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## **Monopoly Medicine Squashes the Alternatives**

by Alan Cassels

After 12 years of conducting research in and around the pharmaceutical industry, I have developed a single, compelling hypothesis. Orthodox medicine, which is supported by, partnered with and sometimes dependent upon the pharmaceutical industry, has worked to squash the competition and effectively deprive us of alternatives to prescription drugs - primarily vitamins and herbal treatments - and other potentially useful treatments.

There, I've said it. The problem is I am not sure I believe it.

I mean, can Big Pharma really wield that much power over the medical orthodoxy and push complementary and alternative medicine (CAM) to the margins, where it may be ignored or otherwise not taken seriously?

If this is true, where's the evidence? Show me the smoking gun, I say.

Thus begins my journey to see if there is enough evidence to prove or disprove this theory and to determine if modern healthcare - the monolithic and largely pharma-centric enterprise that it has become - has been able to so thoroughly dominate the field of medical practice that safe and effective alternatives go unused.

Essentially, I would define "alternative" treatments as those that are not produced by corporations, which are granted monopoly licences (patents). In other words, today's medical orthodoxy largely, but not completely, involves patentable products that are controlled by federal regulation, prescribed by doctors and dispensed by pharmacists. Western industrial medicine has marginalized anything that isn't... well, industrial.

Regardless of whether a treatment is patented or not, there are commercial vendors deceptively hawking and hyping medicine of all sorts, both inside and outside the sacred paradigm of modern drugs'n'surgery medicine.

If you think that orthodox medicine has cornered the market on virtue, however, you only need remember the Vioxx debacle, a fiasco of truly gargantuan proportions, where armies of rheumatologists-for-hire, celebrity salespeople, arthritis "experts" and Astroturf patient groups all toiled together under accepted practices of modern pharmaceutical care. Yet even with all the well-meaning physicians, in the US, Vioxx morphed into a 50,000+ body count catastrophe, eclipsing anything that any unscrupulous vitamin or herb hawker has been able to perpetrate before or since.

To help me on my quest to find the smoking gun, I consulted an expert in our own neighbourhood, Dr. Warren Bell, a family physician in Salmon Arm and the president of the Association of Complementary and Integrative Physicians of British Columbia. For more than 20 years, Dr. Bell has been involved in issues of social development, the environment and global health. He speaks thoughtfully, pausing carefully to pluck le mot juste from the air, as he outlines the main reasons that alternative medicines continue to be kept out of many patients' hands.

Bell believes that any discussion about modern healthcare, if it does not include the growth of corporations, is incomplete, and he cites the increasingly large and ominous role that corporations play in defining, shaping and profiting from treating healthcare as an industry, and patients as commodities in this industry.

He also sees that the pharmaceutical industry, which is at the centre of modern medicine, employs a number of methods to deal with the "competition," including reducing the influence of a range of effective biological remedies, or CAM (complementary and alternative medicine) that may threaten corporate profits. He breaks down the methods into three broad categories: "controlling them, buying them, or discrediting them."

In terms of control, Bell refers to the modern push to use regulations to limit access to alternative remedies, the most striking example being the UN body called Codex Alimentarius, which has "... taken on the task [egged on by industry] of regulating biological remedies." The other way to deal with the competition is to buy it.

Since as much as 60 percent of the retail market for non-patentable biological remedies is owned by the drug industry, it is merely doing what many companies do: setting itself up to more readily capitalize on the markets' shifting winds. The companies can either profit from selling the alternative products or otherwise prevent those products from competing with the industry's most profitable (patented) products.

The last method, which constitutes denying or discrediting the alternatives, is where I see my search getting warmer. One of the undeniable ways that alternatives are discredited is by defeating them with science. On the surface, most of us would agree that if the alternatives can't compete with pharmaceuticals on the basis of good science, then they don't really belong in a physician's armamentarium. As a society, we decided long ago that prescription drugs should not be marketed on the basis of untested claims. Therefore, should the alternatives not also be required to similarly prove their worth?

There are a 101 ways to answer this, but suffice to say that the bar for getting a product tested in a randomized, controlled trial is high. And it is largely within the realm of the lucrative patent drug producers to fund such studies. Since the bar is money, there is an automatic financial bias; call it the bias of tons 'o' money that, from the start, molds the shape of the evidence base, which underlies modern medical practice. Basically, if you can't patent it, why would you study it?

What this means is that perhaps much of the basic research behind the alternatives doesn't actually happen because there is no commercial incentive for that type of research. That, plus the fact that the amount of investment of public money is a pittance.

Bias also creeps in through the industry facilitating studies that make the alternatives seem useless. Those negative studies are then published, stating that vitamin E, oat bran or vitamin C do a lot less than you think they do. (Big Pharma more craftily tends to just bury its negative studies.) According to Bell, all of this helps "... facilitate the professional scepticism, which allows criticism [of the alternatives] to happen with ease."

While Andrew Saul, assistant editor of the online Journal of Orthomolecular Medicine (JOM) <http://www.orthomed.org/jom/jom.html> would agree with Bell, Saul would go much further. In an interview from his office in upstate New York, he tells me that "replication" studies to prove or disprove previous research are often set up to fail. Orthomolecular medicine uses high doses of vitamins to help treat and cure a variety of diseases from psychiatric illness to cancer. Despite very good evidence underlying orthomolecular medicine, there has been some activity to keep it at the margins. He tells me about a study that came out of the Mayo clinic a few years ago slamming vitamin C in cancer treatments.

It appears the Mayo clinic was trying to replicate some of the early work done by vitamin pioneer Linus Pauling, who believed that high doses of vitamin C would strengthen the immune system. Pauling tested intravenous vitamin C (about 10 grams per day) and found that it extended the lives of cancer patients. After the Mayo clinic published its replication study (showing it didn't work), Pauling critiqued that study in detail and pointed out that where his research tested mega doses of intravenous vitamin C in cancer patients, the Mayo clinic study used oral doses. Curiously, those important critiques of these alleged replication studies, which show the alternative to be not so terrific, gain wide currency and become well known in medical circles.

So who would push the uptake and widespread attention to vitamins-don't-work" studies? Is this the smoking gun?

If you followed the money, you might find a guiding hand, but not necessarily

the smoking gun in the industry's efforts to discredit the alternatives. We know there are more than 100,000 drug detailers (drug salespeople) on the streets in the US and about 5,000 in Canada, who, in their daily visits to your and my doctor could very easily facilitate the delivery of the latest study showing that vitamin D didn't fare so well in osteoporosis-prevention, (delivered by a rep promoting the company's osteoporosis drug) or that vitamin E was less than stellar in treating heart disease, (dropped off by a helpful cholesterol drug saleslady).

Are there any examples where the drug industry has actually funded a study to show that the alternative competition (herbal treatments or vitamin therapy) has been proven in a clinical trial to be just plain lousy? Typically, the drug manufacturers wouldn't want their fingerprints on such studies, but one recent example that comes to mind, and there are many more, involves a study of St. John's Wort (a flowering herb) for treating mild to moderate depression.

Other cultures have embraced herbal treatments more fully than we have in Canada and I bet Canadian doctors would be surprised if they knew that St. John's Wort is the number one selling antidepressant therapy in Germany. There are more than two dozen published studies that show St. John's Wort improves depression in patients, compared to placebo. Yet some say the studies are not without their weaknesses, citing short trials and small samples of patients, a criticism you could level equally at most tests of patented antidepressant therapies in use today.

In April 2001, drug giant Pfizer, which sells sertraline (Zoloft), funded a study that compared its drug to St John's Wort extract and placebo in 200 patients over eight weeks. It found, surprise, surprise, that St John's Wort "failed to produce significant differences vs. placebo." Time to jettison St. John's Wort? Not yet.

A year later, a study which tested remission for severe depression found the placebo beat both St John's Wort and Zoloft, and another study with 375 patients showed that St John's Wort "produced significantly greater reduction" in depression scores over the comparators. You can imagine which study would more likely be presented to our doctors during after dinner talks or dropped off at physicians' offices by those thousands of drug reps. The message is out and driven home by repetition: St. John's Wort bad; Zoloft good.

Another way to make the alternatives look bad is through skewing the research of those alternatives. In the words of Dr. Bell, who sums up the state of research in vitamin therapies, "If you want to show something doesn't work, then use too small a dose, for too short a period, on a condition where any effect would be modest at best, slow to be achieved, and require largish amounts of the substance in question. The results, often, are a foregone conclusion."

Recently, there has been a spate of meta-analysis studies (studies that look at an overview of a body of studies), which has shown vitamin therapies to be losers. One recent meta-analysis of vitamin E included nearly 20 studies, all of which were positive for the vitamin's benefits for cardiovascular disease. However, two of the studies included were negative, and in the magic of statistical re-analysis, the weight of those two negative studies tipped the balance in favour of an overall negative result. Message to doctors? Forget vitamin therapies.

I felt I was getting warmer and wanted to see what has been done in terms of basic research on alternative therapies. I only had to travel a few kilometres to visit Dr. Abram Hoffer, who runs the Orthomolecular Vitamin Information Centre down on Quadra Street in Victoria.  
([www.orthomolecularvitamincentre.com/](http://www.orthomolecularvitamincentre.com/))

Now in his late eighties, Hoffer is one of the true granddaddies of orthomolecular medicine. One of his key contributions to medical knowledge is his research in using large doses of vitamins to treat people with mental illness. He tells me he's successfully treated thousands of schizophrenic patients, of whom 85 percent are "normal" after two years of treatment. By "normal" he means that his patients are returning to productive lives within society, able to do productive work, have relationships and so on.

As well as vitamin therapies (as opposed to toxic drugs), Hoffer saw better housing and decent nutrition as important in treating schizophrenia. How Dr. Hoffer's treatments would fare against what is now standard schizophrenia therapy - widely-prescribed, very powerful and somewhat toxic anti-psychotic drugs, which patients sometimes stay on for life - is hard to say given that those comparative studies have not been done.

As someone who has worked from the margins of medicine for nearly five decades, Hoffer stands as an important researcher in a field that has essentially been sidelined and marginalized by orthodox medicine. Even with Pauling's high profile (he is the winner of two Nobel Prizes) as a drawing card, orthomolecular medicine has never seen the light of day in orthodox circles. Just ask anyone who treats cancer patients or schizophrenics whether they would consider using high-dose vitamin therapy and they will likely look at you as if you're some kind of quack. And they will then say that there's no evidence for those therapies.

End of story.

Hoffer admits that most physicians believe nutrition plays a large part in the healing arts, but he knows that the average medical school curriculum is almost entirely deficient in any education on nutrition, other than perhaps a few hours over four years of medical training. By contrast, he notes that naturopathic

doctors spend about 30 percent of their education studying nutrition. Dr. Bell also echoes the deficiencies in current medical training, noting that other potentially important aspects of health, such as exercise and environmental influences, are simply not taught at all.

While most physicians might dismiss alternative medicine as something that lacks a solid base of research, there is, in fact, decades of research out there, much of which doesn't see the light of day in today's medical schools. Hoffer, for example, started doing the first double-blind placebo studies using vitamin B, also known as niacin (three grams per day), to treat schizophrenia in 1952. Unfortunately, he began this research at a time when the new forms of powerful psychiatric drugs were just being developed by pharmaceutical firms and enthusiastically embraced by psychiatrists as the "modern" way to treat severe mental disturbances.

But surely alternative medicine gets published and exposed to the anvil of peer review, or criticism from peers, to separate the base metals from scientific gold. For some commentary on the published science around orthomolecular medicine, I go back to Andrew Saul.

Saul confirms that Hoffer was considered an early threat by the pharmaceutical establishment and that as he started to publish his research, the psychiatric profession basically closed ranks behind him.

"They wanted to make sure that this upstart wouldn't produce any conflicting treatments," Saul tells me, adding that although Hoffer's early research was published, "he was warned from psychiatry that he would never publish again." Hoffer then started his own journal.

Similarly, there may be other methods that continue to sideline alternatives, such as orthomolecular practitioners. Hoffer's Journal has been published for 39 years, but it has never been indexed on Medline, the world's premier medical journal index.

If one wants their research exposed to the big leagues, getting their journal indexed on Medline is vitally important, as that's where all the serious medical literature is indexed and stored. Medline is considered the world's medical "Library of Record," where medical researchers can conduct quick and precise searches through an exhaustive repository of millions of journal articles.

Yet it appears that after five attempts, the National Library of Medicine in the US, the body that runs Medline, continues to refuse to index Hoffer's Journal of Orthomolecular Medicine. Why?

Andrew Saul would say this is the smoking gun I am looking for: clear evidence of an organized effort on behalf of the drug industry to dismiss and disallow

alternative medicine by not allowing the Journal of Orthomolecular Medicine (JOM), which contains nearly four decades of peer-reviewed science, into its club.

Saul says point-blank that the “National Institutes of Health are in bed with Big Pharma” and that “there is so much health research money from Pharma, that they pretty well have a lock-step on what is considered good research and what is considered bad. He maintains that institutionalized medicine is actively biased against vitamins and points to JOM being continually rebuffed by Medline as clear evidence of bias.

Another researcher, Dr. Steven Hickey from Manchester in the UK, has dug into the Medline conundrum, trying to verify Saul’s claims.

Hickey tried to submit an application to index JOM, stating that his application was “aimed at testing your [Medline’s] responses and, in that, Medline has failed rather miserably. Medline is filtering out important information concerning people’s health on the basis of prejudice and profit for the pharmaceutical companies. The result is that people will be unnecessarily sick and will die.”

In the course of his application, Hickey wrote to Sheldon Kotzin, the administrator who oversees the committee that indexes journals for Medline, complaining that the committee is biased by its very nature. He noted: “The appropriate metaphor is this: if the prosecutor chooses the jury, the result can be a foregone conclusion.” Despite being given ample opportunity, Kotzin didn’t reply to these accusations.

Some might say that the tug-of-war is between a journal that believes it deserves recognition from the medical community and the gatekeepers of that community, who decide that membership is a private matter. Is this the smoking gun that delivers the clearest evidence yet of systematic bias?

There is no doubt that bias is at work everywhere, especially from within the conventional medical community, which sees itself as waging perpetual war against quackery. But what is maintaining that status quo? Bell maintains that there is an inherent bias in conventional medicine against “unproven” complementary and alternative medicine (CAM) approaches. He points to a most interesting study in Germany that may provide some of the strongest evidence of bias yet.

A randomized, controlled study of reviewer bias against an unconventional therapy carried out in Bad Elster, Germany, was designed to test the hypothesis that experts, who review papers for publication, are prejudiced against an unconventional form of therapy.

The investigators produced version A and B of a short report relating to treatments of obesity, which were identical except for the nature of the intervention. Version A related to an orthodox treatment, version B to an unconventional treatment.

The investigators found that the reviewers, unaware that they were taking part in a study, were three times more likely to favour the orthodox version of the paper and rate it as acceptable. The researchers conclude: "Authors of technically good unconventional papers may therefore be at a disadvantage in the peer review process." The researchers maintained that this obvious bias in the minds of reviewers shouldn't preclude publication of their work in peer-reviewed orthodox journals, a somewhat laughable assertion given the nature of the evidence they just discovered.

A final point needs to be made about how the promoters of alternative medicine tend to get lambasted by the medical orthodoxy. Just last May at a meeting of the World Health Assembly in Geneva, Prince Charles gave a speech promoting complementary medicine, saying that Britain's National Health Service needs to pay for some proven alternative treatments.

This prompted a stinging rebuke from the dyed-in-the-wool medical orthodoxy. A group of 13 scientists, which included some of the most eminent names in British medicine, stated in a letter that they objected to the National Health Service paying for these CAM remedies.

The scientists wrote: "Public funding of unproven or disproved treatments, such as homoeopathy and reflexology, which are promoted by the Prince, are unacceptable while huge NHS deficits are forcing trusts to sack nurses and limit access to life-saving drugs."

It's pretty clear that this is not about what works, but rather what will be paid for. In order for orthodox medicine to survive, it must essentially ensure the competition doesn't receive funding. And at least in BC, which in recent years has been reining in the funding for alternatives, this is essentially what is happening.

Back to my original hypothesis: orthodox medicine is shunting aside alternative medicine. But where's the smoking gun?

I don't think there is one. This is a situation where "death through a thousand cuts" means that alternative medicine will continue to be marginalized. There is much prejudice, bias and outright ignorance on behalf of the medical community against those treatments that don't fit the pharma-patent mold. And it is increasingly clear that overlooked medicines are largely being kept out of our reach.

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