

# Sound Science to Benefit the Public's Health:

**Opportunities and Challenges in Industry-Funded Nutrition Research** 

A White Paper from Two Invited Panels Convened by the American Heart Association<sup>1</sup>

## ABSTRACT

The American Heart Association's Industry Nutrition Advisory Panel (INAP)<sup>2</sup> convened two panel sessions in 2017, in Portland, OR and Chicago, IL, to discuss opportunities and challenges associated with conducting industry- funded nutrition research and communicating the results effectively and accurately. One major goal was to generate stakeholder discussion about how to establish a standard of transparency for funding sources and biases. Another major goal was to improve trust that research is scientifically sound and accurately translated to benefit the public's health regardless of funding source or potential researcher interest and/or bias. The Portland panel's speakers explored the topic from academic, science and industry perspectives. The Chicago panel's speakers presented independent media communications, marketing and publishing viewpoints. At each event, presentations were followed by open discussion during which attendees (INAP members and key invited stakeholders) could contribute their expertise and insights. Four very broad themes emerged from these meetings:

- The benefits of collaboration, particularly in today's environment of limited public research funds;
- 2. The food industry's purpose for and contributions to nutrition research;

- Recognition of the potential risk for bias in all sectors and in many forms in the processes of scientific research and publication; and
- **4.** Recommendations for improving integrity in nutrition research methodology and communication to enhance its credibility and value.

<sup>2</sup> For a listing of INAP members, visit http://www.heart.org/NutritionScience

<sup>&</sup>lt;sup>1</sup> This paper represents a summary of two panel discussions and is not intended to be exhaustive, but rather reflective of the discussions on the topic. Specific examples are intended to illustrate practical experiences and the expertise of the invited speakers. The presentations and subsequent information in the paper do not necessarily reflect the opinions, support, or endorsement of the American Heart Association of its INAP membership. We thank each speaker for presenting at the panels and for reviewing the draft summary of the proceedings to ensure accuracy.



## INTRODUCTION

The American Heart Association's (AHA) Industry Nutrition Advisory Panel (INAP) convened two panel discussions in 2017 to explore opportunities and challenges associated with industry-funded nutrition research. INAP is made up of 14 leaders from the food industry and scientists from the American Heart Association's Nutrition Committee. For more than 20 years, INAP has provided a collaborative platform for open dialogue, information-sharing and planning cooperative programs. INAP offers opportunities for collaboration that can lead to solutions for healthier food and lifestyle options in America and globally. (Figure 1) science, and industry perspectives. At the second panel, in October in Chicago,<sup>3</sup> speakers presented independent media communications, marketing, and publishing perspectives. At each event, speaker presentations were followed by open discussions where INAP members and key stakeholders could contribute their expertise and insights.

The panels took place amid a broader stakeholder discussion and media interest about bias and conflict of interest in nutrition research. Public funding for food and nutrition research is limited and has been declining,<sup>4</sup> and the food industry



FIGURE 1. INAP stakeholders

The panels had a handful of goals: generating stakeholder discussion about how to establish a standard of transparency for funding sources and biases, and preserving trust that research is scientifically sound and accurately translated to benefit the public's health regardless of funding source and researcher interest and/or bias. During the first panel, held in March in Portland, OR, speakers explored the topic from academic, has helped fill the funding gap. Stakeholders and observers have raised concerns about financial and other bias and conflict of interest in industry-funded nutrition research, leading to allegations of subjective interpretation or "spin" of research results and selective publication that favors sponsor interests.<sup>5</sup> The association between industry funding and conclusions of nutrition research has been studied empirically,<sup>6</sup> and guiding principles for these types of public-private partnerships have been developed.<sup>7</sup>

<sup>&</sup>lt;sup>3</sup> The second panel was co-located with and held immediately prior to the Academy of Nutrition and Dietetics' annual meeting, the Food and Nutrition Conference and Expo. <sup>4</sup> Britt, R. Universities report fourth straight year of declining federal R&D funding in FY 2015. InfoBrief No. 17-303, Nov 2016. Arlington, VA: National Science Foundation, National Center for Science and Exposed Statistics (https://www.nef.gov/statistics/011/0182/017309/

National Center for Science and Engineering Statistics. https://www.nsf.gov/statistics/2017/nsf17303/ <sup>5</sup> E.g., Nestle M., Food industry funding of nutrition research: The relevance of history for current debates. JAMA Intern Med 2016;176(11):1685-1686. https://jamanetwork. com/journals/jamainternalmedicine/article-abstract/2548251

<sup>&</sup>lt;sup>6</sup> E.g., Lesser LI, Ebbeling CB, Goozner M, Wypij D, and Ludwig DS. Relationship between funding source and conclusion among nutrition-related scientific articles. PLoS Med 2007;4(1):e5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1764435/; Chartres N, Fabbri A, Bero LA. Association of industry sponsorship with outcomes of nutrition studies: A systematic review and meta-analysis. JAMA Intern Med 2016;176(12):1769-1777. http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2575884.

<sup>&</sup>lt;sup>7</sup> E.g., Rowe S. et al., Funding food science and nutrition research: Financial conflicts and scientific integrity. Nutr Rev 2009;67(5):264-272. https://www.ncbi.nlm.nih.gov/ pubmed/19386030; Alexander N. et al. Achieving a transparent, actionable framework for public-private partnerships for food and nutrition research. Am J Clin Nutr 2015;101:1359–63. http://ajcn.nutrition.org/content/101/6/1359.abstract

The panels were designed to further discuss how to mediate these concerns of potential bias and conflict of interest, to advance nutrition research while preserving scientific integrity in its conduct, and to develop transparency, and therefore fostering trust among all stakeholders that results and their interpretation are objective and credible. A number of terms appear frequently throughout this paper; they are defined in Box 1 according to the way they were used and understood during the panels.

#### - BOX 1-

### **Definitions of Frequently-Used Terms in This Paper**

**Bias:** Inclination or prejudice in favor of a person, thing, or viewpoint; deviation of either inferences or results from the truth, or any process leading to that kind of systematic deviation, including tendencies by which data are reviewed or analyzed or interpreted or published in a way that yields a measurable deviation of research results from the truth.

**Conflict of interest:** A conflict between the private interests and the official responsibilities of a person in a position of trust.

**Industry:** The food and beverage industry, including ingredient suppliers, food manufacturers, retailers, food service institutions, restaurants, commodity groups and associated checkoff programs, trade associations, and other organizations that represent and are funded by these groups.



## SUMMARY OF PANEL PRESENTATIONS AND GROUP DISCUSSION

The Portland panel addressed industry-funded nutrition research from academic, science, and industry perspectives. The following speakers delivered presentations, preceded by disclosure of their relationships and affiliations: The Chicago panel explored the topic of communicating industry-funded nutrition research from independent media communications, marketing, and publishing perspectives. The following individuals participated in the panel:



Connie M. Weaver, PhD Distinguished Professor, Department of Nutrition Science, Purdue University



Kevin Lomangino Managing Editor, HealthNewsReview.org



Gary Foster, PhD Chief Scientific Officer, Weight Watchers International; Adjunct Professor, University of Pennsylvania; Volunteer Professor, Temple University



Jack Graham, Esq. EVP and Director of Continuing Education, Great Valley Publishing Co. (publisher of Today's Dietitian)



Catherine Kwik-Uribe, PhD Director, R&D-Scientific and Regulatory Affairs, Mars Symbioscience (a division of Mars, Incorporated)



Brierley Horton, MS, RD Food and Nutrition Director, Cooking Light



Katie Meyer, ScD, MPH Assistant Professor, University of North Carolina at Chapel Hill



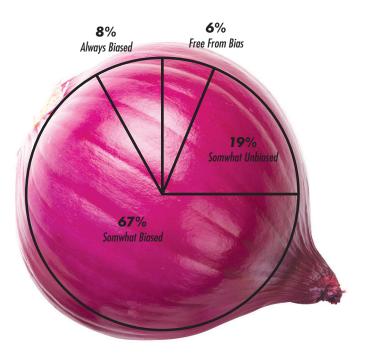
Sylvia Rowe President, SR Strategy (Moderator)

Similar themes arose at both events regarding key issues that should be addressed to help secure public trust. Rather than recounting proceedings sequentially, this paper is an integrated summary of key points and concepts that emerged. These are organized with bold sub-headings below.

## Continuum of Public Perception and Stakeholder Perspectives

Stakeholder perspectives of industry-funded food and nutrition research and activities fall along a very broad continuum featuring widely varying opinions. Some believe there is an inherent bias, even going so far as to compare "Big Food" to "Big Tobacco." Topics of "bad actors," "bad science," and other disingenuous activities were discussed, but not in great detail. Others believe industry funding might compromise research outcomes and interpretation, but that there are also positive aspects. Benefits cited were contributions to advance the knowledge base about the safety and efficacy of foods and food ingredients, and their impact on health outcomes. Still others believe that if industry-funded studies are methodologically rigorous and critically peer-reviewed, following similar quality guidelines as studies with non-industry funding sources, then skepticism is unwarranted. One speaker even shared an anecdote about a consumer who believed private interests, not taxpayer dollars, should fund research.

Similarly, the climate is varied at academic institutions regarding industry-funded research. Upper-level support for academic and industry research collaboration varies across institutions and sometimes even within institutions. Decisions may be influenced by the extent of a company's involvement in the conduct and outcomes of the research, as well as pre-existing pressures to publish and/or bring in extramural research funds, all in the context of a lack of government funding. When Today's Dietitian magazine readers were surveyed about their perception of bias in industryfunded nutrition research, 94 percent thought there was some bias. Of those, most (67 percent) considered it "somewhat biased." (Figure 2).





When survey results were stratified by years in practice (0-5 years, 6-10 years, 11-15 years, and 16+ years), respondents practicing 6-10 years were most likely to respond that industry-funded nutrition research is "always biased" (15 percent), while those practicing 16+ years were least likely (5 percent; results not shown). In the same survey where most felt there was some bias, almost all felt there was some value to this work. Of those, 60 percent perceived industry-funded research as "somewhat valuable." (Figure 3).

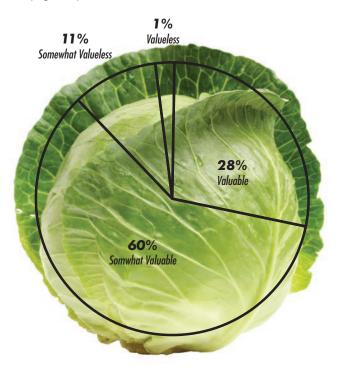


FIGURE 3. Today's Dietitian readers were asked to complete the statement: "Industry-funded research is \_\_\_\_\_\_." Survey conducted October 17-18, 2017; n=418. Source: Presentation by Jack Graham, Great Valley Publishing Co., October 2017

When survey results were stratified by years in practice (0-5 years, 6-10 years, 11-15 years, and 16+ years), respondents practicing 6-10 years were least likely to answer that industry-funded nutrition research is "valuable" (17 percent of that group chose this response, compared to 26-28 percent in other groups; results not shown).

## Collaboration is Critical, and All Sectors Play a Role

Cuts in U.S. federal research funding can slow the pace of discoveries that could help solve global challenges in public health and nutrition. This funding challenge, and potential ramifications, call for multi-level, multi-sector efforts. Creating a healthier food supply and food environment, and making a healthier food system attractive, accessible, and affordable to the public, involves many parties. Among them are researchers, funders, food producers, manufacturers, commodity groups, retailers, and marketers. Proactively working together can develop common ground, discover solutions that can build capacity, facilitate innovation, and increase the support and reach of work for the public good.<sup>8</sup> An example is the USDA Branded Food Products Database, a public resource for the food industry and researchers created by data submissions from manufacturers and retailers containing nutrition details on thousands of name brand prepared and packaged foods available at restaurants and grocery stores. This complements the USDA National Nutrient Database, which serves as a main source of food composition data for governments, the public health research community and the food industry.

Despite these potential benefits, some academic researchers fear industry collaboration will cast them in a negative light. This wariness leads to the formation of silos instead of partnerships. This environment is particularly difficult to navigate for junior investigators who are still building their reputations and establishing credibility, because of fear their career may be compromised if they accept industry funding.

<sup>8</sup> Centers for Disease Control and Prevention. 2014. CDC's guiding principles for public-private partnerships. https://www.cdc.gov/partners/pdf/partnershipguidance-4-16-14.pdf

At the same time, many researchers say eliminating industry sponsorship is not the answer to that criticism. Furthermore, managing conflicts by excluding the expertise of many industry food and nutrition scientists can exclude important perspectives and miss opportunities to confer benefit. And, ironically, discouraging collaboration with relevant stakeholders could be viewed as bias in and of itself.

Policies and guidelines for collaboration that rely on agreed-upon, transparent rules of engagement could encourage collaboration and reduce skepticism or rejection of research results, helping to increase their impact. Some universities already have these types of standards and guardrails in place.

## Industry Engages in Research for Multiple Purposes

Food industry representatives said one fundamental challenge is the perception that industry conducts research solely in support of marketing interests. They noted that industry engages in research for a variety of reasons not typically addressed by other stakeholders' efforts. For example, industry builds research necessary for new product development, innovation in existing products, to satisfy legal or regulatory requirements for safety (for approval of food additives, for example), or for claim substantiation. In the 2015 Dietary Guidelines Advisory Committee Report, the food industry was encouraged to continue making changes to certain foods to improve their nutrition profile, such as lowering sodium and added sugars and reducing portion sizes in retail settings.9

Industry may invest in research and development to reformulate existing products or to create new ones to meet demand for healthier foods and beverages. An example is advancing a new ingredient and generating evidence about its potential health benefits, which requires research to quantify safety and efficacy. This may involve industry resources to develop test materials, provide the product and a well-matched control (in feeding studies, for example), and standardize methods for classifying and analyzing the food component (to help standardize replication attempts). In these roles, industry is not only a research funder but also a collaborator that contributes knowledge, information, and possibly additional investigators to the scientific process. These combined efforts can contribute to the body of peer-reviewed literature.

## Industry Contributions to Nutrition Research

Due to its role in the food supply chain, industry is an active stakeholder with distinct expertise, strengths and resources to contribute to evidencebased research about food sourcing and production, formulation, safety, and distribution. Industry involvement can facilitate practical application and translation of research results, such as scaling up products for institutional food service.

Industry has applied its innovative and creative potential to the development of popular convenience products that encourage healthy food consumption, such as baby carrots and bagged, washed lettuce.<sup>10</sup> Industry also delivers food manufacturing and preparation techniques that reduce nutrients to limit, such as salt microspheres (to reduce sodium) and dynamic radiant frying (to reduce fat).

<sup>9</sup> Scientific report of the 2015 Dietary Guidelines Advisory Committee, pages 22, 46.

https://health.gov/detaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf
Weaver CM, Dwyer J, Fulgoni VL 3rd, King JC, Leveille GA, MacDonald RS. Processed foods: Contributions to nutrition. Am J Clin Nutr 2014;99(6):1525-42. https://

www.ncbi.nlm.nih.gov/pubmed/24760975

The food industry can apply its assets to translational solutions for the global burden of diet-related diseases. These assets include a wide scope of expertise and reach, the capacity to create a high volume of safe and convenient healthy foods and beverages, and diversity across companies and their product portfolios and employees.

Industry support, such as funding or collaboration with additional resources, can assist early-career investigators to the extent that their home institutions are amenable. A positive experience presented on the AHA panel involved industry funding that supplemented financial resources. This led to an accelerated timeline for work toward a National Institutes of Health mentored research scientist development award. The investigator's topic overlapped with the research focus of an industryaffiliated group, and its additional support expedited completion of the research aims. This funding also saved the NIH funds for other aspects of the grant. The investigator reported a stronger study design with a larger sample set than would have been possible with NIH funds alone, and the work published earlier. In this example, industry was not involved in the research design, implementation, or results reporting. A resource to connect researchers with such industry awards could help improve awareness of such opportunities.

A mix of funding sources may be optimal, but it's important to balance the realities of federal funding limits with research priorities, institutional environment, relevance of industry opportunities, and potential for reputational harm and flagrant rejection of results due to skepticism of association with industry. While the NIH and other government funding may be critical for career advancement, industry collaboration, including funding, may help increase a researcher's competitiveness for NIH funding by helping to establish a research program and collect preliminary data. It can also further the understanding of new research questions less suited for current NIH funding opportunities.

### The Potential for Bias Exists in All Sectors

Biases are not exclusive to industry. All individuals in all industries exhibit personal biases big and small. The distinction in these panel discussions is the bias that leads to and/or results in a measurable deviation of research results from the truth. This includes methods by which data are reviewed, analyzed, interpreted, or published in a way that yields conclusions that deviate systematically from accepted, transparent scientific practices.

There was a prevailing sentiment about the need to manage the overgeneralization of broadly blacklisting all who are affiliated with industry, because industry-funded research is not all biased; nor is all non-industry-funded research unbiased. There may be "bad actors" who may produce "bad science" or act unethically, such as by falsifying data, within both industry and non-industry sectors. There are also "good actors" in both groups, and some industry scientists hold shared goals and values with public health scientists and academics. Neither group is a faceless entity that deserves a blanket label of bias or objectivity.

All research should be carefully and appropriately designed and use proper statistical analyses, following established best practices and guidelines. It should include a measured interpretation of findings that are suitable for the study design, and be scrutinized via the peer review process. Readers are urged to consider the totality of evidence on a topic, and in doing so could also compare results of similar studies funded by groups with and without apparent financial interests.

There was overarching frustration that in today's environment, the results of almost any scientific study are viewed from a baseline of skepticism stemming from a narrow view of why the research was funded; for example, the misperception that industry funds research only to sell products, and that government does so only to promote policies.

## Many Biases Can Be Found Within Formal Research Process

Another recurring theme was that there are many potential biases – irrespective of funding source – that may occur in scientific research and communication. These include scientific and publication biases as well as biases that are independent of the formal research process. Box 2 lists some sources of potential bias. The interpretation of research data and the translation of research results that inform public health policies and impact health are too important to ignore managing the many potential sources of bias. Trust and transparency form the foundation for recommendations and best practices that can help manage these biases and foster scientific integrity.

## - BOX 2 -Potential Sources of Bias in Scientific Research and Communication **Biases in Scientific Research Biases Independent of the** and Publication **Formal Research Process** - Desire for fame/respect among peers - Sample selection bias - Sample size bias (underpowered) - Pressure to publish results, win prizes, or please the funder - Data collection bias (poor measures) - Fear of losing one's job - Data quality bias - "Group think" facilitated by social - Statistical analysis bias (intention to treat vs. or professional networks completers) - Previous body of work - Confounding variable bias - Personal ideology, passion, - Publication bias (null vs. positive results) or political orientation - Religious or ethical orientation - Nationality/ethnicity SOURCE: Presentations by Connie Weaver and Gary Foster, March 2017

## Guiding Principles for Industry-Funded Food and Nutrition Research

The science and public health communities, including industry scientists, have an important role in defining terms of collaboration ("rules of engagement"). They ensure creation and execution of a rigorous study design and appropriate statistical analyses, and objectively communicating outcomes, the latter drawing from established best practices for reporting various types of research results (such as STROBE, CONSORT, and PRISMA). Rules of engagement help foster transparency, integrity, reliability, and credibility of research results. This involves processes and training for how investigators and institutions collaborate to uphold scientific rigor, including the peer-review process.

The panel recognized a previous effort that defined conflict of interest guidelines for industry funding of health, nutrition, and food-safety research.<sup>11</sup> The principles listed in Box 3 are intended, in conjunction with scientific best practices, to protect the credibility and integrity of the scientific record by outlining ground rules for industry-sponsored research.

#### - BOX 3 -

## Guiding Principles for Public/Private Collaboration on Health, Nutrition, and Food Safety Research

In the conduct of public/private research relationships, all relevant parties shall:

- Conduct or sponsor research that is factual, transparent, and designed objectively; and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome.
- Require control of both study design and research itself to remain with scientific investigators.
- **3.** Not offer or accept remuneration geared to the outcome of a research project.
- 4. Ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame.

- **5.** Require, in publications and conference presentations, full signed disclosure of all financial interests.
- Not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations.
- Guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers.
- Require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

SOURCE: Rowe S, Alexander N, Clydesdale F, et al. Funding food science and nutrition research: financial conflicts and scientific integrity. Am J Clin Nutr 2009;89(5):1285-1291.

<sup>&</sup>lt;sup>11</sup> Rowe S, Alexander N, Clydesdale F, et al. Funding food science and nutrition research: financial conflicts and scientific integrity. Am J Clin Nutr 2009;89(5):1285-1291.

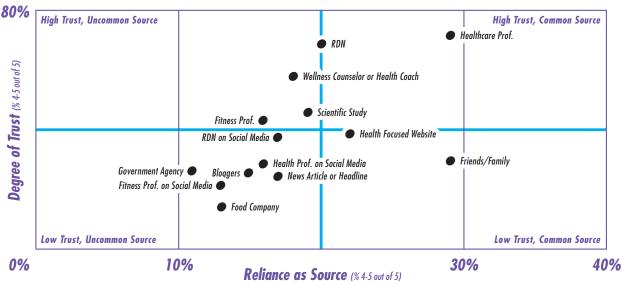
INAP presenters and attendees shared ideas to proactively ensure broader uptake and more consistent adherence to these principles:

- Make it standard practice to distribute the principles to new faculty members in academic departments as onboarding guidance for industry-funded research.
- Share the principles at annual meetings of university food and nutrition science department heads.
- Urge department heads and other universitybased administrators to distribute the principles to faculty members.

## Strategies to Improve Trust of Industry-Funded Research

The scientific community has experienced a relatively steady level of public confidence since 1973, according to a recent survey. The percentage of Americans who have a "great deal" of confidence in its leaders has consistently registered around 40 percent, second only to the military.<sup>12</sup>

Regarding food choices, Americans trust healthcare professionals and registered dietitian nutritionists more than other sources such as news articles, blogs, government, the food industry, and friends and family. A graphic comparing the level of trust with the reliance on various sources for food advice is shown in Figure 5.



## Level of Trust vs. Reliance as a Source

Q: How much would you tust information from the following on which foods to eat and avoid? (n=1,002), Q: How often do you get information from the following on which foods to eat and avoid? (n=1,002)

#### FIGURE 5. Level of trust vs. reliance as a source

SOURCE: International Food Information Council Foundation. 12th Annual Food and Health Survey. Washington, DC: IFIC Foundation, 2017. http://www.foodinsight.org/press-releases/survey-nutrition-information-abounds-many-doubt-food-choices

<sup>&</sup>lt;sup>12</sup> Funk C. and Kennedy B. Public confidence in scientists has remained stable for decades. General Social Surveys, NORC, 2016, as reported by the Pew Research Center, 2017. http://www.pewresearch.org/fact-tank/2017/04/06/public-confidence-in-scientists-has-remained-stable-for-decades/.

To maintain and even improve public confidence, it is clear that transparency and trust in research are imperative, but not enough. Participants put forth several suggestions for enforcing ethical behavior and maintaining integrity in nutrition research, guided by standards of conduct so that all parties involved are above reproach.

#### Standardize Authorship Guidelines

Include authorship guidelines in collaborative agreements to clearly standardize the participation threshold at which authorship is granted. For example, funding alone does not warrant authorship. Substantive contributions to the design, execution, or analysis or interpretation of data for a study and critical input into the writing and/or revision of its manuscript are important contributions toward the designation of authorship. In addition to these contributions, the International Committee of Medical Journal Editors' recommended authorship criteria also include final approval of the version to be published and agreement to be accountable for all aspects of the work, including resolution of any questions related to accuracy and integrity.<sup>13</sup>

## Disclose Relationships and Manage Conflicts of Interest

Investigators should not accept research funding from boards to which they belong or serve as advisers. If they receive a funding award from the board, they should remove themselves from its membership.

Disclosure of funding sources and formal business relationships is commonly offered as a solution to dealing with the potential conflict of interest. Such disclosure should be part of one's personal identity as a researcher and communicator, but it may produce the bias it intends to prevent – i.e., leading readers to assess the research based more on funding source and less on design and execution, or worse, to reject the research altogether.<sup>14</sup> This negative connotation can have a bigger impact on junior investigators, compared to more senior researchers who have already established their professional network, reputation, and other funding streams.

Disclosure, while necessary, has some value, but is not sufficient on its own to address criticisms raised. For example, relevant relationships may not be mentioned, perhaps because of a lack of vigilance or because of intentional withholding. Furthermore, some have contended that current disclosure practices in nutrition science are inadequate and have proposed a broader definition of the type of information that individuals should disclose, such as advocacy or activist work and personal dietary preferences if any are relevant to their authored works.<sup>15</sup> It may also be helpful to disclose the nature of relationships with the funder and the funder's level of involvement in the project.

## Freedom of Information Act (FOIA) Requests

One concern associated with industry collaboration is being the subject of a Freedom of Information Act (FOIA) request. While expressing confidence that outgoing communications would be innocuous, some expressed concern about incoming communications out of their control. Guidance on navigating FOIA issues could help mitigate this concern. INAP presenters or participants did not offer detailed suggestions but raised this as an issue for which to be prepared; they also raised the issue of how to share government-funded data with the public.

<sup>14</sup> Thomas O, Thabane L, Douketis J, Chu R, Westfall AO, Allison DB. Industry funding and the reporting quality of large long-term weight loss trials. Int J Obes 2008;32:1531– 1536. http://www.nature.com/ijo/journal/v32/n10/full/ijo2008137a.html?foxtrotcallback=true

<sup>15</sup> Ioannidis JP and Trepanowski JF. Disclosures in nutrition research: Why it is different. JAMA. Published online December 7, 2017. doi:10.1001/jama.2017.18571.

<sup>&</sup>lt;sup>13</sup> International Committee of Medical Journal Editors. Defining the role of authors and contributors. http://www.icmje.org/recommendations/browse/roles-and-responsibilities/ defining-the-role-of-authors-and-contributors.html.

## Establish Practices to Diminish Bias and Enhance Quality in Each Stage of the Research Process

One speaker outlined steps of the research process that could introduce bias and suggested developing safeguards at each step. These steps include framing of research question(s), selection and execution of study design and methodology to address the research question(s), recording of data, choice of appropriate statistical analysis, interpretation of outcomes and decision to publish results.<sup>16</sup> Participants proposed practices for enhancing quality and reducing bias during the research and review processes.

#### **During the research process**

- Use Data Safety and Monitoring Boards to enhance credibility. These boards help ensure good design, appropriate outcome measures, and proper intervention implementation and follow-up rates. Initially involved with large multi-center studies to monitor data and terminate trials at the indication of early harm, these boards are now required by many universities to standardize the rigor of intervention research.
- Maintain firewalls by using an independent third party to maintain codes on test products to ensure investigator and participant blinding.

#### **During the review process**

- Devise a more objective method for rating trials and observational research, in which funding source is obscured and scrutiny is redirected to methods and rigor.
- Use gatekeepers such as peer-reviewers, academic institutional review boards, and academic conflict-of-interest offices to help enforce policies to manage bias. Journal editors also can help, with guidance from bodies such as the International Committee of Medical Journal Editors and tools such as the CONSORT Statement. These exist to improve the quality

of science and its reporting. While peer review isn't guaranteed protection from bias or "bad science," it is an important step. The peer-review process could be strengthened by instituting more formal structure and criteria so it is done equitably for all manuscripts and journals.

 Publish and reference works in legitimate, reputable, peer-reviewed journals and be cautious of pay-to-publish journals that may lack legitimacy.

Professional associations and scientific organizations could play a role by rewarding high-quality studies in their domains. This can promote an organization's ability for recognizing high-quality research, particularly with early career members. Similarly, journalism could be rewarded more often for its quality and accurate science translation in a recognition of success that goes beyond sheer reach as measured by copies sold, impressions, or internet traffic. Examples include the American Society of Magazine Editors Ellie awards and the American Society of Journalists and Authors annual writing awards.

## Challenges in Translating and Communicating Nutrition Research

The Chicago panel discussed communicating nutrition research, a complex task and an acquired skill regardless of funding source.

Interpretation of research results and the implications, whether by authors or by the media or other sources, is another juncture at which bias can occur. This may result from an underlying tension fostered by the different (and sometimes conflicting) motives of the scientific community and the media. For publishers, health communications is a business. Selection of content (including continuing education pieces and supplements) and advertisements may be influenced by their potential to generate revenue

<sup>&</sup>lt;sup>16</sup> Thomas O. et al. 2008

and reprints to advance a publication. In this way, commercial interests can affect what professionals and the public learn about health.

Overall, there is frustration in the science community when media headlines and messaging exaggerate or misrepresent study data, especially regarding important context about the study and/or the broader literature. Misleading media coverage without context causes confusion and erodes trust in nutrition science. Common examples of such "spin" are listed in Box 4.

In the age of instantaneous and widely shared news throughout a 24-hour news cycle, a story may be designed, or the headlines sensationalized to generate press for the study's authors, the venue where it was presented (if not yet published), or the media outlet. Social media can rapidly disseminate inaccurate information, often by those lacking knowledge or expertise. Several sources of information can contribute to the "spin cycle" in the health news stream. The cycle can start with the original manuscript, such as an abstract that slants the results or conclusions that go beyond what the data support. This can then seep into the study news release. In an analysis of how randomized controlled trials were translated to news releases and news coverage, positive spin was identified in about half of releases and stories. The main factor associated with this misrepresentation in news releases was the presence of spin in the journal article abstract's conclusion.<sup>17</sup>

Access to original research is often restricted to journal subscribers and many journalists do not have access. Reporters facing quick deadlines may rely solely on a study news release and/or abstract for information and derive their own interpretation of the study. Yet their training often does not include the skills to interpret results, verify statistical methods, discern bias, limitations, or overall credibility of the research. In addition, reporters often do not

## BOX 4 Examples of "Spin" in Health Reporting As Expressed by Panel Attendees

- Using sensational headlines, hyperbole, and bold, embellished claims that go beyond what the research indicates
- Making negative or unremarkable study results sound positive
- Extrapolating animal research to humans and/or concealing or burying the fact that the study was conducted in animals
- Exaggerating effect size
- Omitting or downplaying funder involvement
- Making cause-and-effect claims based on data indicating correlation only

- Using ambiguous terms to quantify changes in variables (e.g., "a three-fold improvement in blood pressure") and failing to state the associated clinical relevance, if any
- Equating surrogate endpoints with hard outcomes
- Failing to qualify the generalizability of results from studies with small sample sizes and/or highly specialized study populations
- Failing to explain findings in context with the full body of literature on a topic

<sup>&</sup>lt;sup>17</sup> Yavchitz A, Boutron I, Bafeta A, Marroun I, Charles P, Mantz J, et al. Misrepresentation of randomized controlled trials in press releases and news coverage: A cohort study. PLoS Med 2012;9(9):e1001308. http://journal.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001308&imageURI=info:doi/10.1371/journal.pmed.1001308.t002

write the story headline, which adds an additional perspective (and one that may be particularly concerned with the story's reach). Many news outlets are struggling financially, making it challenging to find time and resources to verify information.

Unfortunately, news releases do not always accurately reflect research results in context. In an analysis of 127 news releases issued by nine high-profile medical journals, only 23 percent mentioned study limitations. Most releases covering industry-funded studies did not mention funding sources, and almost half of the releases presented data in a format that may exaggerate the perceived importance of findings.<sup>18</sup> In a similar analysis of 200 randomly selected news releases issued by 10 different academic medical centers, authors concluded that the releases often promote research that has uncertain relevance to human health and do not provide key facts or acknowledge important limitations.<sup>19</sup> News release content often affects other content developed to promote the study – such as news stories, videos, graphics, and blog posts. Breakdown of information becomes more likely as the content is relayed by messengers farther from the source who may be less-informed about science, equipped with their own agendas, biased or not knowledgeable.

HealthNewsReview.org is an independent watchdog group that aims to improve the quality and flow of consumer healthcare news. Its systematic reviews of health news stories and news releases evaluate content from academic medical centers, universities, government agencies, food companies and their public-relations agencies, and non-profits and advocacy groups. In its evaluation of healthcare journalism, advertising, marketing, public relations, and other messages that may influence consumers, HealthNewsReview.org provides criteria (Box 5) that stakeholders can use to evaluate these messages and make healthcare decisions.

 <sup>&</sup>lt;sup>18</sup> Wolshin S. and Schwartz LM. Press releases: Translating research into news. JAMA. 2002;287(21):2856-2858. https://jamanetwork.com/journals/jama/fullarticle/194960
<sup>19</sup> Woloshin S, Schwartz LM, Casella SL, Kennedy AT, Larson RJ. Press releases by academic medical centers: Not so academic? Ann Intern Med. 2009;150(9):613-618. http:// annals.org/aim/fullarticle/744471/press-releases-academic-medical-centers-so-academic

### — BOX 5 —

## **PR News Release Review Criteria**

Does the news release ...

- 1. Adequately discuss the costs of the intervention?
- **2.** Adequately quantify the benefits of the treatment/test/product/procedure?
- **3.** Adequately explain/quantify the potential harms of the intervention?
- 4. Evaluate the quality of the evidence?
- 5. Commit disease-mongering (e.g., exaggeration of a condition)?

- **6.** Identify funding sources and disclose potential conflicts of interest?
- **7.** Compare the new approach with existing alternatives?
- 8. Establish the availability of the treatment/test/product/procedure?
- 9. Establish the true novelty of the approach?
- **10.** Include unjustifiable, sensational language, including in the quotes of researchers?

#### **News Story Review Criteria**

Identical to the list above, except for criterion 6 and 10:

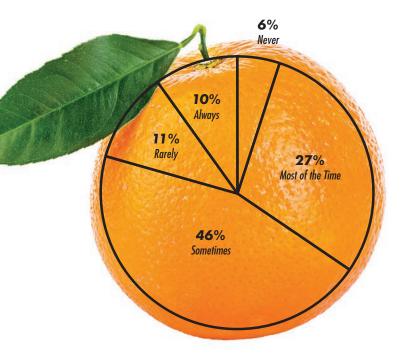
Does the story ...

6. Use independent sources and identify conflicts of interest?

10. Appear to rely solely or largely on a news release?

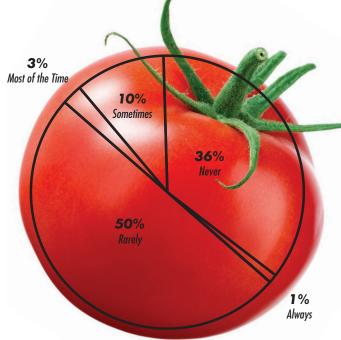
SOURCE: Health News Review https://www.healthnewsreview.org about-us/review-criteria/

The ability to critically evaluate nutrition research communications is especially important in our digital age. Despite having access to more information than ever, today's society is not necessarily better-informed. Information overload from sources that may or may not be credible, news literacy, and time influence how information is accurately understood and applied. Often professionals don't always have time to thoroughly fact-check or review original sources when presented with new information. In the same survey of Today's Dietitian readership referenced in Figures 2 and 3, respondents were asked how often they review the studies on which nutrition articles in the media are based (Figure 6). Thirty-seven percent reviewed studies most (27 percent) or all (10 percent) of the time, and nearly half (46 percent) sometimes reviewed them.



**FIGURE 6.** Today's Dietitian readers were asked to answer the statement: "When reading nutrition articles in the media, I review the studies that the articles are based upon..." Survey conducted October 17-18, 2017; n=418. Source: Presentation by Jack Graham, Great Valley Publishing Co., October 2017

Results were vastly different when respondents answered how often their patients/clients reviewed the studies on which nutrition articles in the media are based (Figure 7). Only 14 percent reviewed them at least some of the time – sometimes (10 percent), most of the time (3 percent), or always (1 percent).



**FIGURE 7.** Today's Dietitian readers were asked to answer the statement: "When reading nutrition articles in the media, my patients/clients review the studies that the articles are based upon..." Survey conducted October 17-18, 2017; n=418. Source: Presentation by Jack Graham, Great Valley Publishing Co., October 2017

When relying solely on media interpretation of nutrition research – whether for lack of time or inability to access the original scientific sources – news literacy becomes even more important. News literacy is the ability to assess the veracity of information and the quality of news stories.

According to the News Literacy Project: "News today comes from many directions – often in packaging that is confusing, if not downright contradictory. Even the most sophisticated audiences find it increasingly difficult to distinguish between legitimate news – information gathered in a dispassionate search for truth – and materials that are created to persuade, sell, mislead or exploit."<sup>20</sup>

20 News Literacy Project. http://http://www.thenewsliteracyproject.org/about/need.

A related discussion topic was the slippery slope of marketing material masquerading as "content," including the sentiment that publishers erode their credibility and purpose when they blur the line between news and sponsored content. Consumers, and sometimes even professionals, have difficulty discerning the difference between objective news and advertorials that appear to be journalistic content but are marketing pieces designed to promote a brand or product. The difficulty is exacerbated when an advertorial's graphic treatment blends in with the publication's other content. The journalistic landscape is further muddled by other types of writing such as false news and satire. Other times, journalists may be approached for stories by front groups that don't disclose their connection to a commercial interest.

## Strategies to Improve Communication of Nutrition Research

Attendees shared ideas for reducing bias and misleading information in the journalistic interpretation of research results, a problem with both industryfunded and non-industry-funded research.

### Improve Journalists' Training

Some suggested enhancing journalists' education and training so they can distinguish between intervention and observational research and understand the suitability of each for determining correlation versus causation. Others were less optimistic about how well this would work to ensure balanced, accurate reporting and to temper sensational headlines in the competitive media landscape. This suggestion may be more realistic in programs that train students in health or medical journalism. Part of the problem points to poor financial health of the media and finding a way to solve the problem of losing talented would-be journalists to other industries, particularly when it comes to health and medical reporting. As a result, there are fewer reporters spread thinner, leading to mistakes and lack of expertise.

## Help Shape Messages and Put Them in Context

There was more optimism around the potential for researchers themselves to help control the message, even to include greater involvement in social media. Because an abstract and manuscript's wording can influence a news release and beyond, authors should consider framing messages and putting them into context in a way that they would feel comfortable being disseminated in the media. There was also speculation as to whether scientists have a moral obligation to use social media to communicate results of research conducted with public, taxpayer funding.

In some cases, researchers may entrust stronger communicators to carry messages. But they can still work with those messengers to ensure accurate translation and identify the importance of the research in a way that will resonate with readers, without overstating or twisting its conclusions. Many journalists are keen to adhere to the Code of Ethics from the Society of Professional Journalists, which includes the journalistic responsibilities to seek truth and report it, minimize harm, act independently, and be accountable.<sup>21</sup>

There was agreement around the importance of early planning for communicating research results. It is important for researchers to develop a communications plan up front to try to control headlines and messages (to the extent possible) so that they are not misleading and are less likely to be manipulated or misconstrued. This includes citing critical details (e.g., distinguishing characteristics about the study population) near the beginning of the release. This is especially important when research results have high public interest and may appear contrary to common beliefs or popular claims. Universities should require that news releases be reviewed by the senior author(s) or principal investigator(s), in addition to the first author who is typically contacted regarding the release.

<sup>&</sup>lt;sup>21</sup> Society of Professional Journalists. SPJ Code of Ethics. Indianapolis, IL: 2014. https://www.spj.org/ethicscode.asp

Consumers often make decisions based on emotion or on input from friends and family instead of logic. Examples of such misperceptions are that pregnant woman should not eat seafood, that white foods do not have any nutritive value, that eating after a certain time in the evening causes weight gain, or that canned and frozen produce isn't as healthy as fresh. One strategy to effectively communicate nutrition science where misinformation abounds is to use fact-based appeals that also register emotion and clarify important context.

## Enforce Accreditation Guidelines for Continuing Education Providers

For peer-reviewed science journals and professionalfacing periodicals such as Today's Dietitian, content is typically written by health and science professionals and often includes continuing education components. Professional associations may have accreditation guidelines for continuing professional education providers, which may include disclosure of conflicts of interest and commercial bias; agreement to promote a balanced discussion of the topic, including risk vs. benefit information where appropriate; and commitment to prevent controversial or disputed issues as such, supported by documentation from current and reputable refereed scientific journal. When combined with a comprehensive (even if brief) literature review and practical application, this increases content's value for practitioners.

## Reconsider Publication of Negative and Null Results

According to participants, bias exists around publishing positive results vs. negative findings. The perception that industry sponsors research primarily for self-serving reasons could be diminished by publishing more negative or null findings of high-quality studies. These findings are often less provocative and thereby more difficult to publish, a phenomenon that is not exclusive to industry-sponsored studies. Attendees discussed the value of learning from negative results, which journal editors could opt to feature in special sections devoted to null, unexpected findings. Publication bias was also anecdotally attributed to editor rejection of industry-sponsored manuscripts.

Related to this was an appeal for the quality of publications to be weighted more heavily than quantity when it comes to achieving academic promotion and tenure. Publication of a complete research paper in a high-quality journal would be more valuable than publication of partial or repeated aspects of a study in multiple publications in lower-tier journals, though the latter yields a higher publication count for the same amount of research.



## CONCLUSION

This white paper summarizes two events held by the AHA's Industry Nutrition Advisory Panel. It addresses ways to strengthen the understanding of and support for the rigor and integrity of industry-funded nutrition research while simultaneously considering the challenges of negative connotations that are often conferred on industry scientists and their work. It is important to help stakeholders understand the industry's rationale for and contributions to nutrition research, as well as the various sources of bias (beyond commonly cited funding source bias) that can influence nutrition research in all sectors. Assessment of research findings should favor the quality of the science, irrespective of funding source.

Complex global public health and nutrition challenges call for multi-sector collaborations. The food and beverage industries have a key role in creating a healthier food environment by producing a healthier food supply and making it attractive, accessible and affordable. To leverage this sector's strengths, it would be beneficial to ensure consistent adherence to guiding principles for collaborative scientific research, publication, and communication, as well as to strengthen the rigor of peer review. The American Heart Association, through INAP, welcomes the opportunity to continue the dialogue with additional stakeholders about operationalizing and enforcing guiding principles for industry involvement in nutrition research. The public health and science communities, including industry scientists, should examine best practices and attain consensus on the creation of a framework to promote the upright conduct and translation of nutrition research.