

# RESPONSIBILITIES OF EPIDEMIOLOGISTS IN THE CONDUCT AND DISSEMINATION OF RESEARCH IN THE PUBLIC INTEREST



UNIVERSITY OF  
CANBERRA  
AUSTRALIA'S CAPITAL UNIVERSITY  
Adjunct Professor

— Colin L. Soskolne, Ph.D. —

[www.colinsoskolne.com](http://www.colinsoskolne.com)



Professor emeritus

## Introduction

Beginning with its accidental discovery in 1965, aspartame has historically been marred by several controversies, with significant economic interests and political influences suspected of being brought to bear in the scientific debate. Although currently considered “safe” by prominent health authorities around the world, vested corporate interests and influence are still at work today; they quickly spring into action whenever a scientific study tackles the potential harms associated with aspartame consumption.

Approved in over 90 countries around the world, aspartame (and other artificial sweeteners) address the highly profitable market that serves those people who repeatedly try to curb their energy intake. However, obesity rates in North America and elsewhere have been climbing ever since aspartame was approved as a food additive in the 1980s. Obesity rates have now reached alarming levels, casting serious doubt as to aspartame's alleged health benefits. But, if aspartame is, on the whole, ineffectual, is it also harmful? This is what some scientists are still trying to determine, despite what appear to be attempts at undermining their research.

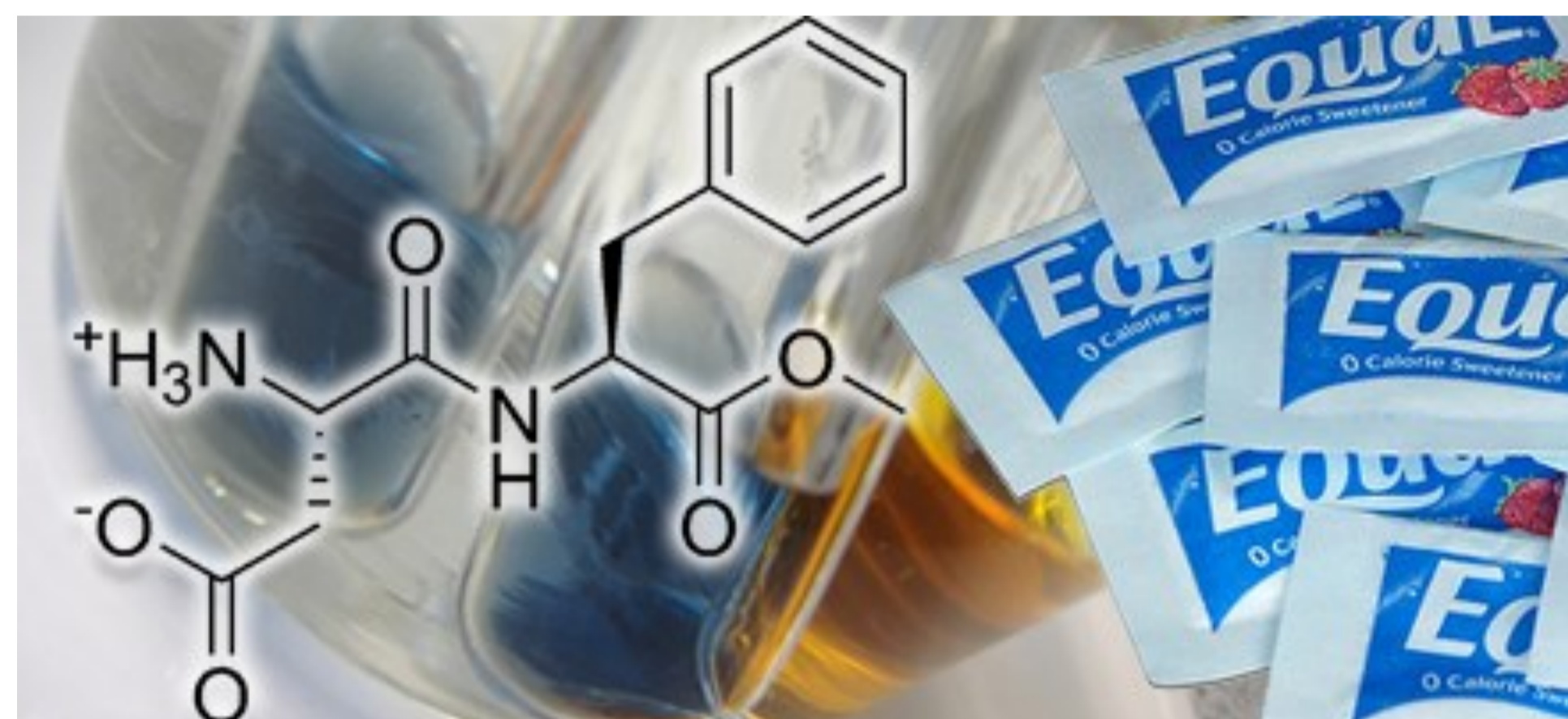
The largest toxicological (animal) study ever conducted to examine the association between aspartame consumption and cancer incidence was published out of Italy in 2005 and 2006. Alerted to this statistically significant and positive finding in animal models, researchers at the Channing Laboratory (affiliated with Brigham and Women's Hospital [BWH] and Harvard Medical School, Boston, USA) recognized that they had access to a human data repository containing the prospective collection of aspartame-related information on a large, long-term cohort of both men and women.

## Objective

To bring to attention the controversy initiated in the Boston USA area on October 24, 2012, when epidemiologists, fulfilling their role in protecting public health, had their research undermined by their employing university/affiliated hospital.

## Methods

Media releases form the basis of this analysis.



## Factual Background

The Channing Laboratory-affiliated researchers convened to retrospectively explore the relationship in humans between aspartame and cancer incidence. Their study demonstrated a significant increase in certain hematopoietic cancers in men (correlated with aspartame consumption), but not in women, thus replicating, in part, the findings from the Italian animal studies in humans.

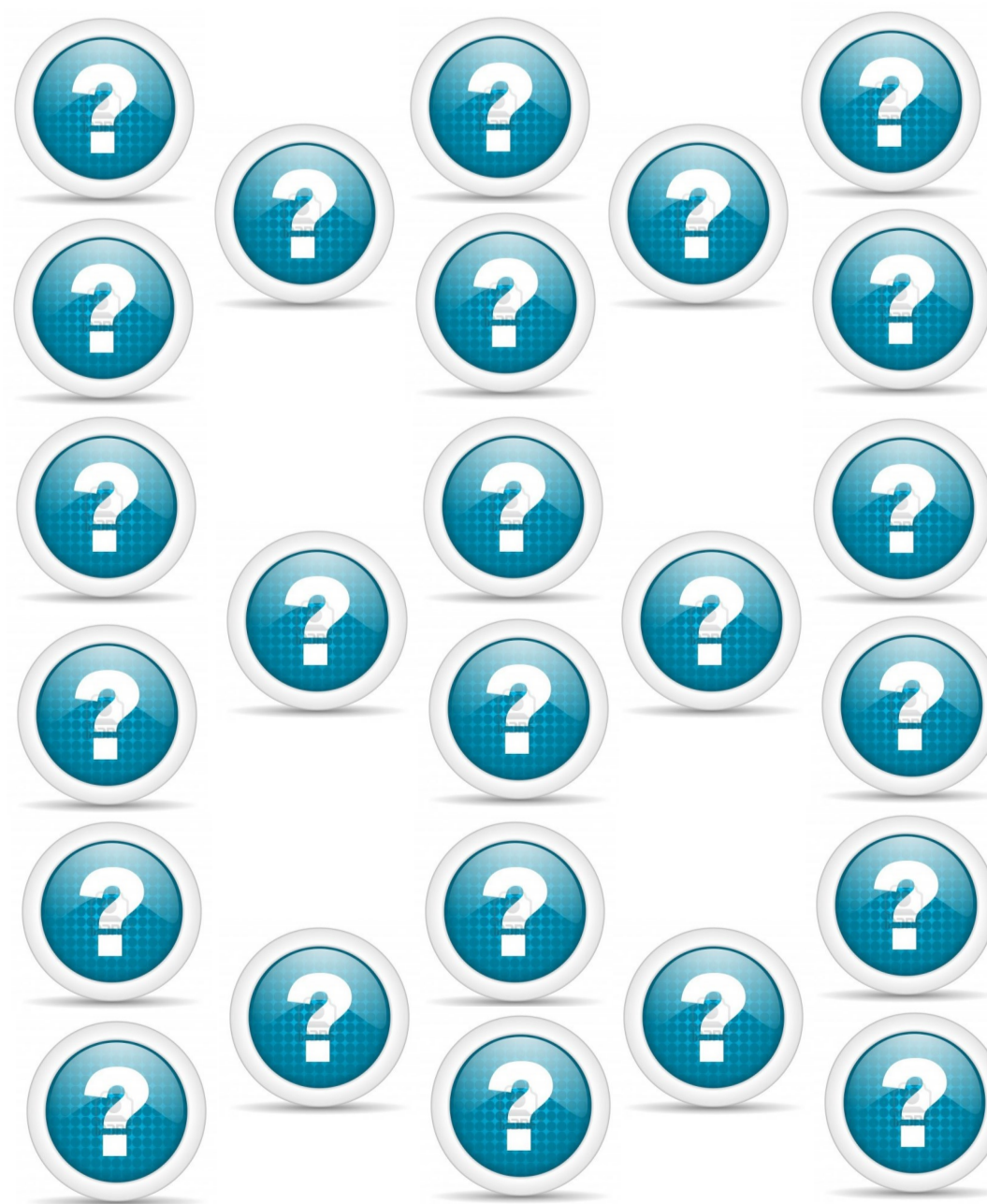
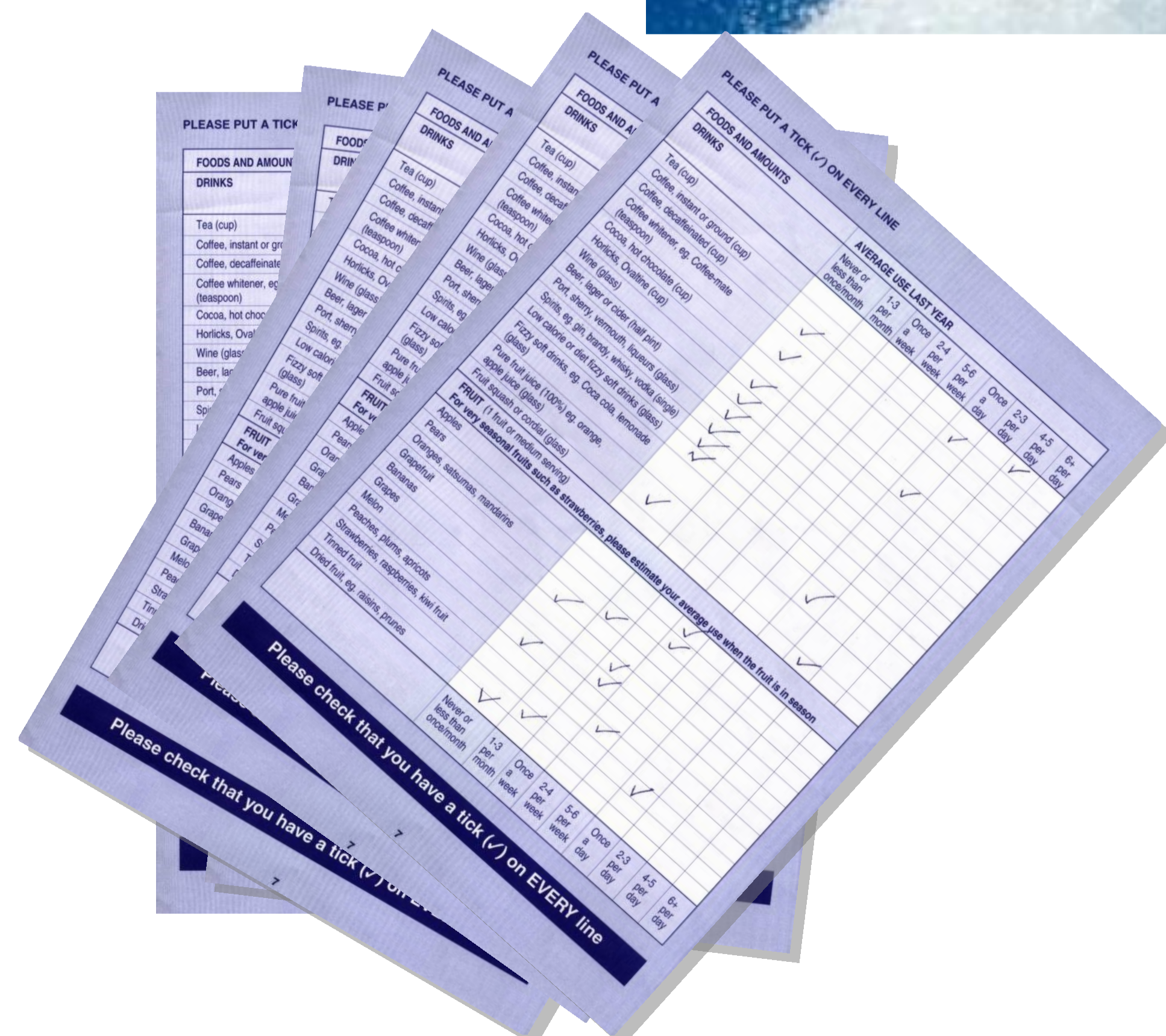
**Attempts to publish their research article in six leading scientific journals demonstrating their positive finding in human males, but not in females, was rejected each time.** The article by Schernhammer et al eventually was accepted by the *American Journal of Clinical Nutrition* (AJCN) and was released electronically on October 24, 2012.

**Some 35 minutes prior to its release by the AJCN, BWH used its public relations/communications office to effectively cast doubt on the study by withdrawing support of its promotion of the work to the media earlier that week.** Through a media release, they explicitly withdrew their support of the study's findings, claiming that "... the scientific leaders at Brigham and Women's Hospital did not have an opportunity, prior to today, to review the findings of the paper. ..." This action has resulted in controversy for the researchers, the affiliated institutions, and a confused and frustrated public.

Earlier in the week, BWH had promoted the study in a press release. Then, according to media reports, they changed their position a few days later. The claim by the Senior Vice President of communications at BWH was that "... BWH Media Relations was premature in the promotion of this work ...," apologising for the time that the media had invested in the story.

Following on the withdrawal of its initial support, all interviewed outside of the BWH public relations office, including members of the research team and AJCN editorial team, had stated that, despite its limitations, the findings were significant enough to warrant publication and to encourage further research. The lead researcher made the point that the team's study did not prove aspartame to be dangerous.

In the media coverage of the withdrawal of BWH's support, it was recognized that *science worth publishing* (my emphasis) often serves solely to alert other researchers to the need for further study. Indeed, most epidemiologists would agree that no single epidemiological study demonstrates causation, but it rather adds to the body of evidence for use in any future attempts to infer causation.



## Emerging Questions and Possible Answers

- 1 Q. What was the initial reason for public attention being brought to this particular article, about to be published in the AJCN, by the BWH Media Relations office?

A. To inform the public of a potential health concern and bring acclaim to the Institution through the discovery made by its researchers.
- 2 Q. What reason was offered by the BWH Media Relations office for withdrawing, a few days later, their initial support for the article about to be published online in the AJCN?

A. To correct its earlier enthusiasm for the research based on its Board of Regent's consideration of last-minute senior scientists at the institution's assessment that the data "were not ready for prime time."
- 3 Q. What interests were at play to bring such pressure to bear?

A. The scientific pursuit of truth on the part of the scientists, concern about causing (unjustified) alarm among the artificial sweetener-using public, and distress to the artificial sweetener industry from research impugning its products.
- 4 Q. The role of the Public Relations office at BWH is to promote the research undertaken at that institution and that it considers worthy. Were they premature in so doing earlier in the week?

A. Unlikely, given that the article had been peer reviewed and was deemed by the gatekeepers of quality science at the AJCN to be worthy of publication.
- 5 Q. Why would the BWH Board of Regents suddenly want a rapid review of an article by its own in-house "senior scientists" and why would the assessment of these senior scientists be permitted to trump the recommendation of the AJCN editorial process in its decision to publish the article?

A. Here lie reasons for concern in that such conduct on the part of the Board of Regents is not only unusual, but entirely inappropriate in relation to the notion of academic freedom and respect for the autonomy of the research team.
- 6 Q. To what extent, if any, was the artificial sweetener industry behind the actions taken by the Harvard Medical School and BWH's Board of Regents in casting doubt on the research?

A. While such actions would not be novel, a response to a more recent direct communication with corporate headquarters resulted in a negative answer.
- 7 Q. Does the artificial sweetener industry, or its affiliates, donate money to Harvard University and/or its affiliates? If so, was there a veiled threat that donations could cease if this line of research incriminating their products were to continue at Harvard and BWH?

A. Unknown, but it would be important for the sake of transparency to know the answer to these questions. Regardless, such actions would not be novel.
- 8 Q. Did pressure and influence, direct or indirect, from the artificial sweetener industry have any bearing on the sequence of events experienced by the research team in its attempt to disseminate its findings? Is this type of influence known at other universities and, indeed, on the editorial boards and/or among the peer reviewers of some scientific journals?

A. Unknown, but it would be important for the sake of transparency to know the answer to these questions. Regardless, such actions would not be novel.
- 9 Q. What does requiring clearance by "the scientific leaders" at any academic institution mean for academic freedom? Is this censorship leading to the suppression/oppression of science? Could these influences/biases be operating at some level in this situation?

A. Unknown, but it would be important for the sake of transparency and the future of the role of science in protecting the public interest to know the answers to these questions. Regardless, such actions would not be novel.
- 10 Q. Should the public and, indeed, other scientists be concerned about the kind of public relations exercise used by the Harvard Medical School and BWH? What are the implications for other researchers on other topics?

A. Indeed, we should be concerned because the whole question of academic freedom is at stake.
- 11 Q. The first six journal editorial boards rejected the article. Are these boards infiltrated with editors/board members aligned with or even beholden to the artificial sweetener industry? Or, was the article, indeed, fatally flawed, aspects missed through the AJCN review process and then detected by the last minute review conducted by BWH senior scientists through the BWH Board of Regents?

A. It is unlikely that the article was fatally flawed because, if so, it would have likely also been rejected by the AJCN. The need for impartiality in the pursuit of truth is what this question underscores.
- 12 Q. Is it possible that the researchers could lose their jobs if they were to persist with this line of inquiry, unless, of course, they were in the future to show "no harm" or raise doubt as to the relationship between aspartame and hematopoietic cancers?

A. Pressure and influence from powerful interests, especially on junior academics, whether conscious or subconscious, to tow the party line for fear of consequences relating to their tenure and promotion underscore these questions and also reveal how much repression bias may operate in the world of academic research. Mechanisms are needed to protect against such pressures.
- 13 Q. Does this give us cause to examine the relationship between academia and industry?

A. Indeed, undue influence goes counter to the notion both of transparency and impartiality in the pursuit of truth in the public interest.
- 14 Q. Once ethics clearance is obtained, is it not only right that the research move to completion (including dissemination), as long as it complies with the rigors of scientific ethics and integrity?

A. Indeed, and the autonomy of the research team ought to have been respected through the dissemination phase of their study.
- 15 Q. Are there similarities between this experience and others relating to, e.g., tobacco, asbestos, cell phones, behind which powerful moneyed interests wield dominating influence?

A. There seem to be parallels between this case relating to aspartame and the other instances of oppression and suppression bias.

## Conclusions and Recommendations

This experience provides a case study in professional and scientific integrity with ethical, moral, and public health implications. It raises several questions, including whether the aspartame industry wielded any influence, direct or indirect, in blocking the work from being published, and any role that a university can play in vetting research prior to publication in terms of an academic's autonomy. Fifteen questions are raised and deserve to be discussed among all scientists, especially applied scientists, internationally, if the integrity of the scientific enterprise, academic freedom, and the public interest are to be protected. Being the key stakeholder, the public ought to be engaged in these discussions; thus, mechanisms for ensuring broad-based public engagement would be appropriate.