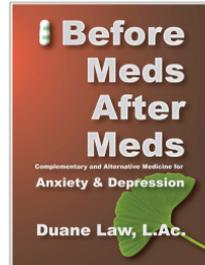


# Appendix E: References

## & Reflections on the Evidence Base

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Excerpted from the  
forthcoming book.  
[More.](#)

*“... take any theory beyond its limits, beyond its life span, beyond its utility, beyond its community, and claim for it an absolute truth, then it becomes absurd; and hubris beckons.”*

— Angell, I. & Demetis, D.  
*Science’s First Mistake*<sup>1</sup>

*“You shall not crucify mankind  
... upon a cross of gold.”*

— William Jennings Bryan

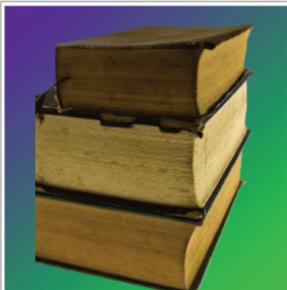
Recently a student remarked that an old chestnut of a prejudice still makes the rounds, at least at her school. The disinformation involved is the idea that there’s no evidence that diet influences mental health in any substantial way.

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1. Angell, Ian & Demetis, Dionysios. *Science’s First Mistake: Delusions in Pursuit of Theory*. 2010. New York: Bloomsbury Academic. Available online at: [http://sciencesfirstmistake.files.wordpress.com/2010/07/sciences\\_first\\_mistake\\_angelldemetis.pdf](http://sciencesfirstmistake.files.wordpress.com/2010/07/sciences_first_mistake_angelldemetis.pdf)

“No evidence,” in this context, is usually shorthand for “there’s no *convincing* evidence.”

“Convincing” in this context is code for evidence rising to a predetermined level of statistical significance produced by properly-designed and executed randomized controlled trials (RCT) with at least 50 enrolled subjects completing the trial. Others then need to replicate those results (a condition that opens the door for all kinds of shennanigans by researchers with corporate agendas unfriendly to the ideas explored by the initial researchers publishing their results) and *then* those results have to catch the attention of a few prestigious front line professional journals, edited by editors sometimes resistant to new ideas. The process is designed to be deliberative.



***Competent nutrition research is incredibly expensive and time-consuming. Short cuts in modeling real world situations tend to produce the false negative results we've all read about. Some of the best work is decades old.***

But this process also enables the development of a very dangerous “group think” dynamic ... something we’ve observed in the last half century in the American financial and political sectors with results visible to all.

Chapters 1 and 1.3 introduce some of the issues raised by the elevation of placebo-based RCT trials to the “gold standard” of medical evidence.

Papers questioning the model are now beginning to appear. Technically, the problematic aspects of RCT trials with respect to Complementary and Alternative Medicine (CAM) include:

- Expense. CAM interventions, drawn in many cases from world medical traditions that are the cultural inheritance of mankind, are not patentable. That means investigating them rarely draws deep-pocketed corporate interest.

In an RCT trial participants may not be receiving an actual treatment; therefore it's clearly unethical to charge for participation. But in an age when funding of all types is becoming harder to come by, the need of RCT trials to be free to the participants is one factor that tips the evidentiary playing field in favor of those with deep pockets and away from CAM.

- Oversimplification. The expense of RCT trials also skews the RCT evidence base toward investigations of standardized single or simple combinations of substances and away from investigations of the highly-individualized complex therapeutic interventions characteristic of best-practice CAM.

Investigating the effects of combinations of substances in RCT trials necessitates an approach called multivariate analysis (MA.) MA requires much larg-

er (and therefore more expensive) trials, and much more sophisticated (and therefore expensive) statistical analysis. This skews the RCT evidence base away from a competent evaluation of the kinds of complex mixes of interventions characteristic of CAM interventions as well as toxic environmental exposures. The lack of adequate funding coupled with the expense of the multivariate trials required undermines the validity of the extant work, at least in terms of volume and analyzed in conventional terms.

- Trial Length. Short-term trials are less expensive than longer-term trials. Also, fewer people drop out of short-term trials, so RCT trials tend to be brief compared to the real-world situations they model. This skews the RCT evidence base away from the kinds of longer-term analysis required to competently assess both toxicity issues and CAM interventions.
- Lack of Relevant Researcher Expertise. It's also sometimes the case that otherwise well-qualified researchers are nevertheless inexperienced in the clinical application of the interventions they're testing. Crucial details get overlooked. Particularly with botanicals but sometimes also with micronutrients, this lack of expertise in the area of inquiry can combine with economic pressures resulting from the difficulty of obtaining adequate funding, resulting in incorrectly formulated or inadequate dosages.

- Substandard Interventions. There's lots of poor quality botanicals and supplements out there. One needs to have contacts, know what one's doing and be prepared to pay for a well made, potent vitamin and mineral or herbal product. Not all conventional researchers have the requisite knowledge, resources or interest.
- One-Size-Fits-All Interventions. Best practice CAM requires that dosages and intervention mix be titrated to an individual's response. So it's easy to design and execute bad protocols, especially if one is limited to a single protocol for all variable group participants.
- Diagnosis. An assumption of the primacy of conventional medical diagnostic categories can create false-negative results when applied to medical systems with their own conceptual frames and diagnostic systems.
- Placebos. The need of "gold-standard" RCT trials for an "inert" version of the active intervention, applied to a control group that cannot distinguish between a placebo and the active intervention limits their scope to interventions which can be so blinded. Changes in habits and lifestyle cannot be adequately blinded, particularly when those habits involve diet and nutrition. One cannot placebo-control a juice fast or a good massage. So any evidence of the efficacy of non-blindable interventions cannot rise to the level RCT-advocates consider "convincing."

- Primacy of the Latest Research. The biases introduced into the evidence base by the adoption of RCT evidence as the “gold standard” of medical research have contaminated the evaluation of non-conventional medical interventions for the last fifty years.

One reflection of this contamination is the widespread assumption that the latest research is necessarily the best informed. In light of the systemic biases identified above, the assumption that the most recent findings trump earlier work is best seen as an artifact of a research community over-focused by intellectual inertia and even perhaps economics on the effects of novel and invented substances.

It may well be appropriate for a science concerned with the application of invented substances to a system as ancient as the human body to be concerned primarily with research less than five years old. But this bias is less appropriate when more naturalistic interventions are examined. New understandings regarding biochemistry naturally lead to new medical breakthroughs—as those breakthroughs seem to have regular encounters with Murphy’s Law it’s only right for those concerned with these approaches to stay up to date.

In contrast, some (*only some*) of the best research into nutrition’s effects on health was done in the early-

to-mid-twentieth century, before corporate interests gained the leverage over science they have today.

Vitamins were the miracle drugs of the early 20th century. The fact that the relationship of pellagra to niacin was established nearly 80 years ago does not make that research irrelevant (especially as the psychological expression of pellagra, rebranded as schizophrenia, bipolar or personality disorders, has attracted new attention for its responsiveness to niacinamide.)

But a therapeutic and research community over-focused on work less than five years old may well miss connecting the dots between new research into the tryptophan/sugar/serotonin relationship and mid-twentieth century research into niacin's utility in recent-onset schizophrenia (as well as buying into the disinformation that later research, focused on niacin and *chronic* schizophrenia, somehow disproved the earlier work on fresh, *acute* cases.)

- Lastly, it's important to recognize that this cascade of biases in favor of a very thin slice of the research pie has a multiplicative effect on the body of medical knowledge as time goes by.

The RCT-based medicine of the late twentieth century produced an explosion of medical knowledge, saving many lives and improving the quality of life for billions.

But there's no denying any conceptual approach to an issue as enormous as the workings of the human body is going to have its limitations. As RCT-based medicine exhausts its economic and intellectual potential we're seeing those limitations expressed today as rising costs coupled with declining outcomes and reduced access. We've reached the point of diminishing returns.

Perhaps, in the interest of empowering patients and society with the tools we all need to take better care of ourselves under the circumstances ... maybe it's time to consider that the totality of the evidence should be at least as convincing, should it reveal any consistent trends, as the RCT slice.

Or, as an MD boss of mine once quipped in the midst of "evidence-based" cutbacks of our work together,

*"You can put a man to death in this state (California) on weaker evidence than it takes to get him his medical care."*

It's time for that to change.

We're going to have to be the ones who change it.

Normally the totality of evidence is dismissed by RCT fans as being error compounded. But when an overwhelming body of evidence accumulates pointing in the same direction, the time comes when it's important to ac-



knowledge it. Just as radioastronomers aggregate the information from dozens of far-flung stations, combining their data in ways that increase resolution while reducing noise, just as *JAMA* finally got around to acknowledging the therapeutic benefits of acupuncture at the dawn of the new century ... perhaps if we want to take the next steps medically we need to piece together a mosaic of data points that will allow us a much richer, fuller picture of all of the available evidence than an overfocus on the RCT slice alone allows.

Perhaps as we grope our way toward a simpler, more accessible “greener” medicine that prioritizes human over corporate needs and empowers the individual ... perhaps it’s time to move off the “gold standard.”