increased risks of cancer of the brain, pancreas, uterus, ovaries, skin and women’s breasts.

**Methotrexate (leukaemia)** - caused intestinal haemorrhage, severe anaemia and tumours.

**Urethane (leukaemia)** - caused cancer of liver, lungs and bone marrow.

**Mitotane (leukaemia)** - caused kidney damage.
Cyclophosphamide (cancer) - caused liver and lung damage.
Isoniazid (tuberculosis) - caused liver destruction.
Kanamycin (tuberculosis) - caused deafness and kidney destruction.
Chloromycetin (typhoid) - caused leukaemia, cardiovascular collapse and death.
Phenolphthalein (laxative) - caused kidney damage, delirium and death.
Clioquinol (diarrhoea) - caused blindness, paralysis and death.
DES (prevent miscarriage) - caused birth defects and cancer.
Debendox (nausea) - caused birth defects.
Accutane (acne) - caused birth defects.
Kanamycin (tuberculosis) - caused deafness and kidney destruction.

The preceding list, taken from VIVISECTION - SCIENCE OR SHAM (67) (by Dr Roy Kupsinel, 1990) and NAKED EMPRESS (68), is just a very small sample of a far greater number of therapeutic disasters that have taken place.

“In fact, the therapeutic disasters, steadily on the increase today, did not exist before the imposition of the safety-tests done on animals. They are a direct result of widespread animal experimentation.” (69)

(Hans Ruesch in NAKED EMPRESS, 1992.)

VIVISECTION - THE DISTORTED ISSUE

The issue of animal experimentation has been a very contentious one for well over a century - since the time the French physiologist, Claude Bernard (1813-1878), founded the modern vivisectionist method.

Defenders of animal experimentation, through their aggressive campaigns, with the help of the industry-beholden media, have largely succeeded in convincing the public that vivisection is responsible for any medical progress and that the only possible objection is solely based on animal welfare.

On the contrary, medical historians, such as Hans Ruesch, (70) Dr Beddow Bayly, (71) Dr Robert Sharpe, (72) and Dr Brandon Reines, (73) to name a few, have repeatedly demonstrated that important discoveries were made through human clinical research, observations of patients and human autopsies among other human-based research methodologies, and that vivisectionists have distorted medical history in their favour. Animal experimentation has served primarily to “prove” in animals what had already been demonstrated in people.

Also, contrary to what the proponents of vivisection would have the public believe; the strongest objection to vivisection has been from the medical and scientific community. The book, 1000 DOCTORS (AND MANY MORE) AGAINST VIVISECTION (74) (1989), by Hans Ruesch, highlights this fact. 1000 DOCTORS is a compilation of an impressive collection of anti-vivisection statements made by doctors and scientists from around the world. The professional verdicts that start as far back as 1824, are a reminder of the fact that there have always been members of the scientific and medical profession strongly opposed to vivisection on scientific and medical grounds.

With today’s medical research being heavily based on fraudulent animal experimentation, is it any wonder that diseases remain uncured and are on the increase: diseases such as cancer, diabetes, heart disease, birth defects, arthritis, muscular dystrophy, leukaemia, all kinds of mental disease, Alzheimer’s, and the latest tragedy, AIDS.


Disclaimer: This article is presented for educational purposes only and is not intended as a substitute for professional or medical advice. CAFMR disclaims all liability to any person arising directly or indirectly from the use of the information provided.
References and Notes


5. ibid.


8. Braithwaite, op. cit., p. 54.


10. ibid.


13. Braithwaite, op. cit., p. 82.


20. ibid., pp. 22-4.


25. See ref. 23.


36. Statistics from the March of Dimes organisation.


42. Roy Kapsinell, Vivisection: Science or Sham, People for Reason In Science and Medicine, PO Box 2102, Anaheim, California 92814, 1990, p. 15.


47. Hans Ruesch, Naked Empress or The Great Medical Fraud, CIVIS Publications, Massagno/Lugano, Switzerland, 1992, p. 9.


49. Ruesch, Naked Empress, op. cit., p. 361.


52. Sharpe, op. cit., pp. 112-4.


58. Irwin Bross, “Animals in cancer research: a multi-billion dollar fraud” in Fundamental and Applied Toxicology, Nov. 1982,
60. Repr. in ref. 61.
64. Intercontinental Medical Statistics (Australasia), MIMS Annual and MIMS (bi-monthly), IMS Publishing, Crows Nest, NSW.
65. Walter Modell in Clinical Pharmacology and Therapeutics, repr. in Time, 26 May 1961; and ref. 47, p. 9.
69. ibid., p. 14.
70. Ruesch, Slaughter of the Innocent, op. cit.
72. Sharpe, op. cit.
73. Brandon Reines, Masked Men of Medicine, Paragon House, New York, 1990.
A Medical Madoff: Anesthesiologist Faked Data in 21 Studies

A pioneering anesthesiologist has been implicated in a massive research fraud that has altered the way millions of patients are treated for pain during and after orthopedic surgeries.

By Brendan Borrell | March 10, 2009 | 54

SURGEON AT WORK: Investigation reveals anesthesiologist published a string of studies based on bogus research touting the supposed benefits of drugs for pain management.

Over the past 12 years, anesthesiologist Scott Reuben revolutionized the way physicians provide pain relief to patients undergoing orthopedic surgery for everything from torn ligaments to worn-out hips. Now, the profession is in shambles after an investigation revealed that at least 21 of Reuben’s papers were pure fiction, and that the pain drugs he touted in them may have slowed postoperative healing.

“We are talking about millions of patients worldwide, where postoperative pain management has been affected by the research findings of Dr. Reuben,” says Steven Shafer, editor in chief of the journal Anesthesia & Analgesia, which published 10 of Reuben’s fraudulent papers.

Paul White, another editor at the journal, estimates that Reuben’s studies led to the sale of billions of dollars worth of the potentially dangerous drugs known as COX2 inhibitors, Pfizer’s Celebrex (celecoxib) and Merck’s Vioxx (rofecoxib), for applications whose therapeutic benefits are now in question. Reuben was a member of Pfizer’s speaker’s bureau and received five independent research grants from the company. The editors do not believe patients were significantly harmed by the short-term use of these COX2 inhibitors for pain management but they say it’s possible the therapy may have prolonged recovery periods.

Baystate Medical Center in Springfield, Mass., began investigating Reuben’s findings last May after its chief academic officer, Hal Jenson, discovered during a routine audit that Reuben had not received approval from the hospital’s review board to conduct two of his studies. Reuben “violated the trust of Baystate, the community and science,” Jenson says. The story of the investigation was first reported by Anesthesiology News late last month.

Reuben, 50, has been stripped of his research and educational duties and has been on medical leave since May. He received his medical degree from the State University of New York at Buffalo School of Medicine & Biomedical Sciences in 1985 and did his residency at the Mount Sinai Medical Center in New York City. In 1991, he joined Baystate, which serves as the western campus for Tufts University School of Medicine, and has worked as a staff anesthesiologist and the director of acute pain management.

His lawyer, Ingrid Martin of Dwyer & Collora, LLP, in Boston, told ScientificAmerican.com that Reuben has cooperated with the investigation and that he “deeply regrets that all of this happened.” She added that “with the [investigating] committee’s guidance, he is taking steps to ensure this never happens again.” She declined to answer any further questions, and Reuben did not respond to an e-mail request for comment.

Beginning in 2000, Reuben, in his now-discredited research, attempted to convince orthopedic surgeons to shift from the first generation of nonsteroidal anti-inflammatory drugs (NSAIDs) to the newer, proprietary COX2 inhibitors, such as Vioxx, Celebrex, and Pfizer’s Bextra (valdecoxib). He claimed that using such drugs in combination with the Pfizer anticonvulsant Neurontin (gabapentin), and later Lyrica (pregabalin), prior to and during surgery could be effective in decreasing postoperative pain and reduce the use of addictive painkillers, such as morphine, during recovery. A 2007 editorial in Anesthesia & Analgesia stated that Reuben had been at the “forefront of redesigning pain management protocols” through his “carefully planned” and “meticulously documented” studies.

Many orthopedic surgeons, however, were slow to adopt COX2 inhibitors due to animal studies that showed short-term use might hinder bone healing. Then, in 2004, Vioxx and Bextra were pulled from the market because of their link to an increased risk of heart attacks and strokes, leaving Pfizer’s Celebrex as the only COX2 inhibitor available. Celebrex sales plunged 40 percent after a study that same year suggesting that it, too,
posed a heart attack risk. Despite this, Reuben continued to present “findings” in research funded by Pfizer that trumpeted Celebrex’s alleged benefits and downplayed its potential negative side effects.


Three years later, Reuben’s career would begin to unravel as Ekman began to suspect foul play. In addition to collaborating with Reuben on the now-retracted Celebrex study, Ekman agreed to review a Reuben manuscript on surgery on the anterior cruciate ligament (ACL) in the knee. But when he asked the anesthesiologist for the name of the orthopedic surgeon on the study, Reuben ceased communication with him.

Then, last year, Ekman was invited by Pfizer to give a talk. While there, he was handed a version of the very manuscript Reuben had asked him to review, which had subsequently been published in Anesthesia & Analgesia. To his surprise, and horror, he was listed as a co-author: Reuben had forged his signature on the submission form, Ekman says.

By then, Editor in Chief Shafer had already put several Reuben manuscripts on hold after learning that Baystate had initiated a probe into the validity of his research. The investigation later identified 21 articles based on patient data that had been partially or completely doctored. Although Pfizer funded Reuben’s research between 2002 and 2007, Baystate has no records of those payments and says that the research funds could have been paid directly to Reuben. Such an arrangement would be “highly unusual,” Shafer notes. “It’s just a little frustrating,” Baystate spokesperson Jane Albert says. “I don’t know how many dollars went to Dr. Reuben or his group.”

Pfizer spokesperson Sally Beatty insists the grants were properly disbursed to Baystate in accordance with Pfizer policy. “Pfizer is not familiar with the records retention policies of Baystate Medical Center,” she says, “However, independent investigator-initiated research grant agreements were executed between Pfizer and Baystate Medical Center.” Beatty was unable to provide information on the dollar amount of the grants, but editor White says they typically range between $10,000 to $100,000.

The question is: Why did it take 12 years before a “routine audit” revealed Reuben’s widespread data fabrication? “Baystate publishes about 200 [studies] every year, and of those [articles], the audit rate might only be 5 percent,” Baystate’s Jenson says, acknowledging that ultimately “Baystate is responsible” for making sure that research done there is properly conducted and reported. He says that the hospital has been trying to strengthen its oversight program over “the past few years” and that it is in the process of applying for accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in Washington, D.C., which provides an independent evaluation of an organization’s ethical standards and oversight. The lack of accreditation is not unusual because the nonprofit program was not established until 2001 and only recently has grown to include 159 hospitals, academic institutions and other organizations.

In hindsight, Anesthesia & Analgesia editors Shafer and White admit that it should have been a “red flag” that Reuben’s studies were consistently favorable to the drugs he studied. White, who has also received drug company educational grants, says that such funding comes with “subtle pressure” to give the companies the results they want. For now, at least, neither the drug companies nor Reuben’s co-authors are officially sharing in the blame, but that’s expected to change. “There’s a lot of responsibility to pass around,” White says, “It’s all being focused on Scott Reuben, but the reality is there are many other responsible parties.”
Millions of surgery patients at risk in drug research fraud scandal

Millions of NHS patients have been treated with controversial drugs on the basis of “fraudulent research” by one of the world’s leading anaesthetists, The Daily Telegraph can disclose.

Guidelines for British anaesthetists regarding colloids are being revised after it emerged that four of the key studies on which they were based are to be formally retracted.

By Heidi Blake, Holly Watt and Robert Winnett
10:31PM GMT 03 Mar 2011
147 Comments

Joachim Boldt is at the centre of a criminal investigation amid allegations that he may have forged up to 90 crucial studies on the treatment. He has been stripped of his professorship and sacked from a German hospital following allegations about his research into drugs known as colloids.

Experts described Mr Boldt’s alleged forgeries as possibly the biggest medical research scandal since Andrew Wakefield was struck off last year for falsely claiming to have proved a link between the MMR vaccine and autism.

Guidelines for British anaesthetists regarding colloids – used to boost blood volume in patients undergoing surgery – are being revised after it emerged that four of the key studies on which they were based are to be formally retracted.

Mr Boldt, 57, was regarded as a leading specialist in intravenous fluid management, and his work was published widely in British medical journals.

He claimed to have proved that colloids were as safe as other, similar treatments despite earlier studies showing them to be more dangerous. Mr Boldt’s alleged forgeries date back up to a decade.

RELATED ARTICLES

EU red tape making drugs trials ‘impossible’ 13 Feb 2012
Career built on charisma and charm 03 Mar 2011
Dispute over rival treatments 03 Mar 2011
Patients at risk as NHS trim out-of-hours care 03 Mar 2011

The Consensus Guidelines on Intravenous Fluid Therapy, published by six British medical groups including the Association of Surgeons and the Intensive Care Society, were being withdrawn last night. Prof John MacFie, president of the Association of Surgeons, suggested that some British patients could have been put in danger. He said he would urge other medics to abandon colloids.

“We have withdrawn the guidelines from our website and we will need to rewrite the article,” he added. “The profession I represent does not want to be to be associated with potentially fraudulent research.

“Some people are comparing this to the Andrew Wakefield scandal. What Wakefield did had terrible implications on children’s lives, and the principle of this is the same.” As chief anaesthetist at Ludwigshafen Hospital in the Rhineland, Mr Boldt was the leading advocate of colloids, which are now commonly used across Europe.

He published dozens of papers “proving” their benefits and contradicting studies which suggested they could increase the risk of death in surgery and cause kidney failure, severe blood loss and heart failure.

German medical authorities are scrutinising 92 of his key publications and a criminal investigation is under way into allegations that he forged documents, tested drugs on patients without their consent and fraudulently claimed payments for operations he had never performed.

Mr Boldt received funding from manufacturers of hydroxyethyl starch (HES) – the colloid he most strongly advocated – including B. Braun, Baxter and Fresenius Kabi.
He was frequently paid to speak at international medical conferences where he hailed HES as “the holy grail” of fluid drugs.

HES and other colloids are up to 10 times more expensive than the alternative fluid management drugs, crystalloids, which some experts believe are safer as they contain smaller molecules and are more easily absorbed. Mr Boldt was sacked from Ludwigshafen Hospital last November. It has established an investigating commission to review 29 of the 92 papers which have been identified as “highly suspected” of containing forged or distorted data. The others will be examined if serious evidence of forgery is found.

Prof Eike Martin, head of the investigating commission, told The Telegraph: “At first we thought that all the studies were 100 per cent invented, but now we have found a huge amount of clinical data from trials that were conducted.

“Our suspicion is that the trials are not reported accurately in the papers. Prof Boldt was an advocate for colloids and that was the conclusion of his studies, but the data he published is different from the original data we have seen.”

Prof Martin said investigators examining one study, which purported to show that HES caused less inflammation than another fluid management drug, had found that the original data contradicted the conclusion.

The editors in chief of a consortium of medical journals which published Mr Boldt’s work are also reviewing the 92 publications.

Sources close to the investigation said that the editors would announce the formal retraction of 89 papers next month.

Rhineland state prosecutors are investigating Mr Boldt over allegations that he forged the signatures of his alleged “co-authors” on his studies, conducted drugs trials without official approval and claimed money for operations that he never performed. Police raided his home and his offices at the hospital in December and seized paperwork and computers.

Lothar Liebig, the state’s director of public prosecutions, said: “Boldt published certain studies about medical drugs in order to get them accepted.

“There there is a strong suspicion that he deliberately failed to obtain the approval of the institutional review board in Ludwigshafen, which is a criminal offence.”

Other medical research has contradicted Mr Boldt’s findings.

Research by Dr Gill Schierhout and Dr Ian Roberts of University College London found in 1998 that the use of colloids during surgery increased the risk of death by four percentage points – equivalent to four extra deaths in every 100 patients.

A review published 10 years later by Konrad Reinhart and Christiane Hartog of Friedrich Schiller University in Jena, Germany cited two large-scale clinical trials which found that HES could prevent the blood from clotting, which can cause heavy bleeding. Other studies have shown that some colloids can result in complications including heart and kidney failure, fluid entering the lungs and anaphylactic shock.

Suspicion first fell on Mr Boldt in October when readers of an article that he had published in the US journal Anesthesia and Analgesia, about the benefits of HES in bypass surgery, noticed that the pattern shown by his data was “too perfect to be believed”.

Dr Rupert Pearse, a senior lecturer in intensive care medicine at Barts and the London School of Medicine, and co-author of the British guidelines on fluid drugs, said last night: “I specifically remember looking at a paper of his last year and being surprised at how lucky he had been with his results.

“For me, it shakes the world I work in and makes me feel less confident in it, and if I were a member of the public I would feel the same.”

Mr Boldt was unavailable for comment.
Massive Fraud Uncovered in Work by Social Psychologist

Investigation claims dozens of social-psychology papers contain faked data.

November 1, 2011 | 30

By Ewen Callaway of Nature magazine

When colleagues called the work of Dutch psychologist Diederik Stapel too good to be true, they meant it as a compliment. But a preliminary investigative report (go.nature.com/tqmp5c) released on October 31 gives literal meaning to the phrase, detailing years of data manipulation and blatant fabrication by the prominent Tilburg University researcher.

“We have some 30 papers in peer-reviewed journals where we are actually sure that they are fake, and there are more to come,” says Pim Levelt, chair of the committee that investigated Stapel’s work at the university.

Stapel’s eye-catching studies on aspects of social behaviour such as power and stereotyping garnered wide press coverage. For example, in a recent Science paper (which the investigation has not identified as fraudulent), Stapel reported that untidy environments encouraged discrimination (Science 332, 251-253; 2011).

“Somebody used the word ‘wunderkind’,,” says Miles Hewstone, a social psychologist at the University of Oxford, UK. “He was one of the bright thrusting young stars of Dutch social psychology -- highly published, highly cited, prize-winning, worked with lots of people, and very well thought of in the field.”

In early September, however, Stapel was suspended from his position as dean of the Tilburg School of Social and Behavioral Sciences over suspicions of research fraud. In late August, three young researchers under Stapel’s supervision had found irregularities in published data and notified the head of the social-psychology department, Marcel Zeelenberg. Levelt’s committee joined up with sister committees at the universities of Groningen and Amsterdam, where Stapel has also worked, to produce the report. They are now combing through his publications and their supporting data, and interviewing collaborators, to map out the full extent of the misconduct.

Mistakes made

Stapel initially cooperated with the investigation by identifying fraudulent publications, but stopped because he said he was not physically or emotionally able to continue, says Levelt. In a statement, translated from Dutch, that is appended to the report, Stapel says: “I have made mistakes, but I was and am honestly concerned with the field of social psychology. I therefore regret the pain that I have caused others.” Nature was unable to contact Stapel for comment.

The report does not identify specific papers that contain manipulated or fabricated data, pending the completion of the investigations. The investigators conclude, though, that Stapel acted alone. “The co-authors, and in particular the PhD students, were absolutely not involved, they really didn’t know what was going on in this data fabrication,” Levelt says.

Often, the report says, Stapel and a colleague or student came up with a hypothesis, and then designed an experiment to test it. Stapel took responsibility for collecting data through what he said was a network of contacts at other institutions, and several weeks later produced a fictitious data file for his colleague to write up into a paper. On other occasions, Stapel received co-authorship after producing data he claimed to have collected previously that exactly matched the needs of a colleague working on a particular study.

The data were also suspicious, the report says: effects were large; missing data and outliers were rare; and hypotheses were rarely refuted. Journals publishing Stapel’s papers did not question the omission of details about where the data came from. “We see that the scientific checks and balances process has failed at several levels,” Levelt says.

At a press conference, Tilburg University’s rector, Philip Eijlander, said that he would pursue criminal
prosecution of Stapel. The committee is also producing a list of tainted papers to guide co-authors and journal publishers in what will probably be a long list of retractions.

Joris Lammers, a psychologist at Tilburg who did his PhD under Stapel’s supervision, says he is “shocked” by the findings. Lammers says he worked independently of Stapel and collected all the data in his PhD himself—the report notes that his dissertation is not under suspicion. Several other former collaborators contacted by Nature declined to comment.

Hewstone, who has never worked with Stapel, had initially fretted that Stapel’s fraudulent oeuvre would undermine other findings in the field of social psychology. While editing a new edition of a social-psychology textbook, however, Hewstone turned up no references to Stapel’s work in 15 chapters, suggesting that Stapel’s work was not as influential as he had thought. “I think the impact is going to be particularly devastating for the young people he worked with, but not for the field of social psychology as such,” he says.

This article is reproduced with permission from the magazine Nature. The article was first published on November 1, 2011.
There is a climate of elation in the world of pharma: A recent study seems to suggest that cholesterol lowering medication should perhaps be given to everyone, regardless of their level of cholesterol, to prevent future heart attacks. This is big money. At present, sales of cholesterol lowering medications are worth tens of billions of dollars, on a much more limited set of prescribing guidelines.

Yet, there are huge numbers of people suffering from the side effects of statins, which include severe muscle pains, cognitive trouble and even Amyotrophic Lateral Sclerosis and Alzheimer’s disease.

Vera Hassner Sharav of the Alliance for Human Research Protection discusses the JUPITER study and its implications for our health in an article that looks at the study’s limitations and inherent conflicts of interest, as well as the financial aspects of medicating healthy people to lower cholesterol.

Pharma Marketing Tactics Threaten Public Health and Wealth

by Vera Hassner Sharav

Amid much fanfare, on Sunday, November 9, AstraZeneca announced the results of its drug trial, Justification for the Use of Statins in Prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER). The results were announced at the American Heart Association conference and simultaneously published in The New England Journal of Medicine (Nov. 9). The study was hailed as a watershed event in heart disease prevention: “In this trial of apparently healthy persons without hyperlipidemia but with elevated high-sensitivity C-reactive protein levels, rosuvastatin [Crestor] significantly reduced the incidence of major cardiovascular events.”

Current treatment algorithms for the prevention of myocardial infarction, stroke, and death from cardiovascular causes recommend statin therapy for patients with established vascular disease, diabetes, and overt hyperlipidemia. Last year Statins commanded a $34 billion market share.

Not satisfied with selling pharmaceuticals to the sick, drug manufacturers seek to expand the market for prescription drugs to healthy people. They promote drugs as though they were toothpaste - disregarding the drugs’ hazardous effects. Companies do this by persuading an unsuspecting public about the need to take drugs as a preventative measure against presumed risks of future illness. And, more importantly, drug companies set out to convince doctors - providing cash incentives - to prescribe drugs for healthy people despite documented, even life-threatening risks.

To their credit, the NEJM published an editorial by Mark A. Hlatky, M.D., who took a more critical view of the study design, its reliance on a single biomarker, CRP. He raises doubts whether the findings warrant expanded use of statins. Dr. Hlatky points to other flaws in the JUPITER study design:

“…the study provides only limited and indirect information about the role of high-sensitivity C-reactive protein testing in clinical management, since the trial did not compare subjects with and those without high-sensitivity C-reactive protein measurements, nor did it compare the use of high-sensitivity C-reactive protein with the use of other markers of cardiovascular risk.”

“The relative risk reductions achieved with the use of statin therapy in JUPITER were clearly significant. However, absolute differences in risk are more clinically important than relative reductions in risk in deciding whether to recommend drug therapy, since the absolute benefits of treatment must be large enough to justify the associated risks and costs. The proportion of participants with hard cardiac events in JUPITER was reduced from 1.8% (157 of 8901 subjects) in the placebo group to 0.9% (83 of the 8901 subjects) in the rosuvastatin group; thus, 120 participants were treated for 1.9 years to prevent one event.”

“On the other side of the balance, of concern are the significantly higher glycated hemoglobin levels and incidence of diabetes in the rosuvastatin group in JUPITER (3.0%, vs. 2.4% in the placebo group; P=0.01). There are also no data on the long-term safety of lowering LDL cholesterol to the level of 55 mg per deciliter (1.4 mmol per liter), as was attained with rosuvastatin in JUPITER, which is lower than in previously reported trials. Long-term safety is clearly important in considering committing low-risk subjects without clinical
disease to 20 years or more of drug treatment. Finally, the cost of rosuvastatin (roughly $3.45 per day or $1,250 per year) is much higher than that of generic statins.”

The cost—for the drug alone—of treating 120 people for 1.9 years to prevent one serious cardiac event would be $285,000.

Dr. Hlatky further notes: “Ridker et al. suggest, from their meta-regression analysis, that the risk reduction observed in JUPITER was greater than that expected on the basis of previous trials. Meta-regression is not a reliable technique, however, and the early termination of JUPITER owing to the efficacy data probably exaggerated the results to some degree.”

Which brings us to the issue of conflicts of interest:

AstraZeneca funded the JUPITER study in order to justify prescribing its cholesterol-lowering statin, Crestor for people with normal cholesterol levels. Needless to say, a favorable result would exponentially increase the sales of the drug. The potential profit is in the trillions of dollars.

The research objective had a built-in bias, and the sponsor and principle investigator had a strong stake in a desired outcome. Furthermore, in light of the increased incidence of diabetes among the group prescribed Crestor (3.0%, vs. 2.4% in the placebo group), the trial’s early suspension raises red flags about the extent of that (and other risks) that are known to occur mostly after extended exposure.

Not disclosed in the NEJM, is the discovery by Merrill Goozner: “the first thing you need to know about this trial is that its lead investigator, Paul Ridker of Brigham and Women’s Hospital in Boston, owns a patent on the $20 test that measures CRP.” (posted below)

The JUPITER trial screened nearly 90,000 people to find the 17,800 with elevated CRP measures who were eligible for the trial. If 10 million people are tested to find the estimated two million with elevated CRP levels, “it’s $200 million in test sales, which, if the royalty is only 1 percent, amounts to a hefty $2 million a year in extra income for Dr. Ridker.” If AstraZeneca can get two million more “apparently healthy men and women” on rosuvastatin, it’s an additional $2 billion-plus in sales.”

In light of AstraZeneca’s record of corrupt practices[*], the following authors’ statement should taken with a high degree of skepticism: “The trial was financially supported by AstraZeneca. The sponsor collected the trial data and monitored the study sites but played no role in the conduct of the analyses or drafting of the manuscript and had no access to the unblinded trial data until after the manuscript was submitted for publication.”

American medicine has been derailed from its therapeutic focus and ethical principle, “first, do no harm,” into a commercially driven enterprise since it aligned itself with the pharmaceutical industry. Industry’s unconscionable marketing strategy - promoting the use of drugs for healthy people - is accomplished with assistance from professional medical societies and influential physicians at prestigious academic centers.

Doctors have adopted a specious corporate rationale to justify prescribing drugs for healthy people as “preventive therapy.” All-too-often, doctors accept findings from company-controlled, biased studies, ignoring the indicators for potential serious hazards posed by drugs. In the case of the JUPITER study, there was “a higher incidence of physician-reported diabetes” in the group exposed to Crestor.

Doctors at the American Heart Association, lent legitimacy to prescribing statins for long-term use in healthy people, simply on the basis of a screening test that showed they had elevated levels of CRP, a biomarker for inflammation. They predicted that the JUPITER study might lead as many as 7 million more Americans to consider taking cholesterol-lowering statin drugs, such as: Crestor, Lipitor, Zocor,

Similarly, the prescribing practices of US psychiatrists are driven by industry’s marketing agenda with no scientific medical evidence to support the widespread prescribing of psychotropic drugs. Dubious screening tests - such as DISC, TeenScreen, KiddieSADS, TRAYY - provide the basis for “diagnosing” mental disorders in millions of otherwise healthy American children who are then exposed to harmful toxic drugs that interfere with normal physiological and neurological development. Even as these drugs’ labels now carry black box warnings, the most severe drug warnings mandated by the FDA-including the increased risk of suicide-
prominent psychiatrists promote the use of these drugs in children. Financially compromised psychiatrists regularly pen their name (for hefty fees) to industry-generated clinical trial reports and clinical practice guidelines whose prescription drug recommendations have propelled the most toxic psychotropic drugs into blockbuster sellers.

*AstraZeneca in the news:

**Nov. 6, 2008:** Astra Zeneca Reps Told To Use Disney Characters In Seroquel Marketing

How is this for creative selling? The idea was conveyed at a national sales meeting and on field rides with sales reps, who were told to use Tigger as a bipolar patient and Eeyore - the down-in-the-mouth donkey - as a depressed patient. The reps were allegedly encouraged to use Tigger dolls as giveaways.” See:


**June 19, 2008:** Judge Price of the Montgomery County Circuit Court upheld the fraud verdict obtained by the State against AstraZeneca in the Medicaid drug pricing suit. Judge Price upheld the compensatory damage award of $40 million and, pursuant to the statutory cap on punitive damages, cut the punitive damages from $175 million to $120 million, making the total verdict $160 million. AstraZeneca has stated they will appeal, so the Alabama Supreme Court will be looking at it. For more information, follow the link to an article on Forbes:

(www.forbes.com/feeds/ - link no longer active)

**May 6, 2008:** AstraZeneca released limited performance data for a trial using its antipsychotic, Seroquel for depression. The company released the data during a poster session at the American Psychiatric Association’s convention. The data has not been published yet in a peer-reviewed journal, so we have no information on drop out rates or whatever statistical methodology may have been used. The expanded use of antipsychotics for depression would represent a “huge tectonic shift” in treating depression - and a huge influx of profits. AZ hadn’t released any efficacy data for Seroquel XR’s performance versus placebo in treating depression (or Major Depressive Disorder, as AZ has it).

**April 6, 2007:** AstraZeneca, ‘Bucket of Money’

Group of 7 Whistleblowers Allege Off-Label Campaign for cancer drug, Faslodex, “There is a big bucket of money sitting in every office. Every time you go in, you reach your hand in the bucket and grab a handful. The more times you are in, the more money goes in your pocket. Every time you make a call, you are looking to make more money.” See:


**June 21, 2003:** AstraZeneca, the large pharmaceutical company, pleaded guilty today to a felony charge of health care fraud and agreed to pay $355 million to settle criminal and civil accusations that it engaged in a nationwide scheme to illegally market a prostate cancer drug. The government said the company’s employees had given illegal financial inducements to as many as 400 doctors across the country to persuade them to prescribe the drug, Zoladex. Those inducements included thousands of free samples of Zoladex, worth hundreds of dollars each, which the physicians then billed to Medicare and other federal health care programs, prosecutors said. The company also gave doctors financial grants, paid them as consultants and provided free travel and entertainment, the government said.

See: AstraZeneca Pleads Guilty In Cancer Medicine Scheme By MELODY PETERSEN, The New York Times

**CRP -- The Next Chapter in Medical Waste?**

The latest study on statins and heart disease, which appeared in the New England Journal of Medicine website yesterday and in all the major papers this morning, is worth a second look, not because of what it says about heart disease, which is mildly interesting at best, but because of what it reveals about profit-driven medical research and how it contributes to making the U.S. health care system the most bloated and wasteful in the world.
Jumpin’ Jupiter: Study Author Defends His Work

By Ed Silverman // September 28th, 2010 // 10:15 am

Two years ago, a study called JUPITER looked at AstraZeneca’s Crestor cholesterol pill and measured levels of a protein called CRP that can indicate arteries are inflamed and point toward heart disease. But the results prompted debate over the extent to which CRP should be used as a guidepost for treating cholesterol and prescribing Crestor and other statins to people with low cholesterol (see here).

In June, a “critical reappraisal” appeared in The Archives of Internal Medicine calling the trial “flawed,” because there were various methodological problems and a “strong commercial interest” may have resulted in biased outcomes. Nine of 14 authors had ties to AstraZeneca and the principal investigator, Paul Ridker of Brigham and Women’s Hospital (pictured), is a co-holder of the patent for the CRP test and headed the Data Safety Monitoring Board (see here and here). Yet another analysis found no evidence that prescribing statins to patients at risk of heart disease reduces the chance of premature death in the short run (see this).

Now, Ridker and co-author Robert Glynn have published a response in the American Journal of Cardiology, since the other journal would only publish a “brief” letter, which they found insufficient to explain the complexities. And it is complex, but worth reading (here is the abstract). To summarize, they argue JUPITER “addressed the core clinical question posed using the most robust and widely accepted form of clinical scientific inquiry available, the randomized-placebo-controlled, double-blind trial.”

They also insist the trial “used high levels of scientific rigor, achieved exemplary participant follow-up, used rigorous end point adjudication, prespecified a highly conservative monitoring plan in the charter of its Data and Safety Monitoring Board, and followed a prespecified analysis plan conducted exclusively on an intention-to-treat basis.”

Then, they take aim at one criticism that suggested the decision by the DSMB to halt the trial early “substantially overestimated trial benefits,” that the rules were not prespecified and that the end point used to define those rules was not defined. However, Ridker and Glynn maintain there was a specified charter that spelled out any stoppage “would require proof beyond reasonable doubt that prolonged use…was clearly indicated or clearly contra-indicated for all or some specific types of patients.”

They then criticize the critics for failing “to address the appropriateness of continuing a trial after the main study question has been answered definitively; trialists and study monitors have an ethical responsibility to stop experiments and inform their participants as well as society when uncertainty and equipoise no longer hold with respect to the question under evaluation.”

Yet another point raised by their critics was the magnitude of the effect of stopping the trial early and whether that effect is large enough to alter clinical interpretation. To that, Ridker and Glynn write “there is no credible evidence that early stopping of the JUPITER trial had anything more than a marginal effect on the true estimates of efficacy. If anything, the magnitude of benefit in the trial was increasing over time, not decreasing.”

As to conflicts and industry influence, they argue the critics did not provide any evidence to back up their claims, and goes on to assert that the trial was initiated by the study team, AstraZeneca did not play any role in analyzing the data and drafting the manuscript, or had access to the unblinded trial data until after the manuscript was submitted for publication. However, they do not address the individual ties between the study team and the drugmaker or how Ridker benefits from the CRP patent.

For those of you who read this far, one of the critics, Michel de Lorgeril, last June posted this question-and-answer on his website in response to questions from a journalist about the controversy.
ANSWERS TO R. RIDKER BY M. DE LORGERIL

1- "He says that the opening premise of your article ignores "more than a dozen major statin trials going back 15 years that consistently demonstrate efficacy for statin therapy ..."

Obviously, we are aware of the more than a dozen major articles that reported beneficial effects of statins. Likewise, we (and probably also Paul Ridker) are aware of the more than a dozen major recent trials that failed to show any effect of statins and other cholesterol-lowering drugs. All these negative trials are cited in our article. There is one exception, JUPITER published in 2008. Without going into tedious details on how recent negative and old positive trials have been conducted, we propose to simply consider the moment of the turning point.

This was around 2005-2006 (after the Vioxx and other affairs), i.e. when the new Regulations for clinical trials came progressively into force in Europe and USA. Actually, the new Clinical Trials Regulations changed the face of drug trials. Investigators and sponsors now must comply with a complex and demanding set of legal, ethical and regulatory requirements, contravention of which may lead to criminal proceedings. It would be too lengthy to go into details but you can find a simple summary of this critical issue in the following article [Review of new regulations for the conduct of clinical trials of investigational medicinal products. BJOG 2007;114:917-21]. The important thing is that there is a “before” and an “after” the new Regulations. Most trials published “after” have been negative except for JUPITER. Thus, it is important to carefully review both the methods and results in JUPITER. Then, the whole “statin story” needs urgently to be reconsidered.

2- "He says "Only an author group with a strong pre-disposition against pharmacotherapy (and data) could avoid noting what is so well documented in the medical literature and what forms the core basis of all international guidelines for the prevention and treatment of atherosclerotic disease."

This is the classical comment! Instead of speculating on our “strong pre-disposition” for anything, Paul Ridker should first explain the many clinical and scientific inconsistencies seen in JUPITER, as described in our article.
That being said, the 4 cardiologists who cosigned the present article use pharmacotherapy in their patients on a daily basis when necessary and for as long that it is in accordance with truly evidence-based medicine.

When referring to the “core basis of all international guidelines for the prevention and treatment of atherosclerotic disease”, Paul Ridker actually makes another of our points. We (and many others) think that it is high time to seriously reconsider these guidelines in light of the recent negative trials. This means critically reviewing the positive trials published before the new Clinical Trial Regulations. We are presently in the process of that review (manuscripts in preparation) establishing that most positive trials show biases similar to those seen in JUPITER.

3- “He says the early stopping rules were published in the Data Safety Monitoring Board’s charter”

We all know that early stopping rules were used in JUPITER. Statisticians have proposed various strategies to justify premature ending of clinical trials and this is the subject of a permanent controversy. See for instance the references 23, 25 and 26 of the present article. However, the most important thing is not the rules themselves but whether the rules were publically available (not only in the DSMB charter) and clearly formulated (detailed) before starting the trial, for instance in the study protocol described in reference 22 of the present article. This is not the case.

By looking at the reported clinical data, one can check whether the application of these rules resulted in any bias. Our aim was to show that the JUPITER results are not clinically and scientifically consistent. It was therefore a mistake to prematurely stop the trial.

4- “He says the curves for all-cause mortality weren't converging and your statement shows you don't understand how Kaplan-Meier curves are interpreted and drawn”

The sentence with the words “curves were converging” (in the 3rd paragraph of the section “Methodological problems in JUPITER” of our article) is a way of speaking to help nonscientist readers to understand that critical issue. When we state that the curves were converging, we refer to the original article in the New England Journal of Medicine (reference 10 of our article). It is indeed true that in a later “version” (reference 27 of our article) the converging aspect had been erased. We believe that
Paul Ridker should provide an acceptable explanation to the fact that he changed his way of presenting mortality data in the articles reporting JUPITER results. For your interest, the curves are reproduced below.

**Chapter 1**: in the first JUPITER article, we see the following graph for overall mortality. This is a scan of the figure1D in the JUPITER article (reference 10).

![Graph 1](image1.png)

**Chapter 2**: let’s have a look now at the same data presented one year later in another journal (scan taken in reference 27 of our article in the Archives).

![Graph 2](image2.png)

There is a striking difference between the two graphs although they are based on the same statistical data. On the first graph (year 2008), curves are apparently converging whereas in the second graph (year 2009), curves are diverging. This is a critical issue in the context of a truncated trial. As written in our article: “the 2008 curves suggest ANSWERS to Ridker by de Lorgeril, 2010 June 30, p.3/6
that the borderline difference between groups may have disappeared in case of a slightly longer follow-up”.

It is as if Paul Ridker and colleagues have intentionally truncated the curves (4.5 years in the 1st graph but only 4 years in the 2nd one) to render the picture less controversial.

This change is not an error or a mistake.

We avoid qualifying it so as to keep the debate at an acceptable level.

Now a few words regarding how to interpret Kaplan-Meier curves: the curves represent the ratio of the numbers of death (in both groups) to the total number of patients enrolled in the trial and still in the trial (their vital status is known) at the moment we count the deaths. Let’s look at the 1st graph. In the left part (left red arrow) of the graph, when the numbers of patients are large but the average follow-up short (one year), there is no difference between the two groups. In the right part (right red arrow), the numbers of patients are small but the average follow-up for these small groups are longer (4.5 years) and again there is likely no significant difference between the two groups. It means that at the two extreme sides of the trial (large numbers and short follow-up versus small numbers and long follow-up), the treatment seems to have no effect. This is very puzzling and a very good reason not to prematurely stop the trial.

In the 2nd graph, the curves were truncated so that at the level of the right red arrow (only 4-year follow-up) the hypothetical difference between the 2 curves may appear more convincing!

The “overall mortality story in JUPITER” is verifiable by any curious observer. This strongly illustrates that we must not blindly trust anyone (including great investigator) without careful examination of the data provided in commercial trials.

5- “He says the number of CV deaths is low because of the strict definition used for CV deaths; quite possible some CV deaths were misclassified as other deaths”

The problem in JUPITER is not only that the numbers of CV death are low, but that there is no difference between groups although it was presented as the main justification (read again the references 19 and 20 of our article) of the premature termination of the trial.

Not only the numbers of CV deaths are not indicated in the various JUPITER articles, but when we count them by indirect calculations (see the section “Clinical and epidemiological inconsistencies” of our article), we find 12 CV deaths in each group!
Paul Ridker et al pretend they used a “strict definition for CV deaths”. However, as for the “prespecified early stopping rules” discussed above, we still do not know what these “strict definitions” are.

Moreover, when we consider myocardial infarction (and we suppose that Paul Ridker and coworkers used the same “strict definition” for all, fatal and nonfatal, myocardial infarction), we see in the placebo group (where there is no interference by any medication) that there were 6 fatal infarction and 62 nonfatal infarction (a total of 68) and therefore a case-fatality rate lower than 9%. These numbers are not clinically consistent, and therefore not credible. The use of a “strict definition” of the myocardial infarction endpoint (or of any other endpoint) in JUPITER cannot explain these puzzling numbers.

There is also no explanation regarding the absence of sudden cardiac death in JUPITER although it is the simplest and most reliable diagnosis (with a very “strict definition”) in cardiology and represent about 70% of total cardiac mortality in the US population.

Finally, as we do not have access to the raw clinical data, we cannot say which numbers are wrong in JUPITER. We just can say that the process of validation and classification of the endpoints has been very problematic. In consequence, the whole JUPITER dataset appears flawed.

What becomes even more puzzling is that, on the basis of such weak scientific evidence, several articles reporting analyses of secondary endpoints and of subgroups have been published in international journals. Both types of analysis require using partial data extracted from the whole dataset. With only 12 validated CV deaths (the most objective criteria of clinical efficiency in cardiology) in each group for a sample size of about 18’000 individuals), which kind of conclusions could they seriously draw from subgroup data including only some of these CV deaths?

This is a critical issue and may indicate, as written by Marcia Angell an ex-editor of a great American journal [Angell M. Industry-sponsored clinical research. A broken system. JAMA 2008;300:1069-71], that “the industry-sponsored clinical research is a broken system”.

6- “He says “the US FDA extensively evaluated the JUPITER trial data, convened an outside board of independent scientists to further evaluate the trial, and then concluded in February of this year that persuasive data had been presented indicating that statin therapy (rosuvasatatin) was highly effective in reducing heart attacks,

ANSWERS to Ridker by de Lorgeril, 2010 June 30, p.5/6
strokes, and revascularizations among those with low levels of cholesterol and elevated hsCRP. Further, the 2009 Canadian Cardiovascular Society guidelines - the only national guidelines published since the JUPITER data became available - have fully incorporated the new findings so that (at least in Canada) real progress on prevention can be made. None of these entities have any conflicts of interest that I know of and all came to the same objective conclusion."

This may be the confirmation that the system is indeed broken.

As commented in the previous answer, we note that referees and editors in great international journals did not see any problem with JUPITER and published several versions of the same flawed trial (for instance, references 36, 37 and 38 of our article). If these referees and editors did not see any problem, is it really surprising that the experts convened by the US FDA and the Canadian Cardiovascular Society did not see any problem?

The claim by Paul Ridker that the scientific entities that support the JUPITER extension do not have any conflict of interest that he knows of is strange for anyone who knows the qualifications of most members of these entities. For instance, you could check whether some members of the Canadian Cardiovascular Society (“the only national Society that published new guidelines since the JUPITER data became available” as written above by Paul Ridker) do have some links with the pharmaceutical industry. You will find, for instance, that the treasurer of the Society himself may be known as a member of the JUPITER Study Group.

Beyond the issue of the conflicts of interest, the critical questions are therefore:

- Why did experts not see any problem in JUPITER?
- And then, if any expert has seen some problems in JUPITER, how come nobody knows about it?
THE GREAT CHOLESTEROL SCAM

By K.L. Carlson, MBA

Cholesterol guidelines have been created to increase pharmaceutical profits, not to improve peoples’ health. I know from my experience as a pharmaceutical sales representative for a statin drug. We were trained to emphasize to physicians the new lower LDL guidelines that were ostensibly created by health experts. The truth is the majority of the experts who created the lower guidelines have multiple financial ties to pharmaceutical companies. One expert was found to have ties to ten drug firms.

There is no research that supports the assumption that lower LDL cholesterol reduces cardiovascular events or death in people who have do not already have heart disease. Statins do not prevent heart disease, but that is the myth that the drug companies have made billions of dollars from for more than 20 years. The lower guidelines simply created a larger lasso to rope more people into buying statin drugs.

“The diet-heart idea – the notion that saturated fats and cholesterol cause heart disease – is the greatest scientific deception of our times…The public is being deceived by the greatest health scam of the century,” states George V. Mann, ScD, MD, the co-director of the well-known Framingham Heart Study. In the study more than 240 risk factors for heart disease were uncovered.

The fact that statins, brand names Crestor, Lescol, Lipitor, Mevacor, Pravachol, Vytorin, and Zocor, are not the heart disease preventing wonder drugs that drug companies want physicians and the public to believe is not the worst of it. Both men and women with the lowest cholesterol levels died earlier of all causes, including cardiovascular events.

The death rate was 5 times higher for elderly women with very low cholesterol in a French study reported in the medical journal Lancet.

A 15-year study of several European countries included 149,000 men and women and found low cholesterol was significantly associated with increased all-cause deaths.

A University of Hawaii study conducted over 20 years and involved 3,500 Japanese-American men found men with the lowest cholesterol levels died at younger ages of all causes. Lead researcher of the Hawaiiin study, Dr. Irwin Schatz, warns, “Prudence dictates that we be less aggressive in lowering cholesterol in the elderly.” The research findings also state: “Our data accords with previous findings of increased mortality in elderly people with low serum cholesterol, and show that long-term persistence of low cholesterol concentration actually increases risk of death. Thus, the earlier that patients start to have lower cholesterol concentrations, the greater the risk of death.”

Marketing drowns out the truth of science. The number of young Americans taking statin drugs continues to climb. Now there are more than 5 million men and women aged 20 to 44 taking statin drugs.

Women of childbearing age are especially at risk. Cholesterol is extremely important to the development of the fetus and is naturally contained in breast milk. Pregnant women taking statins have a high rate of premature births and unhealthy babies. The nonprofit organization March of Dimes has expressed its concern about the dangers to infants when pregnant women are taking statin drugs.

“The same cholesterol that we have been led by the pharmaceutical industry to believe is public health enemy number one, is now proven to be absolutely vital in the formation and function of trillions of synapses in our brains,” explains former NASA physician, scientist and astronaut, Dr. Duane Graveline. Dr. Graveline was found wandering in his neighborhood, unable to recognize his own home, only six weeks after he began taking the statin Lipitor. Fortunately he came to his senses later that day and began to suspect it was due to the Lipitor. His physician assured him that memory loss is not listed as a side effect of statins. But when Dr. Graveline suffered a second extreme memory lapse, he stopped taking the drug and wrote an article about his experience. Hundreds of people responded that they had also suffered memory loss from statin drugs. Dr. Graveline did more research and found, “Thousands of cases of memory dysfunction have been reported to the FDA’s Medwatch program, but the agency still has not acted. And most practicing physicians are unaware of the problem.”
Think of the forming brains of children. In July 2008 the American Academy of Pediatrics (AAP) published a report recommending that children as young as 2 years old have cholesterol levels tested and, based on the pharmaceutical industry’s guidelines, be put on statin drugs.

The AAP receives millions of dollars from drug companies every year and the Associated Press reported that Dr. Stephen Daniels, the lead author of the AAP report to test children’s cholesterol and give children statin drugs, admits he has been a paid consultant for drug companies.

“Cholesterol is vital to proper neurological function. It plays a key role in the formation of memory and the uptake of hormones in the brain…Cholesterol is the main organic molecule in the brain, constituting over half the dry weight of the cerebral cortex,” explains Mary Enig, Ph.D. and Sally Fallon in their report, “Dangers of Statin Drugs: What You Haven’t Been Told About Cholesterol Lowering Medicines.”

The most recent attempt to increase statin sales is the Jupiter study funded by statin maker AstraZeneca. Dr. Paul M. Ridker, in charge of the study, reports financial ties with more than ten pharmaceutical companies. Although 90,000 people were screened, less than 18,000 people were selected to participate in the Jupiter study that took place in 1315 sites in 26 countries. “If you extrapolate that, it means there are not all that many people exactly like those who were studied,” said Dr. Nieca Goldberg, Director of the women’s heart program at New York University Longone Medical Center.

As a former pharmaceutical rep. turned whistleblower, let me cut through the boloney and give you the actual facts that came from this study. All the people selected for the study were at a low risk of serious heart problems. The absolute difference in risk (the drug-company-paid researchers only talk in relative terms, not absolute) between the study’s statin group and placebo group was actually less than one percent.

The New England Journal of Medicine editorial about the Jupiter study concluded that treating 120 people who have the same health profile as the study participants for about 2 years would benefit only one person. In other words, 120 people, with a specific health profile, have to take the drug daily for about 2 years in order for one person to benefit. All 120 people would be susceptible to the multitude of the drug’s side effects. The two lead selling statins, Lipitor and Zocor, are in the top fifteen drugs for severe side effects in the FDA reporting system.

A serious fact from the Jupiter study that is not widely publicized is that the statin group developed diabetes at a higher rate than the placebo group. The development of diabetes in people taking statin drugs has also been reported in previous statin studies.

The Jupiter study was stopped early, less than two years, ostensibly so that the people in the placebo group could be offered statins. Since the negative outcome of the trial – the higher rate of diabetes, a disease that often leads to heart disease, in the statin group – was more significant than the positive outcome of one person out of 120 benefiting from the drug, I suspect the study was stopped early because the drug company was fearful of how high the diabetes numbers would climb if the study continued. Drug companies create studies to sell more drugs, not to disclose the truth.

Sources:
“Coronary Heart Disease: The Dietary Sense and Nonsense,” edited by Dr. George V. Mann, M.D., (New York:Veritas Society, 1993)
www.marchofdimes.com/aboutus/10651_11516.asp
Duane Graveline, M.D. at www.spacedoc.net
More Meta-Analysis & Fraud Uncovered in JAMA

Mark Hyman, MD authors this article: Science for Sale:

Protect Yourself from Medical Research Deception

Huffington Post | A recent study in the Journal of the American Medical Association found over 40 percent of the best designed, peer-reviewed scientific papers published in the world’s top medical journals misrepresented the actual findings of the research. The “spin doctors” writing the papers found a way to show treatments worked, when in fact, they didn’t.

Science for Sale | Doctors and health care consumers rely on published scientific studies to guide their decisions about which treatments work and which don’t. We expect academic medical researchers to determine what needs to be studied, and to objectively report their data. We rely on government regulators to prevent harmful medications from being approved, or to quickly remove harmful medications or treatments from the market.

What most physicians and consumers don’t recognize is that science is now for sale; published data often misrepresents the truth, academic medical research has become corrupted by pharmaceutical money and special interests, and government regulators more often protect industry than the public. Increasingly, academic medical researchers are for hire, and research, once a pure activity of inquiry, is now a tool for promoting products.

Science has always been considered an objective endeavor that removes bias and is inherently true and reliable. While we may acknowledge that some science is inferior in design or execution, and that there are a few corrupt scientists, we mostly believe what is published in the world’s top medical journals such as the Journal of the American Medical Association and New England Journal of Medicine can be counted on to guide our medical decisions. We still have trust in the scientific method. That trust may be misguided.

The Danger of “Evidence-Based” Medicine

Evidence-based medicine is considered the highest standard of care and is advocated as the basis for all decision making in medical schools and academic centers. The idea is that we must make decisions based on sound medical evidence. That sounds good in theory, but it only works if that evidence can be trusted; if the evidence at hand has been generated independently, without bias and with the sole desire to find the best treatments—pharmaceutical or otherwise. This model fails to work if the underlying motive is profit.

Publication Study | In a recent report in the Journal of the American Medical Association French scientists reviewed over 600 studies published in the top medical journals during an entire year, and analyzed in detail 72 of those they considered to be of the highest quality. In their analysis they only included studies with the most respected and reliable design—the randomized controlled trial. The authors of this report did not just read the abstracts and conclusions of the studies they reviewed, but independently analyzed the raw data. Their findings call into question the reliability of the very scientific papers that doctors use to make decisions regarding treatment and that the press counts on to communicate the latest medical findings.

Conclusions | They found that 40 percent of the articles misrepresented the data in the abstract or in the main text of the study. Furthermore they uncovered that in cases where studies had negative outcomes—in other words, the treatment studied DID NOT work—the scientists authoring the studies created a “spin” on the data that showed the treatments DID work.

Here is their conclusion:

“In this representative sample of RCT’s (randomized controlled trials) published in 2006 with statistically non-significant primary outcomes, the reporting and interpretation of findings was frequently inconsistent with the results.”

In plain language, 40 percent of the studies we count on to make medical decisions are authored by scientists who act as “spin doctors” distorting medical research to suit personal needs or corporate economic interests. “Spin” can be defined as specific reporting that could distort the interpretation of results and mislead readers.
If the conclusions in 40 percent of the papers published in medical journals are being spun toward independent interests, how can we consider the medicine we are practicing “evidence based?”

Consider the example of the recent large and widely quoted JUPITER trial “proving” that Crestor (a statin or cholesterol-lowering drug) could prevent heart attacks in people with normal or low cholesterol. In this trial researchers twisted the data to suit the commercial sponsor of the study. An independent review of the JUPITER trial published in the Archives of Internal Medicine showed that it was deeply flawed and the actual data did NOT show any benefit for the prevention of heart disease. (iii) If this were an isolated incident, we could overlook it. Unfortunately, it’s a consistent pattern.

**Medicine and Science for Sale**

Marcia Angell, former editor-in-chief of the New England Journal of Medicine recently wrote a scathing analysis of the infiltration of Big Pharma into medical research, education and drug policy. Aside from the $30 billion a year spent on marketing pharmaceuticals to physicians (known as “continuing medical education”), Big Pharma has turned many academic researchers into hired hands.

**Groomed to Sell** | Thought leaders from academic medical centers are provided grants to do research “contracted for” by Pharma, and the research is often designed, executed and ghostwritten by the funders. The conflict of interest statements of authors on research articles now often runs several pages long. These authors not only receive grants but sit on corporate advisory boards, receive large speaking fees and enter into patent and royalty agreements with Pharma.

**Special Interests** | Experts like these are also relied upon to create practice guidelines. These guidelines help physicians determine what medications to use and how to keep up with “best practices.” Yet the panels that develop these guidelines are full of scientists and physicians with financial ties to the industry or to the drugs being evaluated. For example, in a survey of 200 expert panels, one-third of the panelists had a financial interest in the drugs they evaluated.

**What About Statin Drugs?** | Another example: In 2004, the National Institute of Health’s National Cholesterol Education Program, dramatically lowered the ideal “bad” or LDL cholesterol level. This led to guidelines that expanded the number of Americans who “should” take statin drugs from 13 million to 36 million. There was only one problem. Eight of the nine panel members who established these new guidelines had industry ties. An independent group of over 30 scientists in a letter to the National Institutes of Health publicly opposed these recommendations.

**Financial Ties** | Even more recently, 95 of the 170 psychiatrists and contributors to the new manual for psychiatric illnesses (DSM-V) were found to have financial ties to companies that make psychiatric drugs. Studies have also shown that practice guidelines from independent groups such as the American College of Cardiology are based on inadequate or questionable science. It would appear that our evidence-based medicine isn’t based on very much evidence.

**A Threat to Big Pharma: Comparative Effectiveness Research**

A new model of research may help us sort out this messy collusion between science, government and Big Pharma. Comparative effectiveness research takes existing treatments and compares them to determine which are the most effective. Unfortunately, fear mongering and lobbying by the pharmaceutical industry for “rationed care” convinced the Senate to leave a critical provision for funding comparative effectiveness research on the cutting room floor. Apparently, independent comparisons of medical therapies, including a comparison of new expensive drugs to older, proven, cheaper drugs, was considered bad for business.

**Older Drugs More Effective** | This is all the more tragic given recent findings using this model of research. A large independent comparative effectiveness study conducted in July 2010 found older high blood pressure drugs such as water pills or diuretics to be more effective in reducing heart attacks and strokes at dramatically lower cost than “new and improved” blood pressure medication.

**Business Practices is Our Medicine** | Comparing pharmaceutical treatments to lifestyle or integrated approaches to health is even more dangerous, lest we find that lifestyle treatment for heart disease and diabetes which cost our health care system $750 billion a year works better and costs less than drugs and surgery and
has good side effects such as improved quality of life. Unfortunately, in our health care system, business trumps science every time.

**Tobacco Industry Tried To Prove No Link To Cancer** | Such confusion is not accidental but intentional. The more confusion about medication, the more Big Pharma sells. Propagating doubt is big business. These are the same kinds of techniques Big Tobacco used to great profit, claiming that scientific links between smoking and cancer were “not proven.”

**Legal Action Forces Pharma To Tell All** | Take the recent Avandia debacle. For 10 years Glaxo Smith Kline, based on their internal research, knew their blockbuster diabetes drug increased the risk of heart disease. But they hid the data. Even though it was legally required, they did not submit the data to the FDA or post it on their website. After legal action forced them to publish the data on a public website, independent scientists analyzed the data, showed it to be harmful and reported their findings. Despite this, the drug became the biggest selling diabetes drug with sales of over $3 billion a year through corporate lobbying at the FDA, medical deception and intense pharmaceutical marketing.

**Some Call It Mass Murder** | From 1999 to 2009, it is estimated there were over 47,000 unnecessary deaths from Avandia. 600,000 American still take it today. Glaxo Smith Kline was fined a few billion dollars for their deception–a fraction of their profit from the drug–and a small penalty to pay for the mass murder of almost 50,000 people. The Europeans have removed it from the market, but the FDA avoided clear action until this month. However, rather than take the drug off the market, which would have been the responsible thing to do, it is still allowed for limited indications and patients still on it may continue using it (if they haven’t had a heart attack yet and know the risks). Would you want to take it? Would you want your mother or father to take it? Hiding evidence is only one tactic Pharma uses to illegally promote and profit from medication.

**Illegal Marketing Practices & Criminal Acts** | Another is illegal marketing practices. Yet another Big Pharma company, Novartis, was fined $422.5 million this week for criminal activities. They were illegally marketing their drugs to doctors. Drugs can only be marketed for the conditions for which they were approved. If a medication, such as Trileptal (one of six illegally marketed Novartis drugs) is approved for seizures, it cannot be marketed for chronic pain.

This is exactly what Novartis and others do. This is not an oversight, a mistake or unintentional criminal activity on the part of drug companies, but a deliberate and focused strategy that feeds profits. Perhaps, they think of these criminal “fines” as part of their marketing budget.

Novartis earned nearly $10 billion per year for the drugs it marketed illegally. The $422.5 million fine is a small “marketing expense,” a slap on the wrist. They should be fined the entire amount they earned from the illegal marketing of those drugs. Or better yet, the company executives that approve these policies should serve jail time. If an individual knowingly harms or kills another human being, they are convicted and serve time. Pharma just pays a “fee” that is insignificant in the face of their total profits.

Here Are The Numbers | Novartis is not alone. They are in good company. Here’s how much the top Big Pharma companies were fined for the exact same illegal practices for which most pleaded guilty.

**Pfizer:** 2.3 billion  
**Eli Lilly:** 1.4 billion  
**Allergan:** 600 million  
**AstraZeneca:** 520 million  
**Bristol Myers Squibb:** 515 million  
**Forest Laboratories:** 313 million

**Getting the Science Wrong: Misleading Media Reports**

To get beyond this kind of industry deception, doctors and health care consumers need to be wary and read between the lines. In an era of sound bites and sensationalism, we do not receive intelligent and critical
analysis, and most importantly a coherent synthesis of scientific research. The data in any one study is part of a scientific story of how the world works, and medical research is the story of biology. Each study must be evaluated in the context of what we know, existing data, and what makes sense from a biological perspective. We won’t always be right, but we can stop the ping-pong game of what’s good and what’s bad for you that facilitates the newest, not necessarily the best, treatment, and provides fodder for journalistic sensationalism that fuels the 24/7 news cycle.

**Journal Abstracts Don’t Tell The Full Story** Often headlines are taken from the abstracts or summaries of research articles. Studies show that half the time, the abstracts don’t accurately represent the findings of the research. Even when the summary is correct, studies show that the media incorrectly reports the research findings or doesn’t place them in the historical context of other key research on the subject. No wonder patients and doctors are confused.

**Too Close For Comfort** Business interests and the incestuous relationship between scientists and industry have corrupted the landscape of medical research. The media doesn’t do a good job of investigative journalism. But there are things you can do change protect yourself.

**How to Protect Yourself From the Spin Doctors**

1. Follow the money: Be a detective and look up the articles mentioned in the news. Find the study, see who wrote it, and determine what financial conflicts of interest they have. Also check who funded the research.

2. Do your homework: Be suspicious of media reports of scientific findings. Does the finding make sense in the context of other studies and is it the best possible approach. Educate yourself by learning to use PUBMED (the National Library of Medicine) and reviewing different perspectives.

3. Does it pass the “sniff test”: Is the treatment suggested just a “me too” drug that has not been proven to be any better than existing treatments? Does it make sense to you or does something smell rotten? Trust your intuition.

4. Advocate for an arm’s length relationship between industry and academia. Write your Senators and Congressmen to develop new regulations and legislation that will build a fire-wall to protect us. Grants are fine, but Pharma should have no participation in study design and should not be allowed to interpret or publish results.

5. Demand a no revolving door policy between industry and government regulators. Former drug company executives should not be on FDA committees or involved in regulation or legislation.

6. Advocate for comparative effectiveness research. Preventing this research allows Pharma not to play fair.

7. Campaign for finance reform: If done effectively, can limit the influence of industry on government.

**Be A Discerning Reader of the News** Don’t let yourself be confused by poor reporting in the media. Learn to see through the collusion between Big Pharma and medicine by staying ahead of the medical spin doctors using these steps. For more information on the extant comparative effectiveness research between lifestyle medicine and pharmaceuticals see my recent blog posts on drhyman.com.

To your good health,

Mark Hyman, MD

**References**


(ii) Mora, S., Glynn, R.J., Hsia, J., et al. 2010. Statins for the primary prevention of cardiovascular events in women with elevated high-sensitivity C-reactive protein or dyslipidemia: results from the Justification for the Use of Statins in Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) and meta-analysis of women from primary prevention trials. Circulation. (9):1069-77.

(iv) http://bostonreview.net/BR35.3/angell.php

Mark Hyman, M.D. is a practicing physician, founder of The UltraWellness Center, a four-time New York Times bestselling author, and an international leader in the field of Functional Medicine. You can follow him on Twitter, connect with him on LinkedIn, watch his videos on YouTube, become a fan on Facebook, and subscribe to his newsletter