Primum non Nocere, Caveat Emptor, and Diligentia Quam in Suis: First, Do No Harm, Let the Buyer Beware, and Due Diligence

Carl V. Rabstejnek, P.E., M.B.A., Ph.D.

Sauce for the goose may not be sauce for the geese,

The primary edict of medicine is *primum non nocere* — first, do no harm. By extension beyond physicians, surgeons, and psychiatrists, this credo also applies to psychologists, social workers, other mental health practitioners. This responsibility extends to corporate bigwigs, military commanders, human relations officers, and other "buyers" charged with selecting remedial physical and mental health programs for widespread implementation in corporations, companies, and the military. Buyer is used in the generic sense to include anyone who selects protocols for a whole group.

Each group consists of individuals who are often treated as an amorphous mass for the purpose of implementing system wide mental health protocols that for some may be inappropriate. Large organizations, by their nature, tend to favor <u>broad-based approaches</u>, *and that's the rub.* — hence, the modified proverb:^{*} *Sauce for the goose <u>may not be</u> sauce for the geese*.

This means persons in groups process psychic disturbances as individuals, not units, and can be unaffected or harmed by generalized treatments that may help other people. Realizing this, those with purchasing authority (i.e., the "buyers") have a fiduciary, ethical, and moral responsibility to minimize adverse effects of canned wellness programs. This essay addresses a necessary and manageable way to comply with the ancient precept to do no harm.

latrogenic Effects

Unintended iatrogenic effects — (i.e., unintentional physician induced adverse reactions) — that might happen need to be corrected quickly. Of course, it would be better to know the ramifications of dubious treatments before they are initiated, but humans are not always that predictive. Nevertheless, after an intuitively appealing program has been implemented for awhile, independent observers may begin to discover drawbacks and incidents of harm. These findings may eventually make their way into the professional literature. So, sometime after widespread adoption of a popular program, academic publications need to be perused for evaluations of aggressively marketed "cures," before getting on a bandwagon; or get off, if already a "rider."

Due Diligence

In light of ongoing learning, I have joined the first two well-known Latin phrases in this essay's title with the third: *diligentia quam in suis* — due diligence. This admonition is necessitated because the promoters continue to promote their method with fervor and often attack those who provide counter evidence.¹ Therefore, it is the *duty* of the "buyer" to uncover a more complete picture of a treatments' asserts and liabilities.

The tendency of promoters to oversell began to be highlighted around the turn of the century.

^{*}Modification of the Old English proverb: "What's sauce for the goose is sauce for the gander" or "What's good for the goose is good for the gander."

The claimant's lack of scientific integrity, dubbed pseudoscience, in the ongoing selling of psychological programs, became a theme in the scholarly literature. In 2001, Lilienfeld, Lohr, and Morier defined pseudoscience:

... a scientific approach to these assertions demands an open-minded willingness to consider any and all evidence pertinent to their validity ... What renders these claims largely or entirely pseudoscientific is not that they are necessarily incorrect, but rather that their proponents have typically insisted that they are correct, *despite compelling evidence to the contrary* [ital added]. (p. 183)²

Because both sides of the issue can publish in general and scholarly publications, it falls upon the "buyer" to assess the claims and counterclaims and decide whether it is advisable to adopt a popular canned program. In recent years, tort cases seem to focus on drugs, so the motivational burden is presently more from moral than legal influences at this time, but this may change.³ Fiduciary responsibility requires those implementing a wellness, prophylactic, intervention, debriefing, support, or other codified approaches that are applied willy-nilly to a mass of people to diligently seek out pros and cons that were found in practice. Ergo, buyers are obligated to do their homework.

latrogenic History

The history of detrimental practices in physical medicine ranges from ancient erroneous assumptions, such as bloodletting; good intentions that went awry, such as prefrontal lobotomies;⁴ to a wonder drug, such as Thalidomide caused birth defects.⁵ These were broadly practiced methods, prescribed with the best of intentions, that were stopped when harm was finally realized. Admittedly, bleeding took centuries to be abandoned because it was based on a tenacious ancient theory involving humors (bodily fluids, including blood).⁴ Frontal lobe severing was an attempt to efficiently remove distress of mental illness and was stopped after two decades because of the observable misfortunes it caused.⁴ In recent years, three diabetic medications were touted, Actos, Avandia, and Januvia. Later, they were found to be associated with cancer.⁶

Obviously, physical medicine is not infallible when providing treatments within the bounds of limited knowledge and beliefs at any point in time. It shows that good intentions do not guarantee appropriateness of a treatment. Its salvation is timely discontinuance or limited use when contrary evidence emerges. Unfortunately, before correction bloodletting, lobotomy, and Thalidomide-type disasters had occurred. To minimize the possibility of negative effect, oversight agencies were set up to formalize the approval process and to protect the public.⁷

Even with regulatory oversight, however, diabetic drugs were already on the market when adverse side effects were determined. Human intelligence is not fail-safe! So buyers need to be humble and accept evidence of contraindications. Proponents of popular programs are rarely humble.

Regulation

To protect the public against harm, the United States Food and Drug Administration (USFDA or FDA) was formed in 1906⁷ to regulate and supervise what is consumed or physically applied to humans and animals. After the Thalidomide disaster, additional legislation was passed in 1962 to increase the surveillance and approval of drugs.⁸

Procedures that involve non-pharmacological mental reactions between provider and client are not so rigorously controlled by a government agency, nor should they be, necessarily. There is often an initial group for which a codified approach appears to work. It takes later unaffiliated researchers doing independent studies to begin questioning a treatment's effectiveness for widespread use. Unfortunately, cognitive and behavioral changes may take time to be identified. Also, confounding issues may need to be unraveled, because effects due to treatment are not always apparent

By comparison, a common example used in medicine to illustrate diagnosis-specific treatment is the use of insulin for diabetics because of its dangers for use with people who process carbohydrates normally. This analogy is good to show adverse effects of too-broad use of a drug and the need for an individualized approach to treatment. This physical analogy has the advantage, however, of being able to measure the physical sign of blood sugar. Psychological assessments are rarely so cut-and-dried.

Due Diligent Research Process

Because treatment methods are aggressively marketed, it behooves the "buyer," when considering adopting intuitively appealing, apparently helpful, and immensely popular programs to exercise due diligence. The buyer needs to seek non-sales literature to assure their efficacy and safety. Fortunately, technology has made this a relatively straightforward process when approached judiciously: *first*, (1) realize that it is now relatively easy to assess scholarly articles with the advent of computerized databases and readily availability of full-text copies of many digitized papers, often in pdf format; *second*, (2) recognize that many parochial articles are written and proclaimed by apostles, who advocate in all manner of media and interpersonal outlets; *third*, (3) the buyer needs to realize that mental health programs continue to be promoted after contrary information is published in the academic literature; and *forth*, (4) due diligence instructs the buyer to gather the information, but the final decision is a judgement call.

Let the Buyer Beware

As mental health programs operate mainly in the free market, it is the buyer's responsibility to assess their worth, or *caveat emptor* — let the buyer beware. This is a commercial principle that holds the purchaser responsible to assure that the product meets its needs. "Beware" does not imply that the supplier might be selling snake oil or poison. These programs are rarely universally useless or harmful for everyone. There are groups for which they work, but the results are overly generalized by enthusiastic promoters who successfully market them by implying *one-size-fits-all*.

To offset the biased sources, their claims need to be tested by conducting a search of the academic literature. When doing so, it is necessary to watch out for advocacy pieces that may appear scholarly. Realize, there are impressively titled journals billed as "refereed" that are published by the organization "selling" the technique. Apostles are also able to publish in respected journals because they often have academic credentials and their claims *appear* "scientific."

Availability of the Information

Once there may have been a workload basis for accepting a bill of goods and joining others in accepting a popular fad. Research is no longer a difficult operation. Technology has simplified this whole process. There is no longer an excuse for not being aware of the published pros and cons of the treatment. It does, however, require getting access to the resources.

Twenty years ago a literature search was a time consuming process. Academic articles were placed in scholarly (and not so scholarly) journals that were listed in thick annual tomes, under categories. Starting from similar topics, a researcher would locate related articles and would try and find broadly cited key articles and consult a citation index. Then, further leads were found in lists of references. Eventually, one had a reasonable stack of papers to coalesce into a useful review article. Photocopiers were commonplace when I started in the late 1980s, so it was possible to highlight hard copies. A generation earlier, students and academics made notes on index cards.

rabstejnek@HOUD.info

From this stack of paper and cardstock it was possible to construct a "collage" (a.k.a., a literature review), at least for the caliber of a term paper. As one advanced with education, guidance, and experience to theses, dissertations, and professional articles, familiarity with the field, personal research, and related memories, plus journal familiarity extended the field's knowledge base and quality of papers (hopefully).

Establishing the Operational Research Environment

Access to the readily available material requires access to the databases required. Setting-up an in-house system can be expensive so it is usually advantageous to associate with a college or university. I am readily able to do computer searches at two of my alma maters. Many school libraries are not so welcoming toward guests and even alumni, as I found at another alma mater. Some have guards at the front door and deter access to librarians. At some institutions, it is possible to purchase a guest membership. Of course, students and faculty have ready access to the school's computer system. In addition, online sources of scholarly articles, such as ResearchGate and others, are gaining popularity. It is an additional, readily available, and convenient resource.⁹

Once one has access to the database, the searches themself are not difficult. Boolean logic trees pare down the target list and titles provide the first cut at useful articles. Titles and abstracts may further target an article's usefulness. Citations in some articles may locate other key references. At this point one should have a pretty good overview of the method being considered and an indication of the pros and cons of a procedure.

The standard format of scholarly articles facilitates surveying the field. The introduction provides an overview of the field and the discussion and conclusion can give an indication of what the author(s) concluded. The body of the report and analysis of the details can be deferred until later, if such detail is needed. The list of selected publications is enhanced by including letters to the editor and critiques of published articles. These are usually written by those familiar with the field and provide an expertise not expected of "buyers" of well-marketed programs.

Full-text databases instantly provide a digital copy of the article. Many papers can be downloaded to a portable memory, such as a flash drive, that can later be perused elsewhere. For most surveys there are sufficient articles digitized to satisfy information gathering goals.

At times a recent article is embargoed (usually a year) and one has to decide if it is worth the effort to obtain it. If needed, revert to the established process of photocopying a print journal, using interlibrary loan, or purchase a copy from the publisher. As libraries are cutting down on their purchase of hard copies of journals, obtaining copies of non-digitized material might require more time to go off-site. I have found this a rare necessity because satisfactory conclusions can often be drawn from readily available online resources.

Publishers' charges for reprints are generally exorbitantly priced. I think due diligence can be achieved short of doing the exhaustive surveys required by a dissertation. Abstracts provide the gist of articles.

The Internet is also a good source. Sometimes, authors and secondary sources provide a copy of a copyrighted article that is not in the full-text database. Albeit, Google and Bing and other search engines are cluttered with ads and extraneous stuff. Google's Scholar and ResearchGate are now providing access s to many scholars and their papers. These focused sources will undoubtedly continue to be refined and are generally available from one's desktop and portable computers. The need to cull useful and valid data (metaphorically, separating the wheat from the chaff, so to say) carries over to material that is in the academic databases. Remember, there are biased credentialed authors (often with unstated or denied dual relationships). Therefore, judicious evaluation of the sources is another *caveat* that literature explorers need to consider. Some sources are generally accepted as reliable and others just give the appearance of credibility. Be cautions with all sources, however, because even the respected journals may follow a Zeitgeist in the academy that may later be shown to be lacking.¹⁰ Also, anonymous reviewers and editirs may have personal biases that influence their publishing recommendations and decisions.

Independent Reviews

Some protocols may have been independently reviewed, à la *Consumer Reports*. *Cochrane Reviews*¹¹ is highly respected and does extensive surveys of many health care issues and publishes their findings. These reports are often available through medical schools. Also, there are unbiased academics who reviewed the empirical results about codified methods and opined on their effectiveness. Advocates have been known to issue vituperative attacks against these critics.¹

Academics recently began focusing on overviewing several potentially harmful therapies (PHTs). Dr. Scott O. Lilienfeld co-edited *Science and Pseudoscience in Clinical Psychology*,¹² in 2003. After this book, in 2007, he wrote "Psychological Treatments That Cause Harm,"¹³ published in *Perspectives on Psychological Science*. These both provide useful evaluations of many popular approaches. I found a good used copy of the book for much less than the publisher charges for the article, which is also available on full-test databases. To get a sense of the field, it is recommended that at least Lilienfeld's paper be read.

Beyond this recommendation, I am not providing my list of PHTs. Many are covered extensively in Lilienfeld's publications and others. My intent is to advocate a process for reviewing a popular method and not to herein debate the merits of particular codified ways of doing business. I have elsewhere done an analysis of management fads an fashions and listed 100 that were adopted in the last half of the 20th century.¹⁴ It discussed the human propensity to ride on bandwagons in the business world. The National Health Service¹⁵ and psychiatry^{16,17} are not immune to fads.

Wading Though the Arguments

Repeating what was stated or implied above, interpreting the results requires the buyer to exercise judgement. A literature search in the mental health field rarely provides a clear-cut decision basis. One of the major difficulties is adverse effects of a treatment may not surface for weeks, months, or years. Also, there are groups and individuals with vested interest, who for economic or ego reasons, are committed to maintaining support for questionable practices. Anecdotal examples are met with contrary claims. Statistical arguments about experimental design, failure to provide control groups, and selection of samples are met with reasons for the deviance from accepted experimental designs.

Technological Advances

In the quarter century since I transferred from engineering to clinical psychology, this snapshot in time reveals many changes since the late 1980s. Back then, hours were spend wading through lists of cataloged publications, to find key articles. From those lists, citation indexes were consulted to find papers that cited critical papers. Then relevant hard copy journals were scanned for articles and the references they used. Eventually, one had a list of references from which to merge into a research paper.

When I started there were copy machines, so photocopies could be made and highlighted. This was an expedient over notes on index cards.

rabstejnek@HOUD.info

Technology has removed much of the tedium in finding relevant references. The recentness of these advantages can be illustrated by the history of Google, the commercial search engine. It was conceived as a research project in 1996 and matured into an initial program offering (IPO) in 2004, just a decade ago.¹⁸ Since receiving a Ph.D., in 2001, to today, my ability to obtain articles has improved immensely. Early computer searches still referred me to print journals. Later, full-text papers were sent to printers, Now, while there are fewer print journals available on library shelves, many more are digitized, and articles can be downloaded to a flash drive.

Therefore, it is rare that I make a photocopy at the library anymore. At my desk, I can determine what articles to print or send to my e-reader.

Multiple database searchers can be combined and now there is even a way to search the entire online universe simultaneously. Albeit, listings can be extremely large and the boolean tree of terms gets quite long. Broad searches are a useful way to frame a somewhat vague idea in the universe. But herein the interest is in specific methods. Field specific databases, such as Medline, PsychINFO, and SocINDEX can provide a more manageable list.

An online scholarly database, such as ResearchGate, may provide much useful material that is free and readily available. It does not go through the reviewing process that journals require, which can be a benefit or bane. As with any source, the "buyer" needs to consult various sources and use judgement in determining the assets and liabilities of an approach. It would be unethical to make decisions based upon a single source or promoters with a vested interest in the outcome. Mistakes may be made initially, which is why ongoing updating of input needs to be welcomed without selfdefensiveness.

Review

The point I am making is technology has *now* provided expedient ways to find relevant articles on fads and fashions that are popular and aggressively marketed. As time goes on, the short historical arc of search improvements and digitized access is expected to continue to improve upon the scholarly search. So, with the already advanced status of present technology, it behooves the buyer to put in the very manageable effort to find out what is known and to update their knowedge periodically. From a knowledge (and opinion) base a well-informed decision can be made. It is getting harder to use ignorance as an excuse. The moral and ethical practitioner need not wait until legislation and litigation force what is the right thing to do.

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rabstejnek@HOUD.info

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