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THE SCRIPT

University of Houston **College of Pharmacy** **Student News**

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sine remediis medicina debilis est

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The Script is an unofficial student managed publication that provides the University of Houston College of Pharmacy student body with news, articles, and opinions relating to our school and profession. **If you would like to make a contribution or submit an event please do not hesitate to contact us; we'll even help you with writing and editing!**

The Script is available online and is also posted on the board in SR 130.

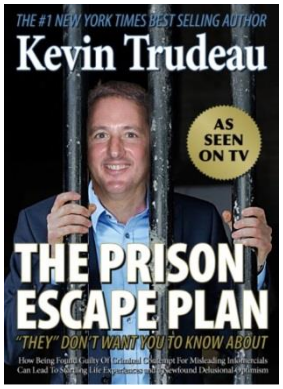
Kevin Trudeau Goes to Jail*: Hidden assets "THEY" don't want you to know about*

By **ROBERT MILLER**

What defines a con artist? Many people are actually *True Believers®*, who unintentionally fraud the public with their dubious medical products because they sincerely think they can help people. To be a con artist, an element of intention is necessary. Kevin Trudeau belongs to the latter category, but also takes it to an extreme that borders sociopathy. Fortunately, despite the clamor of thousands of adoring fans, the infomercial and late-night television huckster was sentenced to 10 years in prison stemming from a criminal contempt conviction in a previous case. *But who is Kevin Trudeau, and how did his books come to dominate the coffee table of that one crazy aunt or uncle everyone has?*

While many people recognize Kevin Trudeau as the author of numerous popular medical and self-help books – *Natural Cures "They" Don't Want You to Know About*, *More Natural Cures Revealed*, and *The Weight Loss Cure "They" Don't Want You to Know About* – his origins are not in medical writing, but in multi-level marketing. In the early 1990s Trudeau was involved with a company, *Nutrition for Life,* which was eventually exposed as a pyramid scheme; both the company and Trudeau were heavily fined. Following this, Trudeau moved from selling marketing to selling actual products. During this time, he also spent 2 years in federal prison for committing larceny and credit card fraud. Alongside his dubious medical 'breakthrough' products, he also offered advice on weight loss, debt relief, and addiction recovery – whatever your problem in life, Trudeau was coincidently and conveniently an expert.

In the United States, medicinal pharmaceuticals for treatment of a disease require rigorous testing for safety, efficacy, and quality. However, because of a brilliant piece of legislation known as the Dietary Supplement Health and Education Act of 1994 there is a simple work-around for companies interested in selling pharmaceuticals that do not want to subject their product to such expensive research and trials: As long as you do not claim that a product is used to treat a particular disease, you are free to sell almost any pharmaceutical product. Dietary supplements belong in a comical legal category – somehow they are both food and drug, yet neither – and it is with these products that con artists always find a way. Trudeau began selling the dietary supplement coral calcium. As relaxed as the DSHEA-94 allows for dietary supplement marketing, Trudeau managed to overstep his bounds. While 'functional' statements such as "*boosts the immune system*" or "*promotes a healthy liver*" are legally acceptable (and medically meaningless), stating your product can cure cancer is a clear violation – and this is what Trudeau did. Though the FDA could not get involved, the FTC was able to take action. In 2003, Trudeau agreed to a preliminary injunction that prohibited him from making claims for *Coral Calcium Supreme®*, effectively banning him from marketing his supplements directly to the public. To clarify, he was perfectly free to continue selling coral calcium, but without his marketing pitch of 'curing', the product would have no advantages over other coral calcium products on the shelves.

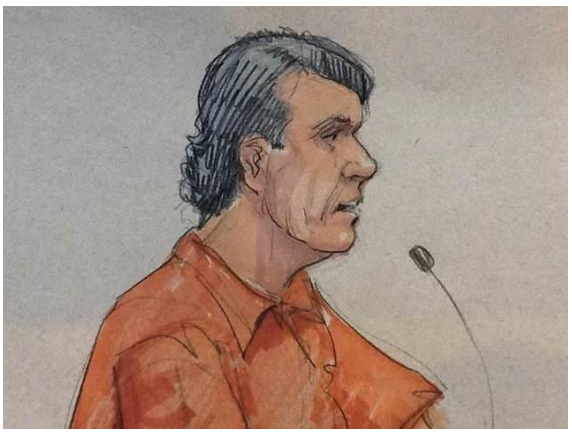


Trudeau found a work around. While he could no longer sell his snake oil directly, he could write a book that recommended his products, which could then be obtained from his online website. In 2005, *Natural Cures "They" Don't Want You to Know* About became a quick success, both being sold in bookstores and through his infomercials. Surprisingly (or not), there were no actual cures described, but only a tirade against the medical-industrial-complex, *Big Pharma*, the FDA, and other groups that represented who "*They*" are. Only at the very end of

the book were the cures located – they could be found online after purchasing a subscription to Trudeau's website for a modest annual fee. In addition to his screed against all things medical, the book also promotes AIDS denialism (the belief that HIV is not a cause of AIDS) and denies the genetic basis of cancers (the belief that all cancers arise from environmental factors). No books contain citations of actual clinical evidence for any of his medical claims, and the few that exist are strongly misrepresented.

All through the past decade, Trudeau either managed to dodge regulators or was able to talk down fines to a reasonable charge. After all, with millions in profits, a few ten-thousand dollar fines are no longer punitive, but merely the cost of doing business. Instead of the constant violations and criminal conduct harming his reputation, he sold the FTC intervention to his customers as proof that "*They*" were out to get him and that it was more evidence he was really onto the secret of healthy living that the pharmaceutical companies did not want released to the public. Like a televangelist, Trudeau took on the role of charismatic pastor and anyone skeptical of the medical establishment gladly became his flock. This is the fundamental logical leap conspiracy theories have to make as they grow in scope; eventually evidence *against* the conspiracy is perceived as more evidence *for* the conspiracy. Trudeau's primary tool to push back against the FDA was to claim that prohibition of his ability to market was a first amendment violation; basically, he felt that by publishing a book he was protected since he was only providing information and not a product. However, medical information is not entirely protected by free speech, as any health care provider can attest, and there is a clear precedent in the United States legal system that medical information should not be *caveat emptor*. The unclear legality of this approach allowed him to drag through the legal system as he continued to profit through his books.

In 2007, the fines stopped being a slap on the wrist and started to become serious. Trudeau was found to be in contempt of court for violating his previous court order in 2003 and was fined over $37 million dollars. This number was not randomly selected, but a calculated value based on the amount of money Trudeau had taken in from deceived consumers. Though he made an effort to appeal, it was dismissed in 2011, and the fine was determined appropriate by the Court of Appeals. Over the next two years, Trudeau began to hide his assets overseas in order to protect them from the court receivers. Somehow, Trudeau could claim poverty with a straight face while also being able to afford one of the best legal defenses money could buy. But to no avail. On March 17, 2014, Trudeau was sentenced to 10 years in prison for failure to pay his previous fines, though he is presently moving to appeal.



While this is probably not the end of Kevin Trudeau, it is at least a reprise from his predatory medical practices. It is now important to ask – what have we learned from this as a society? First, we've learned that fines are often not a penalty. The public might see millions in fines and be surprised by such high numbers, but for wealthy individuals and especially corporations, this is simply 'the cost of doing business' and only ends up on an accounting spreadsheet. Second, we do not have a sufficient legal system for dealing with professional con-artists. Essentially, the legal system is blind to past events. Individual, small acts of criminal activity are rightly punished, but the *pattern* of criminal activity is not taken into account. As a result, an arms race between the legal system and the criminals takes place, and the public receives financial collateral damage rather than justice.

EDITORIAL

Rise from the ashes... take the smokeless road

By CHIEMEKA IKE

Recently, *CVS Caremark*, a pharmacy retail chain giant, made a bold move towards better health by announcing its plan to kick out an enormous source of revenue, cigarettes. The company announced that it would stop selling all tobacco products in all its stores (approximately 7,600) by October, saying the products conflict with its goal of helping people stay healthy. E-cigarettes were not spared either even though they are purported to be less harmful than traditional smokes. By the company's estimate, the decision to drop tobacco means it will forgo about $2 billion in annual revenue, about 1.5 percent of total sales.

What's the big deal?

According to the Centers for Disease Control and prevention, 18.1% of American adults are current smokers, representing about 42.1 million Americans. In lay terms, about one in five people in the United States are smokers. Cigarette smoking is responsible for more than 480,000 deaths per year in the United States, including an estimated 42,000 deaths resulting from secondhand smoke exposure. This is about one in five deaths annually, or 1,300 deaths every day. The cost of healthcare attributed to cigarette smoking is massive: More than $289 billion a year, including at least $133 billion in direct medical care for adults and more than $156 billion in lost productivity**.** About $5.6 billion a year in lost productivity is caused from exposure to secondhand smoke. Smoking causes cancer, heart disease, stroke, lung diseases (including emphysema, bronchitis, and chronic airway obstruction), and diabetes.

How exactly will this play out?

No one really knows how this change will play out. One thing that is certain is the potential impact of such a stance. More difficulty accessing cigarettes might be a deterrent against smoking. While we know customers can always go to the nearest convenience store or retailer, at least this makes it less available and could possibly reduce cigarette smoking. One can hope that other pharmacy retail chains will naturally follow in CVS's footsteps. Additionally, antismoking groups and health care professionals might probably use CVS's decision to try to put pressure on others to consider doing the same. Hopefully, this move will snowball into a giant anti-smoking campaign and lead us to a smokeless society and also contribute to lowering our ballooning healthcare costs. It is hard to predict with much certainty, but drugstore chains are fast turning into big players in the nation's health care system; a system plagued with a shortage of primary care doctors and expanding access to health care coverage under the Affordable Care Act. An uncertain, yet exciting future awaits CVS and retail pharmacy in general and the possibilities are endless!

EDITORIAL

Hormone replacement therapy and breast cancer*: Poster child for poor epidemiology*

By ROBERT MILLER

Hormone replacement therapy generally refers to the administration of estrogen plus progestin to women who have reached menopause. HRT is used to treat menopausal symptoms – painful sexual intercourse, uncomfortable and frequent urination, night sweats, hot flashes, emotional lability, palpitations, and insomnia. During the 1990s, one could have believed that a venerable pharmaceutical fountain of youth had been discovered in hormone replacement therapy, and it is clear that manufacturers in the early days of HRT did not adequately assess risk with proper clinical trials. Though many cohort studies showed no such risks, criticism over possible increases in heart disease and cancer began in the 1980s. However, it was not until 2002 when the Women's Health Initiative (WHI) study was published with its disturbing findings that HRT not only increased the risk of cancer that those in opposite had the evidence of harm they were looking for. Given the financial cost of the study, the prominence of the researches involved, and its publication in the most prestigious journals, these findings quickly received both public and medical attention and almost overnight the HRT prescription rate fell by half. However, one aspect of the study that did not receive much public attention was what the actual increased risk was, and how did the WHI study fit in with all the data that already existed on HRT risks?

The research surrounding HRT is an important lesson on the fundamentals of epidemiology. Epidemiological papers should be seen as pieces of a puzzle, rather than as individual final statements that constantly rewrite each other. Historically, smoking serves an excellent example. For obvious ethical reasons, no randomized controlled clinical trial could be used to demonstrate the harms of smoking; however, a large variety of epidemiological studies looking at the problem with different approaches and perspectives were all consistent with each other that the harms were real. The public (and unfortunately many health providers) tend to view the 'latest and greatest' publication that receives media attention as an "update" rather than an *addition* to a growing library of knowledge. The fundamental rule of science is to examine all of the data together and let the chips fall as they may; science is not like other cultural institutions such as debate where evidence simply means finding something that supports a position that is already established. The WHI had strengths and weakness and undoubtedly contributed to the literature, but it cannot be the final word – no paper ever can.

Another important lesson is the difference between absolute and relative risk. While it is true the Women's Health Initiative found an increased risk of breast cancer, the magnitude of that risk is greatly elevated by reporting only its *relative* increase rather than its absolute increase. The use of Premarin and progestin was shown to have an increased relative risk of 1.24 for breast cancer – this means the association between HRT and breast cancer is 24% greater compared to controls. This sounds concerning until you realize that because this is only a relative risk, it means nothing without being contextualized to the baseline rates of breast cancer. To understand why, take two considerations: First, while HRT has a 1.24 risk ratio associated with its use and developing breast cancer, the consumption of fish or grapefruit in your diet carries a similar relative risk. Alternatively, compare these numbers to the something *we know* is a health risk such as smoking: The relative risk increase for smoking is 26.07 – someone who smokes is over 26 times or 2600% as likely to develop lung cancer as non-smokers.

Yet another lesson HRT teaches us in is to be cautious of *subgroup analysis*, or what is more cynically called in epidemiology a *fishing expedition*. To honestly conduct a study, one should form a hypothesis first and then test it against the null hypothesis. This is the basis for using a P-value. A P-value cannot prove anything, because to use a P-value as proof is to make a tautological statement – *assuming my data is true, the probability the data set would appear this way randomly is low, therefore my data is true* – one can easily notice the circular reasoning. However, P-values are not meaningless and when used properly serve a purpose. However, imagine you completed your research and your findings turn out to be false; disheartened, you might be tempted to go back through your data and look for another potential association. However, this is no longer in the scope of your experiment to make such a conclusion. Subgroup analysis is useful for determining what the hypothesis of the *next* research project should be, but retrospective analysis is extremely prone to turn up false-positives. Remember, the standard $\alpha = 0.05$ we use for statistical significance means that we are willing to accept a 5% chance of the data tricking us – so ask yourself what happens when you perform 20 such comparisons. The more comparisons you make with your data, the more rigorous you have to be with how you set your α level – this is called correction for multiple comparisons. If you're losing track of why this is relevant, the 1.24 risk ratio for HRT and breast cancer was *not even* statistically significant. Though unreported in the media, a follow-up 2006 update on the same cohort patients did not show a statistically significant increase in breast cancer. Again, compare this to the epidemiological data on something like cigarette smoke – studies have variable findings and the degree changes based on how the data is assessed, *but there are no studies showing cigarette smoke is harmless* – the results are consistent. The same cannot be said of the literature on HRT and breast cancer.

Consider the following results that can only occur from subgroup analysis. The Nurses' Health Study found no increased risk of breast cancer among women on HRT. However, when subgroup analysis was applied it was "discovered" there was an increased risk shown for women who had been on HRT for 5 years… but not for women who had been on HRT for 10 years. In contrast, when we look at women who should in theory be the *most* susceptible to breast cancer, those with BRCA1 or BCA2 mutations, we find that HRT use does not correlate with an increased risk of cancer at all. The lesson is that while there are some exceptions, a dose-response relationship should be present with pharmaceutical interventions.

Lastly, though not necessarily an epidemiological issue, is the concern that the medical community exhibited an attitude of *do as I say, not as I do*. For years the rhetoric in health care has been one of stressing the importance of informed decision making shared between the patient and the physician and a subsequent move away from paternal medicine. The use of HRT is an excellent example of such an opportunity – it has documented cardiovascular risks, though small, but it also came with clear and marked benefits for the women who used them for menopausal symptomatic relief. Women should have been given the risks in its proper contexts and allowed to make a decision. Instead, health care committed the nirvana fallacy – the belief that unless a therapy can be completely free of adverse events it cannot be considered useful. Needless to say, this is a naïve attitude to have in medicine – there is a cost to everything, and decisions always require analysis. Ironically, in its effort to protect women by marginalizing the use of HRT, the medical community instead belittled their ability to make an informed decision about their own health and categorized their symptomatic conditions as irrelevant concerns.

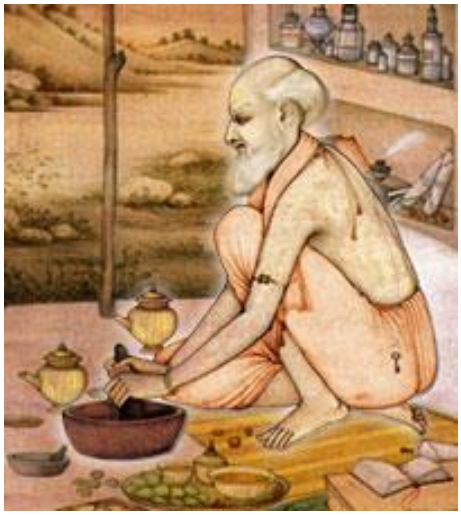
OPINION

On Allopathy

By: ROBERT MILLER

"*Allopathic medicine only treats the symptoms of a disease, but not the root cause*." This is a phrase that anyone who is involved in health care has heard in some varied form, but what does it actually mean? Often in our culture we reduce complex conceptual frameworks into small soundbytes, and we forget about the astounding amount of implicit and explicit assumptions that go into such statements. It can be useful to sit down and dissect such concepts, both analytically and historically, and see if they actually provide useful distinctions, or simply turn of phrase we have inherited as a tradition.

First, one has to ask: *What is the origin of allopathy as a concept?* The etymology of **allopathy** derives from the Greek "*other suffering*"; the term was coined by Samuel Hahnemann to differentiate the medical practices he observed in his own time from his own philosophy of homeopathy. Homeopathy sought to cure disease by using remedies that produced similar symptomatic responses in those who imbibed them. Hahnemann believed that in dilute concentrations, these same substances would produce an inverse response and treat the symptom; this system was based on his understanding of particular philosophy of vitalism. In contrast, allopathy would find remedies to treat symptoms by producing effects that *opposed* those brought upon by a particular illness. While the concept of vitalism has been replaced with pseudoscientific concepts such as "water memory" as a fundamental explanation as to how homeopathy should work, this approach of *like-cures-like* remains the general approach of homeopathic prescribing practices to this day.



It's somewhat anachronistic to be overly critical of Hahnemann: His era was not science or evidenced-based medicine, but of heroic medicine in which the sheer magnitude of an intervention, rather than its outcomes, was a measure of success. Consider, for example, that homeopathy is actually a reasonable critique of the humoral theory of medicine – bloodletting certainly qualified as a heroic intervention and its use was congruent with Galen's theory that emphasized balancing substances against each other; in this case, too much blood required its removal. Certainly, Hahnemann had one thing going for homeopathy – it was safer than medicine at the time. Armed with no understanding of the germ theory of disease and only a rudimentary knowledge of the alchemical, most traditional medications were toxic, unsafe, and addictive; and surgery was almost always more of a danger than the conditions it sought to treat.

However, this is 2014, not the early-19th century; does "*traditional*" "*Western*" medicine actually practice allopathy? While it's certainly true that many pharmacological properties could be said to be an "*intervention of opposition*", it's dubious that this is actually a guiding philosophical mindset in comparison to rational drug design. In perhaps the most amusing historical ironies, one could argue that vaccination is an application of the homeopathic philosophy – yet, most practicing naturopathic and homeopathic practitioners are staunch anti-vaccinationists.

Second, it is also useful to ask the question: *Is Western medicine really focused on symptomatic relief, or is that simply the nature of medicine in general?* One does not need to look far to observe some of the truly astounding successes in Western medicine. It's easy to maintain our perspective simply from where we stand now, while we forget where we were only a century ago. Vaccines have nearly eradicated some of the most devastating contagious illnesses in the developed world. Those with type-1 diabetes are no longer subjected to cruel therapeutic diets and slow painful deaths, but can be given insulin produced through recombinant DNA technologies. Immunosuppressants have made the entire field of organ transplantation possible; much like the anti-septics did over a century ago for general surgery. If you are looking for an example in our own lifetime, it is amazing to see that AIDS has changed in *only three decades* from an unknown disease and guaranteed death sentence to what is essentially a chronic illness that can be managed with medication. The most recent epidemiology reveals that those with AIDS and are managed with medications do not have significantly less life-expectancy than the normal population. It raises the question – if these are the success of a flawed and misguided reductionist Western medicine that 'only' treats symptoms, then what has the alternative given us in terms of disease state reversals or cures that can be used as a comparison?

A perusal through the homeopathic section of your local Whole Foods reveals that despite claims of treating the "root cause" of a disease, homeopathic medicines are marketed predominantly for a wide-range of self-limited, minor illnesses. Many purport to treat acute health conditions such as allergies, cough, cold, and flu *symptoms*. Certainly, everyone in health care would prefer medicines or remedies that could reverse diseases, but there's a reason these successes described above are not the common story – the research involved is extremely challenging. As the Texas politician Sam Rayburn remarked, "*A jackass can knock down a barn, but it takes a carpenter to build one.*" Rhetoric is easy, and there's no shortage of legitimate criticisms with how health care is manages and practiced; however, science is a process, and the limitations of medicine are provided by the complexities of evolution and nature of human physiology. Medicine is hard because that is the card nature has dealt.

So if someone asks me if I'm learning "allopathy" in pharmacy school, all I can do is given them a confused glance. I intend to simply practice the best evidenced-based practices that are available, and in their absence use the best rationalization of biological knowledge we have acquired through immense research efforts. To claim to be able to do more would be mere hubris, and yet many do.