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Nutrition: ethical issues and challenges

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ABSTRACT

For nutrition and its associated disciplines, ethical considerations related to research are often complicated by factors that range from the use of experimental research designs that are overly holistic to inextricable links between nutrition research and marketing. As a consequence, there is the need for constant vigilance to assess and deal with apparent conflicts of interest. Also, there are few scientific disciplines that are defined by cultural, religious, or political codifications as is nutrition. Accordingly, examples of historical, cultural, and political events are described that have influenced ethical approaches related to nutrition research. Furthermore, nutrition research questions are often multifaceted and require dealing with complex variables. In this regard, ethical principles and perspectives that have relevance to data acquisition, the publication and translation of nutrition research, and the marketing of nutritional products and concepts are highlighted.

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1. Introduction

For nutrition and associated disciplines, the development of clear ethical guidelines for research and practice is wrought with complexity. For example, few scientific disciplines are defined by cultural, religious, or political codifications or laws as is nutrition. Moreover, few disciplines have such direct links to product marketing. Accordingly, nutrition is often viewed as controversial because of a need for policies and ethical approaches to aid in resolving areas of conflict (eg, marketing self-interests or conflicts of interests related to funding).

The translation of nutrition research has also stimulated a thriving industry of allied health professions that provide various levels of intervention, such as the self-monitoring of

physical activity or the manipulation of diet presumed related to improving nutrition. To this point, the need for articulation of policy and ethical considerations is viewed as serious enough that the American Society for Nutrition has recently created an Advisory Committee to focus on “improving and ensuring the public trust in academic and professional scientific societies through best practices in scientific rigor and transparency,” which is a task made difficult, given that many of the conflicts evolve from groups that the American Society for Nutrition relies for support (eg, agricultural commodity organizations and similar marketing groups with various self-interests).

Concerning this review, discussions of ethics are now a common feature of academic curricula and the underpinnings for research societies’ and journals’ “codes of conduct.”

Abbreviations: COPE, Committee on Publication Ethics; DSHEA, Dietary Supplement Health and Education Act; FDA, Food and Drug Administration; FTC, Federal Trade Commission; GMOs, genetically modified organisms; RDA, recommended dietary allowances.

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Consequently, a primary objective is to provide ethical perspectives and background with a focus on data acquisition and translation, publication and communication, monitoring, and the marketing of research findings. Examples of historical, cultural, and political events that have influenced nutrition and health policies and practices are also described.

2. Historical, cultural, and religious influences

As Levinovitz [1] has noted, many individuals have value systems that address perceptions of their nutrition and health with an intensity that is similar to their religious beliefs. In this regard, nutrition has an extensive history of cultural and religious codices and influences [2,3]. For example, most of the major religions have dietary guidelines that are followed to varying degrees, such as fasting, dietary exclusions (eg, alcohol, certain or all types of animal flesh), or the premises for which foods are sold, prepared, or eaten (eg, Jewish kosher laws). The recognition of such codices and influences is important not only for their historical significance but for their potential to influence research objectives or nutritional interventions. Research questions that have a religious principle as a component may ignore appropriate controls, develop exclusions or inclusions for subject selection that may insert bias, or ask questions that are less hypothesis-driven than purpose-driven [4-8]. For example, science-based vs faith-based approaches to questions often seek to understand the world in a manner that is intrinsically opposite. A faith-based approach may have as an obligation the interpretation of research observations so that they are consistent with a particular belief system. An important feature of a faith- or belief-based approach is the ease to which it is influenced by confirmation bias (or confirmatory bias), the tendency to interpret information in ways that confirm preconceptions. Science-based approaches do not have such obligations. As a first principle, scientific objectivity is not guided by a perpetual belief system and, when optimal, excludes tendencies that can prejudice consideration of a question.

For early nutrition research efforts, a goal was often to seek or justify dietary protocols to aid in the modification of certain behaviors. In the United States, colorful examples include the work of Sylvester Graham, an 18th century Presbyterian minister and social reformer, whose design of the graham cracker was prompted by a belief that a vegetarian diet would suppress carnal urges [9,10]. His 19th and 20th century Adventist counterparts, John and William Kellogg, founders of the Battle Creek Sanitarium, also promoted nutrition, mostly vegetarianism, as a belief system and a means of achieving moralistic goals [9].

However, their successful attempts at developing a corn flake cereal were not without ethical dilemmas. The initial joint venture between John Kellogg and William Kellogg terminated when William Kellogg split off to form the W.K. Kellogg's Company. One of their disagreements had to do with adding sugar to John Kellogg's original product. Also, there were ethical conflicts between patients at the sanitarium and the Kellogg brothers. William Kellogg provided valuable information related to cereal processing to C.W. Post, a sanitarium patient, who later started C.W. Postum, which eventually evolved into the General Foods Corp. C.W. Post, however, was accused of appropriating information related to

cereal formulations from William Kellogg, that is, allegedly stole an intellectual property. Later, C.W. Post was also accused of marketing misconduct. The magazine, *Collier's Weekly*, objected to C.W. Postum advertisements for its principal product, Grape Nuts, because of their assertion that Grape Nuts could cure appendicitis [11].

In this century, for those who have certain religious beliefs, the use of genetically modified organisms (GMOs) may be unacceptable. Consider that for many individuals, particularly those with biology training, the value of genetically modified organisms or foods (GMOs) for increased crop production, disease and pest resistance, or improved nutritional quality is apparent and viewed as important. The arguments for such modifications often invoke ethical principles that favor utilitarian approaches (eg, "the greatest good for the greatest number"). For others, however, the cloning and manipulations of genes are considered wrong on moral grounds [12-14]. The religious objections range from the view that human-made genetic modifications are tantamount arrogantly assuming God-like roles to the violation of given religious food laws or codifications (eg, aversion to the use of animal or human genes in plants to enhance growth or a given nutritional quality). Concerning ethics, what often is invoked on the religious side of the GMO argument is deontology, a form of ethical argument that determines rightness by given features of an act or activity in contrast to the outcomes of an act or activity [15]. The point here is that belief systems have been and are an important part of nutrition's research history. Ethical issues that have a bearing on animal rights and use, GMOs, and human rights including informed consent are often addressed using differing ethical approaches that set the stage for controversies for which there can be few clear resolutions.

3. The role of politics

The nature and scope of nutrition and its health-related industries dictate the need for various regulations and accordingly the interaction with governing bodies. Some of the control regarding how evidence-based information is used and interpreted lies also with the ultimate consumer. A good example of consumers having a direct voice in the use of science-based information is the controversies over fluoridation and nutritional supplements. The translation of science regarding fluoridation and dental health into public policy often has been the result of public referenda or elections in contrast to a formulation of policies arising out of focused scientific discussions, that is, whether or not to add given amounts of fluoride to a public water supply [16].

Some direct political intercessions have also either ignored or impeded judgments based on scientific findings. Two prominent examples are past legislative bills offered by Senator William Proxmire from Wisconsin and Senator Orrin Hatch of Utah [17]. In the mid-1970s, the Food and Drug Administration (FDA) proposed new marketing rules to combat public confusion about dietary supplements in part to address deceptive claims, as well as use the best science-based information at the time (eg, information that evolved from the development of the Recommended Dietary Allowances). It was proposed that vitamin preparations containing

vitamins in amounts greater than their respective Recommended Dietary Allowances could be regulated as “over-the-counter” drugs.

This action was opposed by the National Health Federation, which organized a campaign producing more than a million letters to Congress urging the passage of laws to stop the FDA’s regulations. The so-called Vitamin Bill, introduced by Senator Proxmire, passed by a vote of 81 to 10, in spite of opposition by the American Medical Association, the National Nutrition Consortium, the American Dietetic Association, the Society of Food Technologists, the Consumers Union, and the Pharmaceutical Manufacturers’ Association.

Senator William Proxmire again became a standard bearer for the supplement industry, when he sponsored the 1976 Proxmire Amendment that became section 411 of the Federal Food, Drug, and Cosmetic Act. The amendment prohibited the FDA from establishing standards that might limit the potency of given dietary supplements. As intended, such non-science-based congressional intercession compromised an important aspect of the FDA mission. As the late Thomas Jukes noted, “the bill served to entrench megavitamin folklore, based on the principle that if a little is good, more is better” [18].

Next, came the Dietary Supplement Health and Education Act of 1994 (DSHEA; Public Law 103-417), which in part defined a dietary supplement as a food in contrast to a potential drug [19]. Under the DSHEA, dietary supplement manufacturers are allowed to market claims about the effect of given supplements. The only notification the consumer receives is a disclaimer. The DSHEA also expands the types of products marketed as “supplements.” For example, almost any substance consumed orally derived from a natural product may be defined as food, which brings forward issues from ignoring not only science and evidence-based principles but also apparent conflicts of interests [17,19]. In addition to the relative absence of regulations, those who sell nutritional products may also be poorly equipped to make judgments regarding the use of dietary supplements and natural consumable products. For example, although pharmacy outlets are a major vehicle for supplement sales, a recent Canadian study reported that only 2% of pharmacists indicated a level of knowledge to advise about supplements and complementary and alternative health care products [20,21].

For many, the rationale and need for the National Center for Complementary and Integrative Medicine (formerly the National Center for Complementary and Alternative Medicine, and before that the Office of Alternative Medicine) is also an ethics-related concern [22-25]. From its inception, there have been conflicts between its political allies and research directors. Senator Thomas Harkin from Iowa was a primary advocate and influential in increasing research funding for the then Office of Alternative Medicine. However, he was also a critic of its management, expressing concern about the “unbendable rules of randomized clinical trials.” A notable Senator Harkin assertion is “one of the purposes of this center was to investigate and validate alternative approaches...I must say publicly that it has fallen short. I think quite frankly that in this center and in the office previously before it, most of its focus has been on disproving things rather than seeking out and approving.” An obvious counter to Senator Harkin’s assertion is that science- and evidence-based policies are about truth and require reasoned oversight, and not laissez-faire approaches that carry with them variable or conditional ethical constraints.

With ample resources, establishing purposeful research centers are among what most might view as an appropriate political and public service activity. Indeed, there are strong arguments for a center directed at what some call alternative medicine, given the public support for the concept [25,26]. There remains, however, an unequivocal obligation to raise ethical questions when there are political influences directed at modulating the outcome or nature of the research product. It is also reasonable to ask whether resources for naturopathic medicine (based on vitalism and self-healing) or homeopathy (based in part on principles, such as the potency of substances increase in proportion to their dilution) are well spent or in the broad public best interest [25].

4. Sources of funding and related conflicts of interests

The relationship of nutrition to the food and health-related industries also comes with a set of ethical obligations. A study by Lesser et al [27] in part addresses this point. The study was designed to assess potential influences by sponsors regarding the health effects related to consuming 1 of 3 beverages (soft drinks, milk, and juice). Examination of approximately 200 published research papers indicated that the funding source was associated directly with the conclusions. For interventional studies, unfavorable outcomes were observed in none of the industry-funded studies, although about 40% of the studies with no industry funding indicated an adverse outcome on the studied health effect or indicator.

In a thoughtful editorial in response to the study by Lesser et al [27], Katan [28] emphasizes the well-taken point that a mere association between funding and outcome does not by itself indicate bias. When producers fund nutritional studies, particularly in support of eventual marketing, it might be expected that there may be an anticipation of a favorable outcome, although such expectations should signal the need to be ethically vigilant. In an editorial [29] related to Katan’s comments [28], some suggestions for ethical vigilance include:

- structuring the research so as not to favor a given outcome;
- developing clear understandings between the client and the researcher; and
- publishing the results whether they are favorable or not to the client, providing full disclosures for all participants.

Is such vigilance important? Given the recent revelations regarding the Sugar Research Foundation (SRF), the answer is regrettably more yes than no. Kearns et al [30] have reviewed internal documents of the SRF, which indicate that SRF-sponsored research programs throughout the 1960s and 1970s were designed to downplay the negative aspects that sucrose had on health. It is now apparent that the SRF had a significant influence on publications that promoted fat and cholesterol as the major dietary causes of coronary heart disease, particularly those that lessened the potential importance of sugar. The SRF also apparently influenced the National Institute of Dental Research to shift emphasis to dental caries interventions other than restricting sucrose. Accordingly, it is reasonable to consider how the research landscape and perhaps policy

regarding sugar (or any given commodity) might be viewed currently if the above suggestions for ethical vigilance had been followed as early as the 1960s and 1970s.

Nonetheless, it also is important to acknowledge that being overly restrictive regarding funding conflicts does have consequences. The funding of research in many areas important to nutrition would likely be diminished. The process could also result in the arbitrary exclusion of individuals with salient expertise from commissions or advisory groups for which the expertise could be of great value.

In this regard, the European Food Safety Agency's Conflict of Interest Practices Committee, based on an independent audit, chose not to strengthen their conflict of interest policies [31]. Instead, the committee elected to address issues of financial conflict and bias with reasoned approaches and management, rather than follow an arbitrary set of guidelines. The guidance offered by the North America Working Group on Guiding Principles of the International Life Sciences Institute is another example of reasoned approaches that provide transparency and a platform for discussions directed at potential funding conflicts of interests (cf. Table 1) [32].

5. Behaviors that contribute to misconduct, malfeasance, and fraud

It is first important to note that there are distinctions between the terms that we use to describe questionable conduct, that is, misconduct, malfeasance, and fraud. Fraud is an explicit misrepresentation of fact, whether by word or conduct that is intended to deceive so that there is the need for a legal inquiry, because of potential injury. Malfeasance is often used to mean a fraud carried out by a public official, particularly when the malfeasance results in the violation of a public trust. Misconduct is most often used to describe a violation of the standard codes of scholarship and ethical behavior. Misconduct is used in a nonlegal sense to include unintentional actions resulting in inadvertent or poor judgment with the potential for correction. In a legal sense, the term (particularly when used in federal statutes) has much stronger implications. For example, at the State and Federal levels, misconduct that arises from fabrication, falsification,

or plagiarism in any phase of a research endeavor can result at the least in loss of funding. At most major research institutions, the punishment for misconduct ranges from notifications (eg, asking for journal retractions of flawed articles, recommending the termination of funding from sponsoring agencies, releasing information to the public) to denial of advancement or termination. Similar to many civil actions, the proof for misconduct relies on judgments based on the "preponderance of evidence."

The factors that underlie fraud are both intrinsic and extrinsic; that is, the factors may be a part of one's lack of moral conscience to external motivating factors. For the latter, the pressure to engage in misconduct, as well as to overlook misconduct by colleagues, has been linked to (1) the "publish or perish" pressure at many research institutions, (2) a requisite for a high frequency of publication to obtain consistent funding, or (3) some exaggerated sense of self-importance by the investigator. Two additional factors, offered by David Goodstein, Vice Provost—California Institute of Technology [33] are (1) the intuitive belief of what the answer should be, thus negating the need for experiments or adequate controls to address the research question, and (2) engaging in research activities for which individual experiments are unlikely to be precisely reproduced. Both seem particularly relevant to nutrition and related health sciences. There are no easy solutions to these situations. Some require a change in institutional attitude or practice, for example, devising ways to equitably address decreasing resources, while dealing with the demands from a large number of researchers or the costs of doing 21st Century science [33].

Intrinsic or psychological factors, although not well understood, are possibly the most important underpinnings of scientific fraud. Two commentaries, one written for *Science* [34] by Efraim Racker and the other for *Nature* [35] by William James, are very useful. In the narrative by Efraim Racker, 4 individuals are described of whom one worked in Racker's laboratory, whereas the others worked with Drs Carl Cori, Davis Green, Melvin Simpson, and Fritz Lipmann, a truly distinguished group (eg, 2 Nobel Prize laureates, 4 members of the National Academy of Sciences, all leaders at the time of major research departments). As might be expected, the offenders were all very smart, well trained, and initially

Table 1 – Provisions that lead to research transparency and integrity^a

1. All forms of sponsored research must be factual, transparent, and designed objectively.
2. Research designs should follow accepted principles of scientific inquiry that evolve from or lead to independent hypotheses. Such designs should not favor a particular or specific outcome.
3. Control of both the final study design and research should be the product of and remain with the scientific investigator.
4. All data and control of statistical analysis should be the product of the principal investigator(s) or consultants, auditors, or reviewers, who can confirm no direct conflicts of interests.
5. Remuneration based on or geared to the outcome of a research activity should be transparent and always open to question.
6. Written agreements should underscore the obligation to attempt to publish the findings within some specified and reasonable time frame.
7. Full disclosures in publications and conference presentations of all financial interests should always be an expectation.
8. Participation in an undisclosed paid authorship arrangement should be approached as a type of misconduct.
9. Researchers associated with contract research organizations or act as contract researchers have an obligation to make clear statements regarding the nature of the affiliation.

^a Guidelines are taken directly or adapted from the International Life Sciences Institute North America, Working Group on Guiding Principles' report: Funding food science and nutrition research: financial conflicts and scientific integrity [32].

well-screened before their appointments. Furthermore, an important characteristic of each of the laboratories is that considerable effort was directed at replication and validation, because of the high stakes for the research. Careful screening and worksite vigilance did not prevent misconduct. Racker describes individuals capable of misconduct as “professionals” with an “unbalanced mind,” that is, an otherwise potentially brilliant person with the intrinsic attributes to commit fraud. He further notes that such intrinsic values may not be easily modified. Likewise, William James comes to somewhat the same conclusion but uses as a label a “hoaxer, who is willing to take risks” to categorize misconduct.

Of the systematic research on the topic (cf. Ref. [36] and those cited), most studies indicate that the perpetrators usually cannot be definitively distinguished, except for some elevated level of ego, vanity, and self-aggrandizement, what is often referred to as narcissism. A vagary is that these same attributes in a different setting may contribute to professional success. Accordingly, mitigating fraud or misconduct is difficult. When misconduct is discovered, it obviously must be addressed aggressively with the knowledge that it may come with a considerable cost, ranging from the dismissal of a colleague to the costs associated with maintaining a high level of vigilance (eg, the costs of experimental research replication and validation).

6. Research journals and publication

Maintaining the integrity of science journals and the honest translation of findings to the consumer should be among our most serious concerns. Although integrity in reporting science starts with the researcher, it is also relatively easy to find flaws in the peer-review process and the roles that editors may play in compromising integrity. As an example, in 2015, the publisher, Springer, retracted 64 articles from 10 different subscription journals after an internal investigation that uncovered fabricated peer-review reports [37]. In a notable example, the misconduct involved a construction of a “peer review and citation ring” using more than 100 bogus e-mail addresses and identities to generate fabricated reviews. [38].

Before the 1990s, several polls indicated that journals rarely had procedures for responding to allegations of research misconduct and were reluctant to accept retractions or corrections. Many journals, however, now follow the guidelines for editors offered by the World Association of Medical Editors [39] or the Committee on Publication Ethics (COPE) [40]. As a resource, COPE also maintains a searchable database with more than 500 cases that have involved some misconduct or editorial mismanagement for those who wish to analyze or research the topic of journal-related fraud. Although within the total scope of research reporting, the number of actual retractions is small (<0.05% of the millions of published articles), it is also apparent that for every clear case of misconduct, it is likely a harbinger for more.

Nevertheless, hundreds of publications on misconduct and ethics have been published over the past decade. For example, a simple PubMed (US National Library of Medicine, National Institutes of Health) search using “scientific misconduct” as a key phrase results currently in ~5000 citations. As Fang et al [41]

have reported, about 70% of retractions are attributable to some level of misconduct or carelessness based on a review of more than 2000 retracted biomedical and life-science research articles indexed by PubMed. The types of misconduct include evidence of suspected fraud (>40%), duplicitous publication, and plagiarism. Others have reported that more than 40% of surveyed researchers could provide examples of misconduct, but did not report them. It also has been observed that journals with high impact are more affected by fraud and errors than journals of lower impact. For the latter, plagiarism and duplication are more prevalent [42,43]. Furthermore, it has been observed that higher-impact journals are more likely to retract publications in which misconduct is a factor [44,45].

Regarding the darker side of the problem, it is now possible to publish fraudulent or careless research findings for a price, particularly when the marketing of the research product is an ultimate goal. The ability to purchase scientific authorship is also possible. The marketing of authorships is a cottage industry that has evolved out of Asian commercial editorial services. Most of these services are designed to improve the quality of scientific manuscripts; however, an investigation by Science [46] uncovered that some services also provided opportunities to pay for authorships on papers written by other scientists. When there is little or no oversight, there are those who will find ways to “game the system.”

Despite the documented cases, however, our views and judgments about misconduct often remain uncomfortable as a topic of discussion. Compromised reporting of misconduct may result from collegial or coworker grievances or institutional embarrassment. Also, misconduct, related to the research reporting process, is not viewed as a crime for which there is recourse in most courts of law. Nevertheless, whether an error, a misconduct, or a fraud, the increase in such problems has prompted *Nature*, Elsevier, and other publishers to adopt new editorial policies in attempts to improve the consistency and quality of reporting of submitted manuscripts. In most cases, the policies are directed at better documentation and validation of research methods. As previously noted, organizations such as World Association of Medical Editors and COPE have been particularly aggressive in suggesting guidelines and protocols for reducing fraud and misconduct [39,40].

It is important to emphasize that success can also play a role in misconduct. Many scientists are ill equipped to handle success. As observed by Ludwig and Longenecker [47], success can lead to complacency or the view that one has privileged access to certain information, which can lead to nonproductive collegial interactions. Success may also lead to the temptation to misuse resources and the personal belief that one has a right to manipulate outcomes. Ludwig and Longenecker [47] have coined this type of behavior as the *Bathsheba syndrome*, paradigmatic of the Old Testament King David-Bathsheba story, in which King David’s leadership becomes complacent and eventually corrupt. The “syndrome” helps to describe the tendency for groups and organizations to look the other way when a highly successful colleague is guilty of misconduct.

In this regard, the former editor of *Nutrition Research* serves sadly as an example of institutional complacency [48-50]. A number of his articles have now been retracted, but no

institutional charges of misconduct were ever filed by his home institution, the Memorial University of Newfoundland, illustrating a “tendency for organizations to look the other way when a highly successful colleague may be guilty of misconduct” [47].

For most, however, it is the less evident practices that result in what is sometimes viewed as “misconduct.” Rather than an ethical breach, the underlying factors are statistical mistakes, poor judgments, or inadequate oversight resulting in flawed experimental design. As examples:

- Inclusion or exclusion bias in the selection of studies for use meta-analyses to gain greater statistical power [51]
- Data dredging, a search for statistical significance within given data sets (cf. Ref. 51 for examples)
- Designing experiments for the purpose of obtaining a particular answer

What can the researcher do? For many types of errors, some approaches are to include independent consultants with appropriate skill sets to examine the data, design strategies directed at convergent and discriminant validation of given data sets, or develop a system for honest and independent in-house review or replication.

Fortunately, many journals now have mechanisms for the storage of original data sets, so that they can be examined and used by others. In this regard, the advice and statements adopted from the American Statistical Society [53] and Nuzzo [54] on statistical significance and *P* values are seminal (Table 2). That is, values for probability are mostly useful in making an inference for a null hypothesis and not for working backward to make a causal statement. It is also noteworthy that the editors of *Basic and Applied Social Psychology* have recently announced that the journal will no longer publish papers containing *P* values because such statistical analyses are too often used as criteria for “lower-quality research” [55].

7. The translation of research findings—another problematic ethical concern

A significant extension of nutrition and health-related research is the need to translate research finding so that they are useful to the client, whether a commercial venture, health professional, or the public. Apart of the process often involves communication through journalists and broadcast communicators. Analogous to biomedical research journal reporting, journalism and broadcasting also have defined codes

of ethics that focus on truth, minimizing harm, independence, accountability, and transparency (eg, the central tenets of the Society of Professional Journalist’s Code of Ethics). Regrettably, there are 21st century aspects of journalism that the codes do not address, such as the apparent need to be entertaining and responding to a “24/7” news cycle [56–61]. For digital publishing platforms, the editorial process sometimes subordinates to the allure of “breaking” a story given the real-time nature of these new publishing mediums [56]. There is also a strong tendency to report highly positive or negative findings with an enthusiasm that is often not supported by the data in the original article, in part due to the decreasing number of trained journalists, who are being replaced by opinion communicators [57]. As an example, Lai and Lane [58] have reported that 43% of front-page stories reporting on medical research are based on research with mostly preliminary findings.

As we move forward, there is the reality that the journalistic landscape is indeed changing. Digital publishers and blogs from various organizations and stakeholders must also be considered as outlets. Most digital publishers, however, lack currently a well-tested system to assess ethical concerns. Although it is suggested that those interpreting science for the public should use some peer review as a benchmark [59], the nature of the newer venues for science communication causes such arguments to be obscured by First Amendment concerns. Regardless, procedures appropriate for a given venue should be developed. As noted by Ransohoff and Ransohoff [57], if the research community does little or nothing to address the problems of misleading public communications or translation, the consequence of lack of action is complicity. The problem is amplified, when there are multiple vested interests involved in research-related communication (eg, the researcher, the journalist, the institutional public relations officer, or the blogger/publication editor). It is not uncommon for researchers from top institutions to distribute press releases with salient, yet limited, information about their research with the goal of self-promotion. This lack of detail leaves the burden of interpreting the research to a journalist who often is not well equipped or takes the time to present an accurate description of the work [59–61]. There must be freedom of the press and recognition of First Amendment rights, but there should be little tolerance for sensationalism and distortion of truth when it is done as a putative public service.

Although often far downstream from initial research efforts, product labeling is another form of research translation relevant to nutrition. The Nutrition Labeling and Education Act of 1990 and recent modifications [62–64] mandate the

Table 2 – Statements regarding the reliability of *P* values^a

1. No single index should substitute for scientific reasoning.
2. *P* values and related analyses should not be reported selectively.
3. For proper inference all relevant data from a study should be reported.
4. *P* values are not a direct measure that the probability of a hypothesis is true.
5. *P* values are not a direct indication that data are produced by random chance alone.
6. Scientific conclusions should not be based only on whether a *P* value passes a particular threshold.
7. A *P* value is a statement about data in relationship to the stated hypothesis, not a declaration of a given explanation.

^a Adapted from the American Statistical Association’s statement regarding the purpose and limitations of basing data interpretations on *P* values [53].

labeling of nutritional information; yet, labeling is often viewed as confusing and misleading, even when it complies with existing regulations. Winters [65] and Mayhew et al [66] argue further that scientific rigor frequently is not met, which is troubling particularly when misleading marketing strategies target children. The difficulties with reinforcement have even led nutrition policy advocates, such as Marion Nestle [67], to suggest a return to the system that existed before the 1980s when health and nutritional claims were not allowed on packages, an argument also addressed by Winters [65].

8. Marketing

As a final point, few disciplines have the short temporal distance between the initial research results to the proposed application or market as does nutrition. In many cases, the research has inextricable links to a marketing decision, which may bring the researcher into the marketing process. As examples, those doing commodity-oriented research often have to deal with marketing agents, a commodity board, or other types of corporate concerns owing to the importance of the investigation to bring about a material change or have an effect on stakeholders at some level. In this regard, there are questions that one may use as benchmarks that lead to an ethical action.

- Does the company have the well-being of all of its constituents as a working principle—from program design to member services?
- If the activity scales across international or distinct regional boundaries or microcultures, does it ethically and effectively address particular sensibilities (eg, use of child labor, utilization of so-called out-sourced subjects [68]), lead to environmental waste, or bypass regulations?
- Does the activity promise too much or result in an exclusionary practice or stigmatization?
- Is marketing the primary driver in anticipation of a probusiness arrangement?

As a marketing case study, the nutritional supplement industry and its lobby are often viewed as nutrition's corporate "gorilla in the room," particularly given the vigorous efforts that are made to modulate political, regulatory, and judicial intercessions to effect positive outcomes on behalf of the supplement industry. To reiterate, under the DSHEA, dietary supplements do not need strict FDA approval before marketing their products. It is the company's responsibility to provide assurance that its products are safe and efficacious. Although there are independent organic or natural product organizations that provide levels of credentialing and oversight services, it is usually a secondary agenda compared to their lobbying or marketing efforts. As an example, in a recent hearing before the Senate Commerce Committee on "Protecting Consumers from False and Deceptive Advertising of Weight-Loss Products," the Natural Products Association supported government efforts to stop illegal consumer fraud, while opposing proposed requirements by the Federal Trade Commission (FTC) for additional studies and research before consumer advertising [69]. The FTC recommended that before

the promotion of a given product, 2 double-blind, randomized control trials be performed to support legal structure-function statements. The Natural Products Association countered that the additional research efforts would be an inefficient use of resources and compromise innovation. A company's First Amendment rights were also invoked along with the difficulty of recouping research dollars. With that said, the nutritional supplement market is clearly extraordinarily successful. About one-third of North Americans consume at least 1 of the 65 000 dietary supplements on the market on a regular basis. Based on several estimates, the global nutrition and supplement market takes in more than 100 billion dollars annually (about one-third in the United States) with a 6% to 7% annual rate of growth with little documented commitments to research [70,71].

Is there aggressive regulation by the dietary supplement trade associates to stop illegal consumer fraud? Although their visible efforts obfuscate FTC and FDA rulings, evidence that trade and supplement associations engage in robust self-regulation is scant at best. Is regulation needed? Based on reports from 2004 to 2012, nutritional supplements accounted for more than half of the FDA class I drug recalls, even with the restrictions in place on the FDA because of the DESHA. A "class I" designation indicates that there is a reasonable probability of a serious adverse health consequence or death [72,73]. Given the current frequency of potential health consequences [72], it is reasonable to consider the admonition by Katz [73] that "Dietary supplements should be treated with the same rigor as pharmaceutical drugs and with the same goal: to protect consumer health."

9. Concluding remarks

What follows are some additional opinions regarding attitudes that we judge to contribute to less than optimal ethical outcomes. They are offered in the same context as those provided by Goodstein [33], as noted in Section 5—behaviors that contribute to misconduct, maleficence, and fraud.

1. *Emphasis is often given to research approaches that are too holistic in their experimental designs.*

The point here is not an argument that a reductionist or basic approach is superior to a holistic or systematic approach in the conduct of research (also cf. Fang and Casadevall [74]). Both are essential in the development of interdependent and complementary views of complex and intergraded phenomena. It is often holistic or systematic approaches that have the most impact on eventual policy. Rather, it is the attitude that many take in approaching research questions from a holistic perspective. The importance of the research question should indeed help drive the overall research effort; however, if the correct methodology is not sufficiently developed or absent, there is a high probability that the work will have little value. The ethical dilemmas evolve when resources are used for research that is too descriptive, that is, provide little mechanistic insight. The value of the research training associated with the effort is also diminished when the correct tools and sufficient background information are not in place.

2. *Nutritional studies often rely too heavily on the inappropriate application of statistics.*

It is worth repeating that too many nutrition-related research papers are the product of so-called data dredging or statistical applications that simply would not be allowed in many other disciplines. This point was made elegantly by Feinstein [52] some 30 years ago, but remains a problem and contributes to the impression of “Why Most Published Research Findings Are False” as asserted by Fang et al [41]. To reiterate, more emphasis should be given to the design of experimental controls and approaches that lead to convergent validation of results.

3. *There needs to be improvement in the interactions that researchers have with the various stakeholders involved in nutrition research and its translation.*

The direct interaction of the researcher with commodity groups and the various research foundations that focus on nutrition needs to be continuously evaluated. The recent report of the SRF influence directed at cardiovascular and dental health assessments is a timely example [30]. Questionable material published more than 5 decades ago still influences nutritional policy. Indeed, many commodity boards fund research under the auspices of their marketing divisions with the principal goal of obtaining an advertising banner or providing a “deflection” from an inconvenient health-related relationship. More negotiation and understanding are needed. There also needs to be better barriers constructed that separate research endeavors from marketing interests and influences. [72,73]. It is clearly disingenuous to argue that research relevant to marketing be held to lower ethical standards (cf. Section 8—Marketing).

4. *Given the importance of nutrition research to health, those involved in research need to become more involved in the translation of their research findings.*

As emphasized by Nosek et al [75] and others [56-61], the self-correction of misleading information is uncommon. When one’s work is provocative, it is important that the researcher is involved in its translation; otherwise, as asserted by Ransohoff and Ransohoff [57], the researcher may become a complicit collaborator in the misinformation process. The recent proliferation of journals and the introduction of entertainment components into journalism have changed the landscape of how information is disseminated. We all need to work at better understanding such changes.

5. *It is important to review regularly the structures that support and define our research efforts and its use.*

As a final point, given that lack of self-correction is common, we agree with the conclusion of Müller et al [76] that it is important to regularly review the structures that define or influence nutrition research (eg, from our journals to the various benefactors of the research). Although we are quick to judge individuals who are clearly guilty of misconduct, we often remain tolerant of ourselves and our colleagues in

situations where consideration of an ethical principle may be inconvenient. Even more regrettable, the latter attitudes open the door to a wide variety of marketers, movements, and doctrines that rely heavily on supposition and pseudoscience. As a demarcation problem, it is another issue that effects nutrition more than many other science disciplines.

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