Wholistic Medicine: Unstoppable juggernaut or losing ground to prescription pad doctors & quackbusters?

By

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To hear critics of complementary alternative medicine (CAM) tell it, wholistic doctors such as myself are having a pervasive and insidious influence not only among medical consumers (aka the public) but we've managed to thoroughly infiltrate academia and hospitals and as a result are poised to catapult medicine back into the prescientific Middle Ages. If you compare the language and reasoning of many modern day quackbusters and so-called skeptics alongside newspaper articles from the 1950s McCarthy era you can't help concluding that we modern day holistic docs cast shadows as long and dark as those Senator Joseph McCarthy believed was the case of the communist “red menace” among Capitol Hill congressman and senators of his era. According to some of the most outspoken CAM critics we are an almost unstoppable juggernaut whose advance undoes all the gains of medical science and ultimately will result in our replacing most if not all of it with voodoo and placebo medicine. To drive home just how menacing we are the label “quack” is slapped on us in the hope (it would seem) of eliciting the kind of revulsion and fear that the label “red” once did.

Of course, some quackbusters find critically examining and challenging ideas and claims preferable to slapping individual practitioners or advocates with pejorative labels. This is surely the high road (all things considered) though seemingly not used often enough by those determined to banish CAM from the land.

There are, yes, more than a few CAM methods and practices that produce no discernible health benefits and are, in fact, without merit beyond inspiring hope or remediating a sad or bleak mood. In fact, placebos have outperformed some CAM treatments in randomized double-blind clinical studies. And yet their proponents and practitioner-users still by-and-large promote and utilize them. This makes them stubborn, misguided or delusional at best and willful charlatans or con artists at worse, right? This is pretty much the conclusion one gets reading articles on the subject penned by prominent spokespeople in the quackbuster movement. But is this always so? I would say no. Consider:

I have had many, many successes with patients that other physicians have failed to help. Much of the time the reason for my success is due to the fact I do what other CAM physicians do. We do a good job. By that I mean we review carefully all of the patient’s medical records and often spend a couple of hours asking questions of the patient and examining the patient employing tests that other physicians never use and won’t stoop to learn.
Now, if I had let the results of so-called well designed controlled studies overrule what I uncovered and used to good effect, scores of my patients who are walking around today would be occupying cemetery plots instead.

I utilize chelation therapy to treat select patients with specific vascular diseases which numerous randomized placebo-controlled controlled studies have shown to be ineffective; that is, no better than the placebo employed. All of these studies had design flaws or didn’t use doses of chelating agents matched to the patient (something a physician experienced with chelation therapy would know but which is difficult to standardize into a “one size fits all dose” required in clinical studies). But this is not why I utilize it in the way I do. What I discovered across forty years of practicing medicine and trying out IV chelation on a wide variety of patients is that there is a subset of patients whose medical histories, test results and genetic profiles tell me they will respond to chelation therapy in appreciable and quantifiable ways. In a randomized group of, say patients with atherosclerosis, given a specific dose of a chelating agent such as EDTA by IV on a set schedule, it is unlikely that enough of these patients would wind up enrolled to raise the response numbers to statistical significance. One has to identify and qualify these patients as belonging to this subset and then randomize them to either the placebo or experimental (treatment) arms of the blinded study. A study done in this way would then reveal a reversal of vascular disease in the participants who received the chelating agent vs. those who received a placebo. In addition, all chelation studies done to-date have tried to prove its effectiveness based on angiographic evidence of reduction of the amount of atherosclerotic plaque in the coronary or peripheral arteries. The reason these evaluations have failed to document the improvements that patients are feeling is because the “scientific research scientists” did not consider the chemistry of the treatment process. It turns out that chelation does not “ream” out the arteries but softens the hardened calcified plaque and artery walls. By making the arteries more elastic, more blood flows through them to the heart and legs which results in less angina and pain with walking. In my first three years of doing chelation I proved that this occurred 100% of the time in over 120 patients but I never published this because the methodology I used was not sophisticated enough to convince a cardiology journal to accept a paper describing these results As a solo practitioner I have never received any government tax payer funds that would have paid for the kind of sophisticated equipment and personnel needed to conduct such a study. All of the costs of my research have come out of my medical practice income which has made it difficult to publish my discoveries. I frankly am more interested in finding out how better to treat my patients optimally than spend my time and money trying to convince the quackbusters that I know what I am doing.

Also, I have found that when chelation is used in tandem with other therapies, in a specific way and according to treatment plans I have worked out over the decades, the clinical results tend to be good to stellar. There is much more to treating most patients than using a single modality or drug or such. Most of my treatment plans are comprehensive and impact all kinds of interacting, sometimes interlocked systems and pathways in cells, tissues and organs in ways that promote repair, recovery and even regenerative activity.
Don’t let chelation fixate or consume your attention though. This is, again, not a blanket treatment for vascular or other diseases but adroitly employed by me in a subset of patients which decades of in-office experimentation has revealed are high probability responders.

Actually chelation is not a major part of what I do on a day-to-day basis. Most of the treatments I prescribe are FDA approved and used in ways that my mainstream colleagues do. For instance, I make use of **external counterpulsation (EECP)**, a wonderful computer-driven device that has produced clinically and statistically significant results in patients with certain forms of angina in numerous well designed studies. However, I do use it “off-label” in some cases where my experience and medical judgment suggest the patient could reap clear clinical benefits. This sort of informal experimentation by doctors is actually how many key discoveries in medicine were made. Even the most diehard skeptics are reluctant to hamstring doctors to the point that their ability to innovate is compromised or even sacrificed altogether.

This in-office, off-label experimentation led me to try **hyperbaric oxygen therapy** as part of a comprehensive treatment program in acute stroke cases back in the early 1990s. This combination was, I reasoned, a logical one that should induce healing in damaged areas of stroke sufferer’s brains. With no undue trepidation I tried this on a lady who had had a massive stroke and was transferred by her family (at their insistence) to my clinic from ICU! She was semiconscious and paralyzed and uncommunicative. Exactly 24 hours later she walked out of my clinic with nary an indication she had ever had a stroke. This singular amazing result still stands as one of the few cases treated in this fashion by any doctor and would likely have prompted some to seek having my license revoked had I continued to treat acute stroke patients using this miraculous combination of treatments. One patient’s death or complication would have led to a complaint to my state medical licensing board and that would have brought my career to a screeching halt. Innovative doctors are not rewarded in medicine and we have no proper procedure to get this type of successful treatment quickly into mainstream medical practice.

In the late 90s I began consulting with doctors using umbilical cord stem cells on patients in Mexico. The clinical response in neurologic patients such as children with cerebral palsy and traumatic brain injury was in many instances nothing short of impressive, even remarkable. When this and other clinical successes (including those seen in a **preliminary open pilot study** I was part of) with cord blood derived stem cells came to light skeptics and mainstream researchers, especially those working with adult (nonembryonic) stem cells, were quick to denounce this as “quackery”, “smoke and mirrors”, “unethical” and worse. Interestingly, within a year many of the most vocal naysayers were surreptitiously steering patients they could not help to Mexico for treatment with pure umbilical cord stem cells while others had secured funding to pursue clinical studies using the very stem cells they has said could not possibly have any salutary impact on damaged brains.

Of course, the use of pure cord blood stem cells here in the US is restricted to FDA approved clinical studies with the exception of a very narrow range of diseases, mostly certain kinds of leukemia and lymphoma. The same is true of stem cell-rich bone
marrow in which stem cells are isolated and cultured or otherwise processed beyond “minimum manipulation” as defined by the FDA. But what if I took bone marrow and give it back to patients? This, I reasoned, would be augmenting a natural process insofar as bone marrow stem cells had been found at injury and disease sites in animals and humans (These stem cells had been mobilized from the marrow in response to biochemical compounds produced by their diseased and/or inflamed tissues and then homed in on these to help effect healing) In 2006 I asked one of my most FDA rules & regulations savvy lawyers, Richard Jaffe (JD, Columbia University School of Law) to check with this agency to see if I could harvest and treat my patients with their own stem cell-rich bone marrow that had not been processed beyond “minimal manipulation” (Click to read an article Mr. Jaffe wrote on this topic). The FDA told Jaffe this was OK; that it lay beyond their purview and fell within the practice of medicine (which is governed by each state’s medical board). Armed with this information I began very cautiously and carefully incorporating bone marrow treatments as part of the comprehensive disease and patient-specific regimens I crafted for such things as chronic stroke, multiple sclerosis, ALS (Lou Gehrig’s disease), cerebral palsy, traumatic brain injury, various eye diseases and much more.

As you might expect, mainstream physicians and a great many university bench researchers working with stem cells began denouncing this using almost the same terms and arguments that the critics of cord blood stem cells had used years before. This included cries of such treatments being everything from “risky” to “worthless” to “reckless”. One prominent university bench researcher even warned that we’d surely be seeing tumor formation in at least some patients with the passage of time. But in the ensuing years – more than six (6) now – and over 1500 patients treated – there have been no calamities or tumors popping up or anything of the like.

Of course, the use of stem cells or stem cell-rich biomaterial such as whole bone marrow is not without some element of risk. Even the safest and most time-tested and well honed medical procedures sometimes cause side effects or worse. But even so, to-date these whole bone marrow procedures have proved to be safe -short and long term.

The only truly disconcerting issue that cropped up during my on-going work with whole bone marrow was the fact that older patients (>40 years of age) did not on-a-whole reap the kind or degree of clinical improvements seen in younger ones. This makes sense as young people heal up quicker than older folks, due at least in part to the fact their tissues are supplied with ample quantities of growth factors, specific hormones and other compounds that they readily respond to; biochemical factors that promote tissue maintenance, homeostasis, as well as repair and restoration when disease or injury strike. Their tissue environment is also free of age-spawned and accumulated damage and with rare exceptions has only trace (if any) chemical residue from plastics and pesticides (All of which can impede various healing mechanisms including stem cell activity integral to tissue repair and restoration).

My personalized treatment programs had actually done a good job of dealing with hormone and nutritional deficiencies, as well as helping remove heavy metals and other toxic compounds from my patient’s tissues and organs. But even so their clinical improvements lagged far behind their young counterparts. And this despite the fact
stem cells from the bone marrow tissue I was infusing was flooding their diseased tissues. Obviously the stem cells were not performing optimally. After doing quite a bit of literature research and running patient blood samples through my stem cell lab, it became apparent that these stem cells were not being inhibited by anything unique to the patients but instead were simply devitalized or nominally active.

Armed with this insight I began to think about what might be done to restore these stem cells to full vigor or, barring this, to get the body to replace them. As I studied on this something came to mind: Older patients of mine who lived or spent time at higher altitudes had more vigorous stem cells than those who dwelled at sea level or below. This suggested that intermittent hypoxia might be effective, something also indicated in various published studies.

So I experimented by having patients do Intermittent Hypoxia Therapy as well as this in tandem with other treatments. Since paradoxically the flip side of hypoxia -- hyperbaric oxygen -- had also been shown to mobilize stem cells, I tried this too (alone and in concert with other modalities).

The results were better but not what I was seeking. It then occurred to me that the mobilization effects of what I was doing should be stepped up; that by purging more of these inactive or senescent stem cells I might prod the bone marrow to replace them with fresh, more robust ones.

To test this little theory out I gave my patients a series of Neupogen® (filgrastim) injections, Neupogen® is a form of a granulocyte colony-stimulating factor (G-CSF) used to stimulate the production of blood cells called granulocytes and neutrophils but which also happens to mobilize stem cells from the bone marrow. Blood was drawn pre- and post- and stem cells numbers and activities were assessed by my stem cell biologist. In time enough results were accrued to tell the tale: My “purge program” was doing just what I had conjectured it would; that is, liberating inactive stem cells which were then replaced by healthier, more vital ones!

The clinical responses of older patients treated in this fashion reflected the activity of the more robust stem cells. Indeed, their clinical improvements were occurring almost in lock-step with every improvement in my Neupogen® “purge & replace” regimen.

Ultimately I came up with just the precise program to insure that my older patient’s marrow was teaming with revitalized stem cells.

In 2011 I began using whole bone marrow to treat older children with cerebral palsy. The clinical improvements were so consistently impressive that I introduced a money back guarantee on this procedure in April of this year (2012).

Not surprisingly, according to the quackbusters what I am doing in many instances including the use of a patient’s own bone marrow is not “science-based medicine” but quackery or fringe medicine. To my way thinking it is “results-based medicine” because it is producing good clinical outcomes in the majority of those treated who follow the comprehensive regimens I prescribe. Were I to do medicine as the skeptics and critics advocate none of the progress I’ve made over the past four decades would have come
to pass. And a great many of my patients who surmounted devastating, even terminal illnesses and grim diagnoses would likely be occupying cemetery plots instead.

Yes, I could have taken the easy road to relative wealth as well as ready acceptance by the mainstream by being one of them; that is, a prescription pad doctor who tows the line and does little off-label innovative clinical work; a doc who lives the kind of comfortable, sanctioned existence that results in few genuine discoveries or advancements but insures mostly smooth sailing through the sea of medicine.

This, however, would have betrayed a commitment I made as a farm boy member of the 4-H; namely, to take their motto “Make the best, better” with me through my medical training and on into the world of medicine. This commitment led me into holistic medicine. It also placed me in a cadre of healing professionals the critics, quackbusters and guardians of the status quo slapped with the label “quack” or “doing quack medicine”; and made me the target of state medical board officials and DAs who actually talked openly of their intention to find a way to “get Steenblock”.

These are not unfamiliar responses visited upon many in my “fraternity” by those determined to make sure CAM shrivels up and blows away – or is driven into the wilderness – leaving mainstream doctors to be the sole judge of what is in each patient’s best interests.

Unstoppable juggernaut or neverending, stalemated war?

During the course of my life and medical career there is no question that there has been a tug-of-war between mainstream doctors and those of us involved with CAM or holistic health care. During my formative years chiropractors (DC), for instance, were jailed in many states. This ceased altogether when Louisiana, the last holdout on licensing chiropractors, granted them licensure in 1974. And in 1976, after years of saying that it was unethical for doctors to associate with chiropractors (“unscientific practitioners”) and that chiropractic was an “unscientific cult”, chiropractor Chester A. Wilk and ten co-plaintiffs filed an antitrust lawsuit against the American Medical Association (AMA) and ten co-defendants which led to two trials and a decision that the AMA had engaged in a conspiracy "to contain and eliminate the chiropractic profession." (Wilk v. American Medical Association, 671 F. Supp. 1465, N.D. Ill. 1987). Judge Susan Getzendanner, who presided over the second trial, added that the "AMA had entered into a long history of illegal behavior".

The naturopathic medical profession, which had a single residential school in operation when I was boy (National College of Naturopathic Medicine, Oregon), gained momentum in the 1960s and 1970s (and beyond) and today has six accredited colleges of naturopathic medicine in North America. Graduates of these schools can sit for licensure in sixteen states, the District of Columbia and the US territories of Puerto Rico and the Virgin Islands.

In addition, in 1991 Congress approved and funded the creation of the formerly the Office of Alternative Medicine (OAM) later dubbed the National Center for
Complementary & Alternative Medicine (NCCAM). Also, many major medical schools opened CAM centers and introduced CAM courses for medical students.

Naturally, there has been steady and sometimes quite vocal, concerted resistance to this by many physicians and all the members of the quackbuster community. But do all these advances by CAM practitioners and the schools of healing they represent truly signal that we CAM practitioners have the upper hand and are virtually an unstoppable juggernaut (The term I employed to open this article)?

I’m sure many doctors, skeptics and quackbusters would say, “Regrettably, yes”. Statistics and expert opinions would seem to support the notion we are indeed living in the age of “the ascent of holistic medicine”. However, perhaps this “victory” is not the sure deal many critics make it out to be. In fact, even the skeptics dispute surveys such as a very famous one that showed a large percentage of the public relied on “unconventional medicine” which appeared in the form of a paper titled "Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use" that was published in the January 1993 issue of The New England Journal of Medicine (NEJM). Many skeptics have written that not only are such surveys flawed, but even if they had been done properly they would not have supported the notion that a disproportionate number of Americans are relying on CAM medicine and treatments.

And while these same skeptics decry the growth of the chiropractic and naturopathic professions and their work and influence, the fact is many chiropractic schools are struggling to stay open and some states such as Colorado that were entertaining licensing naturopathic physicians voted down legislation that would have facilitated this.

The juggernaut is hardly winning territory on all fronts.

There have also been moves by various lawmakers to impose greater restrictions and oversight on the supplement industry and in some instances overtures to make certain supplements and herbal medicines available only by prescription. The public has rejected such moves in no uncertain terms.

However, what legislation could not accomplish the FDA and FTC have worked to bring about through moves supposed meant to “protect the consumer” but which basically protect the turf of those firms that make and sell OTC and prescription drugs. During April 2012 Presidential candidate and physician Ron Paul laid the hammer to the nail head when he openly decried the fact that "the FDA and the drug companies are in bed together" (Click to read more and see a video clip or Dr. Paul on this issue)

The mainstream media, too, has for decades spent far more time letting the antics of a small number of medical charlatans and conmen, as well as the numerically small number of problems linked to CAM practices or products, drown out an almost daily barrage of stories of injuries and deaths caused by doctors using approved drugs and treatments, the retraction of study after study due to fraud, and FDA intrusion into the practice of medicine by such measures as declaring an individual's own stem cells a drug subject to their regulation.
Trench warfare: Some mainstream doctors seize any opportunity to undermine their holistic counterparts

Many wholistic doctors I know have found themselves on the receiving end of a visit by investigators from their state medical board on the heels of having employed a natural substance such as a vitamin, mineral or herb to treat a patient who then mentioned this to his or her mainstream primary care physician. It isn’t that the natural treatment necessarily caused a problem but, rather, typically stemmed from the standard-of-care physician’s perception that the natural measure was quackery and thus constituted a gross deviation from accepted medical care. Sometimes all a wholistic doctor needs is to have his name mentioned! Many years back a lady took her son to a clinic in Mexico I consulted for to have an IV treatment with pure umbilical cord stem cells. The child subsequently developed a mild rash and the mother swung by my research institute to discuss this with me. I suggested she take her son to a hospital ER as a precaution. She did and her boy was then seen by a pediatrician who worked for six drug companies including one involved in promoting an amphetamine-like drug. The mother mentioned my name which the doctor noted and then Googled. After seeing my work with hyperbaric oxygen to treat cerebral palsy in children and consultancy work with foreign stem cell clinics he promptly filed a complaint with state authorities and I wound up facing state investigators and officials. Never mind the fact the child was never my patient and actually reaped all kinds of clinical improvements from his stem cell treatment (So much so the mother and her husband absolutely refused to cooperate with state authorities). Why would a seemingly sharp hospital pediatrician not even bother to ask what my role in the lady’s son’s treatment was? (There was none). Perhaps it was easier to make trouble for me than exert any effort to determine the facts. And the skeptics say we wholistic doctors wear blinders and cherry-pick reality!

Perhaps the fact we wholistic doctors don’t typically have the resources to defend ourselves in proceedings initiated by consumer affair agencies, state medical boards and state DA’s informs some mainstream physician’s actions against us. Sadly, I know of many wholistic doctors “under seize” who simply could not afford to hire topnotch attorneys to do battle for them and wound up losing their license or else being heavily penalized and restricted. The quackbusters not unexpectedly gloated over these decisions but, like those running the state’s enforcement machinery, threw objectivity and fairness out the window.
Concluding Remarks

I have framed the struggle between mainstream medicine & the quackbuster/skeptic collective v. we “unconventional practitioners” in terms of my own medical career to illustrate the fact that while the former makes many valid points and helps brings to light many bogus and worthless therapies, they also indulge in name-calling, intolerance, hypocrisy and judgments that are sometimes based on incomplete and even cherry-picked information. Most of them will deny, rationalize or otherwise try to weave their way around this. They will undoubtedly continue to talk about how quacks and quackery are increasingly dominating medicine, universities, medical schools and Capitol Hill. What they are actually accomplishing is to insure that the “neverending struggle” remains a genuinely perennial one. Sadly, the casualties of this ongoing war appear to be truth, fairness and patient welfare.
Supplemental & Supporting Reading

DOCTORS ROUTINELY PRESCRIBE DRUGS & DO PROCEDURES THAT ARE NOT BACKED BY RIGOROUS SCIENCE

"Reckless Medicine" by Jeanne Lenzer & Shannon Brownlee (November 2010 issue of DISCOVER magazine).

"Research shows, if patients understand the lack of evidence for effectiveness, and the risks of treatments, they would make different decisions than their doctors."

“Less than half the surgeries, drugs, and tests that doctors recommend have been proven effective”!

“87% of drug researchers and writers receive funding from the pharmaceutical industry.”

“More than 770,000 Americans are injured or die each year from drug side-effects.”

“Two drug reps were praised in a company memo for being ‘quite brilliant’ for sending their physicians sight-seeing during a presentation about low-cost safer alternatives to their product”

“Giving patients care they don’t need, and not giving them care they do need, accounts for 30% the U.S. spends annually on healthcare”

Only 1% of the National Institutes Of Health’s budget goes to research for comparing drug effectiveness, while 99% goes to pharmaceutical companies for development of new drugs!

“Most doctors are trained to memorize data, not analyze scientific data…or to think critically”
— Dean of University of California at Davis Medical School

FDA & YOUR STEM CELLS

FDA Suppressing Stem Cells Research and Cures
MEDICAL BOARDS CAN & DO RAILROAD DOCTORS

Here are two examples of how recent misconduct on the part of medical boards in two separate states, Texas and Alabama, became the focus of activism on the part of the Association of American Physicians and Surgeons, Inc:


12/21/2007

DOCTORS SUE TEXAS MEDICAL BOARD FOR MISCONDUCT

Cites institutional culture of retaliation & intimidation

The entire Texas Medical Board (TMB) and its officials have been named in a lawsuit filed by the Association of American Physicians and Surgeons (AAPS). The complaint, filed this week in District Court in Texarkana, accuses the board of misconduct while performing its official duties, specifically:

1. Manipulation of anonymous complaints;
2. Conflicts of interest;
3. Violation of due process;
4. Breach of privacy; and
5. Retaliation against those who speak out.


Hall of Shame - Alabama Board of Medical Examiners

- Politically motivated license revocation on the pretext of sloppy handwriting

The AAPS’s filing (link above) in the case of a physician named Pascual Herrara, Jr. who had his license to practice medicine revoked by the Alabama Board of Medical Examiners, is very telling because this decision was based in part on Dr. Herrara’s alleged sloppy handwritten medical notes with respect to a case involving “three young adults from prominent families died from an overdose of OxyContin in Gadsden,
Alabama” (The AAPS goes on to state in its suit that “Dr. Herrera had no connection or culpability with that tragedy, but as a foreign-born physician he was a convenient scapegoat.”)

Continuing from the AAPS “AMICUS CURIAE BRIEF OF THE ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS (AAPS) IN FAVOR OF PETITIONER” filing:

“The Commission’s asserted reasons for revoking Dr. Herrera’s license are woefully inadequate. The Commission based its revocation in part on the alleged sloppiness of Dr. Herrera’s handwriting. That rationale, if affirmed, would support the revocation of the licenses of hundreds of thousands of physicians, and quite a few attorneys as well. If that were truly the Commission’s concern, then it could simply require training and monitoring to address the issue. In fact, the handwriting of the Board’s own expert was no more legible than Dr. Herrera’s. The other cited bases for revocation are even less legitimate and self contradictory. The Commission found that Dr. Herrera failed to perform an adequate history and physical on three patients, but that he also performed unnecessary diagnostic tests on them and prescribed excessive medication. Thus, he supposedly tested too little and also tested too much.”

PEER REVIEW: IN BAD SHAPE

"Is Peer Review Broken?" The Scientist, Vol. 20, #2, page 26

Excerpt: The literature is also full of reports highlighting reviewers’ potential limitations and biases. An abstract presented at the 2005 Peer Review Congress, held in Chicago in September, suggested that reviewers were less likely to reject a paper if it cited their work, although the trend was not statistically significant. Another paper at the same meeting showed that many journals lack policies on reviewer conflicts of interest; less than half of 91 biomedical journals say they have a policy at all, and only three percent say they publish conflict disclosures from peer reviewers. Still another study demonstrated that only 37% of reviewers agreed on the manuscripts that should be published. Peer review is a "lottery to some extent," says Smith.


"The Ideological Immune System: Resistance to New Ideas in Science" (SKEPTIC Magazine Vol 1, No4)
**Flaws in Popular Research Method Exposed**

“Influential studies into subjects such as the safety and effectiveness of medicines or class size in schools could be called into question by a new report into ways of identifying research bias.

The report by a leading statistician identifies the danger of relying solely on published work during systematic reviews of literature -- a common approach to research worldwide, which is often used to inform public policy.”

**Retraction Watch (Blog) - Tracking retractions as a window into the scientific process**

**PHARMACEUTICAL FIRMS UNDUE INFLUENCE ON MEDICINE & RESEARCH**

BOOK: *On The Take: How Medicine's Complicity with Big Business Can Endanger Your Health* [Hardcover]


⭐⭐⭐⭐⭐ Big Pharma Out of Control, January 19, 2005

By [Joel M. Kauffman](http://www.amazon.com/review/R49G9T1V9JP5K)

**This review is from:** *On The Take: How Medicine's Complicity with Big Business Can Endanger Your Health* (Hardcover)

Fact-dense, well referenced, yet balanced in tone and easy to read, this book is the best exposé I have ever read on the financial conflicts of the medical profession caused by the efforts of Big Pharma, which for this review will include device and test manufacturers as well as drug makers. From pens and pads to cruises and fake consulting arrangements, Big Pharma has caused financial conflicts in many physicians and others "on the take". Many of the consulting deals are to give talks, ostensibly based on good medical science, that promote a product. Much of this is shown to occur at Continuing Medical Education courses sponsored by Big Pharma in which gifts are freely dispensed, reprints of journal articles favorable to products are handed out, and financial ties of the "consultants" giving talks are minimized or concealed.

Academic researchers are tainted as well. By being encouraged by their universities to
obtain grants with overhead from Big Pharma, they must do research that helps in product development. Agreements may delay, prevent or pollute the publication of results. When a product possibility from a government (usually NIH) grant is seen, federal legislation passed 20 years ago allows the researcher to patent discoveries, form a company, and do clinical trials on his own potential product. While this may have led to valuable results, the potential for bias at every step due to financial conflict is clearly laid out.

Journals fare little better, even the prominent JAMA, NEJM and Annals of Internal Medicine. Papers that may have been ghost-written by Big Pharma on clinical trials with selectively favorable results are published [see Joel M. Kauffman, Bias in Recent Papers on Diets and Drugs in Peer-Reviewed Medical Journals, J. Am. Physicians & Surgeons, 9(1), 11-14 (2004)]. Editors and peer-reviewers may have ties to Big Pharma. Editorials and comments in medical journals may be written by authors with financial conflicts of interest. Revealing such conflicts is mostly on the honor system at present.

Clinical guidelines for physicians are promulgated by committees whose members often have close ties to Big Pharma. The products included in formularies of HMOs, Medicare and other insurers, the only products that will be paid for, are influenced by Big Pharma, whose general lobbying efforts are already legendary.

Dr. Kassirer gives many specific examples of financial conflicts. Far from quitting with the devastating description of how bad things are, he goes on to make specific suggestions for reform, while being very realistic about their success without federal action for certain conflicts. He lists many desirable changes, such as no gifts from Big Pharma at all, boycotting meetings sponsored by Big Pharma, disclosure mandated for all financial ties, and selection of journal editors, officers of medical societies and leaders of medical schools who have no financial conflicts. He did not seem to indicate the degree of influence of Big Pharma on the FDA.

Trying not to alienate most of the medical profession, Dr. Kassirer wrote that most MDs are basically ethical and went into the profession for non-financial as well as financial reasons. Reductions in income with increased workloads due to inadequate compensation from HMOs and Medicare is one of the reasons so many MDs have looked outside normal practice for income.

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He dropped a few hints that most major classes of drugs are more beneficial than they actually are [see Joel M. Kauffman, "Drugging Cardiovascular Disease", J. Am. Physicians & Surgeons, 9(4), 98-99 (2004)], and that alternative practices are not worth
much [see Joel M. Kauffman, "Alternative Medicine: Watching the Watchdogs at Quackwatch", Website Review, J. Scientific Exploration 16(2), 312-337 (2002)]. This is a very minor blemish on one of the great exposés of all time, the "Unsafe at Any Speed" of the medical madness in the USA today.

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Daniel Haley's "Politics in Healing" describes the squashing of alternatives. Charles T. McGee's "Heart Frauds" exposes the mythology behind so much medical advice. H. Gilbert Welch's "Should I Be Tested for Cancer?" gives the evidence for the harm in excessive testing. John Anderson's "Overdosed America" reveals the extent of perverted clinical drug trials. Merrill Goozner's "The $800 Million Pill" give the lie to Big Pharma's claim that high prices are needed for the discovery of breakthrough drugs, as does... Marcia Angell's "The Truth About the Drug Companies", which also suggests how the perversion of drug trials can be halted.

**Sponsoring by the Pharmaceutical Industry Can Bias the Results of Drug Studies, Study Suggests**

**EXCERPT:**

In the current issue of *Deutsches Ärzteblatt International* (Dtsch Arztebl Int 2010; 107(16): 279-85), a research group headed by the Chairman of the Drug Commission of the German Medical Association, Prof. Wolf-Dieter Ludwig, describes the influence of sponsoring on the results, protocol and quality of drugs studies.

The authors conclude that pharmaceutical companies exploit a wide variety of possibilities of manipulating study results. Apart from financing the study, financial links to the authors, such as payments for lectures, may tend to make the results of the study more favorable for the company. Not only the results themselves, but also their interpretation is significantly more often in accordance with the wishes of the sponsor.

In some publications, the author's detected evidence that sponsors from the pharmaceutical industry had influenced study protocols. For example, placebos were more frequently used in drug studies than was the case with independently financed studies. On the other hand, some favorable effects were linked to financial support from
the pharmaceutical industry. The methodological quality of studies with industrial support tended to be better than with independent drug studies

**Docs Not Immune to Drug Marketing, Study Finds**

“Pharmaceutical promotion may cause some doctors to prescribe more expensively, less appropriately and more often, according to a new study.”

**How Doctors Rationalize Acceptance of Industry Gifts**

“Despite heightened awareness about the undue influence that gifts from pharmaceutical companies can have on doctors’ prescribing practices and despite expanding institutional conflict-of-interest policies and state laws targeted at preventing such practices, companies continue to reward doctors for prescribing their drugs with gifts ranging from pens and paper, to free dinners and trips.”

**Inverse Benefits Due to Drug Marketing Undermine Patient Safety and Public Health, Study Finds**

“Drugs that pharmaceutical companies market most aggressively to physicians and patients tend to offer less benefit and more harm to most patients -- a phenomenon described as the "inverse benefit law" in a paper from the University of Texas Medical Branch at Galveston.”

**Medicine's Secret Archives**

“In science the phenomenon is called "publication bias," i.e. bias through selective publication. This occurs on two levels: On the first level complete studies remain unpublished. For example, an analysis of 90 drugs that had been newly approved in the US showed that they had been tested in a total of 900 trials. However, even 5 years after approval, 60% of these studies were unpublished. On the second level only selected outcomes from studies are published. Nowadays researchers have to specify in a study protocol which outcomes they want to measure and how they are going to analyze them. Comparisons of protocols and journal articles of studies showed that in 40% to 60% of studies, results had either been completely omitted or analyses changed. "In this way study results are often presented in a more positive way than is actually the case," says Beate Wieseler, Deputy Head of IQWiG’s Drug Assessment Department.

This does not only affect studies sponsored by the pharmaceutical industry. In their paper, the IQWiG authors also cite an analysis in which 2000 studies on cancer topics were analyzed according to sponsorship. The proportion of published studies was extremely low: of the industry-sponsored studies, 94% were unpublished; however, even 86% of university-
sponsored studies were also unpublished. "Due to legal regulations, regulatory authorities are also sometimes obliged to withhold data," says Thomas Kaiser, Head of the Drug Assessment Department.

QUACKWATCH: HARDLY AN UNBIASED SOURCE OF INFORMATION

Quackwatch review - Is Stephen Barrett a Quack? Is he fair, balanced, or biased, by Ray Sahelian, M.D.

From How can Quackwatch be considered a "reliable source"? :

In a critical website review of Quackwatch, Joel M. Kauffman evaluated eight Quackwatch articles and concluded that the articles were "contaminated with incomplete data, obsolete data, technical errors, unsupported opinions, and/or innuendo..." and "...it is very probable that many of the 2,300,000 visitors to the website have been misled by the trappings of scientific objectivity.

From http://en.wikipedia.org/wiki/Talk%3AOrthomolecular_medicine/Archive_3#REGARDING_THE_ALLEGED_RELIABILITY_OF_QUACKWATCH:

A number of webpages (8) were selected arbitrarily because their topics were familiar to this reviewer, and these were examined minutely. The findings are used to make generalizations about the website. The section titles below are from www.Quackwatch.com, as accessed on 31 Oct 01, each one followed by Comments based on the most reliable evidence I have found.

[...BIG snip...] [...full text is at the URL...]

All 8 pages from www.Quackwatch.com that were examined closely for this review, which were chosen simply because their topics were familiar to this reviewer, were found to be contaminated with incomplete data, obsolete data, technical errors, unsupported opinions, and/or innuendo; no other pages were examined. Hostility to all alternatives was expected and observed from the website, but not repetition of groundless dogma from mainstream medicine, examples of which were exposed. As a close friend and colleague reminded me, the operators of this site and I may have the same motivation -- to expose fraud. It remains a mystery how they and I have interpreted the same body of medical science and
reached such divergent conclusions. While Dr. Barrett may (or may not) have helped many victims of quacks to recover funds and seek more effective treatment, and while some of the information on pages of the website not examined in this review may be accurate and useful, this review has shown that it is very probable that many of the 2,300,000 visitors to the website have been misled by the trappings of scientific objectivity.

At least 3 of the activities in the Mission Statement:

-- Distributing reliable publications

-- Improving the quality of health information on the Internet

-- Attacking misleading advertising on the Internet

...have been shown to be flawed as actually executed, at least on the 8 webpages that were examined. Medical practitioners such as Robert Atkins, Elmer Cranton and Stanislaw Burzynski, whom I demonstrated are not quacks, were attacked with the energy one would hope to be focused on real quacks. The use of this website is not recommended. It could be deleterious to your health.

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—The preceding unsigned comment was added by 216.86.90.44 (talk • contribs) 20:09, 28 August 2006 (UTC)
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