

Mr. Edgar M. Swindell, JD
Associate General Counsel
Office of the General Counsel
Ethics Division Room 710E
Humphrey Bldg.
200 Independence Ave, SW
Washington, DC 20201

March 3, 2010

Dear Mr. Swindell:

The purpose of this memorandum is: (1) to request copies of NHLBI's co-sponsorship agreement with Diet Coke for it's the *Heart Truth Campaign* and related events; and (2) to request that NHLBI terminate its co-sponsorship with Diet Coke.

(1) Please provide copies of the co-sponsorship agreement between Diet Coke and the National Heart Lung and Blood Institute ("NHLBI"), a National Institutes of Health ("NIH") institute within the U.S. Department of Health and Human Services ("HHS"), for the 2008, 2009 and 2010 *The Heart Truth* campaign, *The Heart Truth* Road Show, and *The Heart Truth's* Red Dress Collection Fashion Show. As per the National Institutes of Health Ethics Program's August 8, 2002 HHS General Counsel's Co-Sponsorship Guidance Memorandum (hereinafter "Co-Sponsorship Memo") co-sponsorship agreements are to be written and made available to the public upon request.¹

(2) The Co-Sponsorship Memo clearly outlines important ethics standards for use when determining whether or not co-sponsorship of an "educational program, public information campaign or similar event" is permissible.² *The Heart Truth* campaign is a complex and comprehensive national campaign that includes *The Heart Truth* Road Show and Red Dress Collection Fashion Show. Diet Coke co-sponsors *The Heart Truth* Road Show and the Red Dress Collection Fashion Show and is a corporate partner in other aspects of the campaign. We believe that the NHLBI's co-sponsorship with Diet Coke grew out of the genuine desire to take the message of heart health to the nation's women. While the partnership may have begun with the best of intentions, there are many aspects of the relationship, some that have grown and evolved over time, that are irreconcilable with the ethics guidelines contained in the Co-Sponsorship Memo. As such, NHLBI should terminate Diet Coke's co-sponsorship of *The Heart Truth* campaign and related events.

¹ HHS General Counsel's Co-Sponsorship Guidance Memorandum, August 8, 2002, <http://ethics.od.nih.gov/procedures/COSPONSORSHIP-DAEO-memo-Aug-02.pdf>.

²*Id.* at 1.

NHLBI's Co-Sponsorship with Diet Coke has Resulted in a Strong Appearance of Product Endorsement

The “Basic Principles” section of the Co-Sponsorship Memo states: “It is particularly important to avoid the appearance that co-sponsorship of an event with an outside entity constitutes an HHS endorsement of...products of that entity.”³ As part of the *The Heart Truth* campaign, Diet Coke co-sponsors *The Heart Truth* Road Show, a traveling exhibit providing free heart disease risk factor screenings and dissemination of educational materials. According to media reports⁴ and documented in a photograph of a 2009 *The Heart Truth* Road Show event available on the NHLBI's website, free samples of Diet Coke were provided to Road Show event participants. (See Attachment I). The provision of diet soft drink product samples during an NHLBI event where women receive NHLBI authored heart health educational materials and risk factor screening conveys a strong appearance of product endorsement by the primary sponsor of the event—the NHLBI.

The NHLBI's “Heart Truth Corporate Sponsors” webpage also describes an arrangement with Diet Coke whereby:

Diet Coke is also inviting MyCokeRewards (MCR) members to join them in their support of *The Heart Truth* by donating their MCR points. Diet Coke will match each donation and make a monetary donation to the Foundation for the National Institutes of Health to further efforts of women's heart health awareness and research. Visit www.DietCoke.com for more information.⁵

The Diet Coke website features tabs along the left-hand side of the page that read “The Heart Truth,” “Fashion Show,” and “Get Involved.”⁶ The “Get Involved” page encourages women to redeem My Coke Rewards Points in order to benefit the Foundation for the National Institutes of Health via a matching donation from Diet Coke. My Coke Rewards are obtained by consuming Diet Coke and other Coca-Cola Company products. Use of the *The Heart Truth* campaign to encourage My Coke Rewards membership appears to have been highly successful for Diet Coke.⁷

³ *Id.* at 2.

⁴ Richard Tedesco, *Health Quencher*, Promo Magazine, Feb. 1, 2008, http://promomagazine.com/eventmarketing/diet_coke_health_quencher_tour_0201/.

⁵ NHLBI, Corporate Partners, <http://www.nhlbi.nih.gov/educational/hearttruth/partners/corporate-partners.htm>.

⁶ See <http://www.dietcoke.com/hearttruth/get-involved.jsp>.

⁷ In 2008, Coca-Cola sought to double its My Code Rewards membership base of 9 million. In a May 1, 2008 interview, Monika Sola of SearchRev, the online search engine marketing firm Coca-Cola contracted to increase My Coke Rewards membership, told the press that Diet Coke “launched a major campaign last February” with NHLBI's *The Heart Truth* campaign and “[w]e got 60% of registrations [to My Coke Rewards] from that campaign.” *Finding Coke Drinkers*, Promo Magazine, May 1, 2008, http://promomagazine.com/awards/iaawards/cocacola_finding_drinkers/index.html.

While proceeds from redeemed rewards points do not directly benefit NHLBI, NHLBI's endorsement of the My Coke Rewards matching scheme on the NHLBI website combined with Diet Coke's direct appeal to consumers to "Get Involved" to support women's heart health by redeeming My Coke Rewards points obtained by consuming Diet Coke conveys a strong appearance of product endorsement by the NHLBI. Furthermore, the link to www.dietcoke.com (which contains marketing for Diet Coke) on NHLBI's webpage is itself a form of advertising for Diet Coke, for which in other circumstances Diet Coke would actually pay.

Diet Coke Has No "Demonstrable Substantive Interest" in Women's Heart Health

According to the "Legal Requirements" section of the Co-Sponsorship Memo "HHS may not enter into a co-sponsorship with a non-Federal entity that does not have a demonstrable substantive interest in the subject matter of the event."⁸ In a 2008 Coca-Cola Company Press Release announcing Diet Coke's partnership with *The Heart Truth* campaign and *The Heart Truth* Road Show, Diet Coke described its interest in women's heart health as follows:

"Our research with consumers has told us that women today are increasingly mindful of making choices that positively impact their lives. For them, drinking Diet Coke is an essential part of their modern pursuit of well-being," said Katie Bayne, chief marketing officer, Coca-Cola North America. "Through this partnership, Diet Coke can help raise awareness about heart disease, the number one killer of women, while showing women how to incorporate heart health into their lives."⁹

In February 2008, Caren Pasquele Seckler, group director of Low Calorie Colas for Coca-Cola was quoted as saying, "Two of *The Heart Truth's* heart health tips are to engage in moderate exercise and maintain a healthy weight, so if you are looking to cut calories, Diet Coke is an ideal beverage choice."¹⁰ And in 2010, Diet Coke North America's Brand Director stated the following:

"*The Heart Truth* campaign celebrates healthy lifestyle choices, which have become increasingly important to Diet Coke consumers. In the third year of our partnership with the NHLBI, we are proud that we can continue to play an important role in this educational conversation," said William White, Brand Director, Diet Coke North America. "One of the tips from NHLBI is to maintain a healthy weight. Incorporating regular physical activity into your routine is an essential approach to maintaining a healthy, balanced and active lifestyle. And with no calories and great

⁸ Co-Sponsorship Memo at 3.

⁹ Coca-Cola Company, News Release, Diet Coke Teams Up With the National Heart, Lung and Blood Institute (NHLBI) to Increase Awareness of Women's Heart Disease, Jan. 8, 2008, http://www.thecocacolacompany.com/presscenter/nr_20080108_ccna_teams_up_with_nhlbi.html.

¹⁰ *Cause Marketing: Diet Coke's Red Dress Tour Takes Off*, Eventmarketer.com, Feb. 25, 2009, <http://74.125.95.132/search?q=cache:6dTx2JVEluwJ:www.eventmarketer.com/viewmedia.asp%3FprmMI D%3D2366%26prmID%3D1+cause+marketing+diet+coke+red+dress&cd=1&hl=en&ct=clnk&gl=us>.

taste, Diet Coke is not only an excellent choice for managing calorie intake, it also provides refreshment and hydration that helps our consumers be their best throughout the day.”¹¹

As is evinced by Diet Coke’s Marketing Officer and Brand Director, any general interest Diet Coke may have in women’s heart health is eclipsed by its desire to maintain Diet Coke as part of the mix of foods and beverages consumed by heart health conscious women. It is difficult to see how Diet Coke can be said to have a “demonstrable substantive interest” in women’s heart health beyond positioning its product as a heart healthy beverage option in the marketplace.

Diet Coke Should be Classified as a “Prohibited Source”

The “Additional Guidance” section of the Co-Sponsorship Memo describes “prohibited sources” as “any person or entity that:...(d) has interests that may be substantially affected by the performance or nonperformance of the official duties of an employee of that agency....”¹² There are a number of factors HHS must weigh and consider when deciding whether a prohibited source may be engaged as a co-sponsor. One line of inquiry is “Would co-sponsoring an event with the prohibited source create the appearance of partiality toward that source or the appearance of an endorsement of that source with respect to other matters that it has pending before the Government?”¹³ As outlined below, Diet Coke has a variety of interests substantially affected by the NHLBI.

Diet Coke’s interest in maintaining an image of its products as beneficial to heart health may be substantially affected by NHLBI

In 2007 and 2008 respectively, the Framingham Heart Study (funded by NHLBI) and the San Antonio Heart Study (funded by NIH) released research findings of a possible link between diet or artificially sweetened beverages and increased risk factors for heart disease.¹⁴ As long-term observational studies, the Framingham and San Antonio Heart Studies provide invaluable data in the fight against heart disease. As then NHLBI Acting Director Elizabeth G. Nabel stated in response to the Framingham study: “Other studies have shown that the extra calories and sugar in soft drinks contribute to

¹¹ Coca-Cola Company, News Release, Diet Coke and Heidi Klum Inspire Women & Their Families to Learn *The Heart Truth*, Feb, 4, 2010, http://www.thecoca-colacompany.com/presscenter/nr_20100204_heart_truth.html.

¹² Co-Sponsorship Memo at 6.

¹³ *Id.* at 7.

¹⁴ See Ravi Dhingra, et al., *Soft Drink Consumption and Risk of Developing Cardiometabolic Risk Factors and the Metabolic Syndrome in Middle-Aged Adults in the Community*, 116 *Circulation* 480-488 (2007); Sharon P. Fowler, et al., *Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-term Weight Gain*, 16 *Obesity* 1894–1900 (2008).

weight gain, and therefore heart disease risk....This study echoes those findings by extending the link to all soft drinks and the metabolic syndrome.”¹⁵

The Framingham Heart Study research findings sparked a lively public debate about the role of diet soft drinks and heart disease. In order to protect its product image, Diet Coke, and other diet soft drink makers, responded via the non-alcoholic beverage industry trade association, the American Beverage Association, by releasing a press release disputing the Framingham Heart Study findings.¹⁶ The Coca-Cola Company’s Beverage Institute for Health & Wellness also released a webpage entitled “Do regular and diet soft drinks raise heart disease risk?”¹⁷ The webpage remains available to the public and disputes the validity of the Framingham Heart Study findings (“There is no logical explanation for the hypothesis that the behavior of drinking diet soft drinks could cause metabolic syndrome”¹⁸) and counsels consumers that diet beverages “remain a fine choice in moderation and are certainly safe.”¹⁹

Diet Coke has an interest in future government funded studies related to diet soft drink consumption and heart health that may be substantially affected by NHLBI.

Coca-Cola Company’s Beverage Institute for Health & Wellness conceded that the Framingham Heart Study finding “raises interesting questions” and argued that “[o]nly clinical trials can show cause and effect.”²⁰ A number of federal agencies fund research into heart health, including the NHLBI. Diet soft drink sales could be substantially affected by adverse research findings linking diet soft drinks and increased risk for heart disease. Both the Framingham and San Antonio study findings raise important issues around the advisability of recommending diet or artificially sweetened beverages as a part of a heart healthy diet, and strongly support the need for further study of the issue. The relationship between metabolic syndrome and diet soft drinks remains an open question. NHLBI’s public alliance with Diet Coke may have a chilling effect on further research into diet or artificially sweetened soft drink consumption and heart health.

¹⁵ NIH, Press Release, Framingham Observational Study Notes Greater Incidence of Metabolic Syndrome Among Adults Consuming Soft Drinks, July 23, 2007, <http://public.nhlbi.nih.gov/newsroom/home/GetPressRelease.aspx?id=2423>.

¹⁶ American Beverage Association, Press Release, Statement of the American Beverage Association Regarding Soft Drink Consumption Study in Circulation, July 23, 2007, <http://www.ameribev.org/news--media/news-releases--statements/more/63/>.

¹⁷ Coca-Cola Company, Beverage Institute for Health & Wellness, Do regular and diet soft drinks raise heart disease risk?, http://www.beverageinstitute.org/about_us/research_news.shtml.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

Diet Coke's interest in diet soft drink sales and consumption levels may be substantially affected by the NHLBI.

A core part of the NHLBI's mission is to translate "basic discoveries into clinical practice."²¹ To that end, NHLBI releases fact-based guides to the public about heart health. These guides contain information about diet. Diet Coke's interest in soft drink sales and consumption levels is substantially affected by current NHLBI dietary recommendations and any future dietary recommendations made by NHLBI with respect to diet soft drinks.

The NHLBI's current recommendation to "Steer Clear of Fast Food" substantially affects Diet Coke's interest in soda fountain sales of its product

"The Healthy Heart Handbook for Women" (hereinafter "Handbook") was produced by NHLBI, NIH and HHS and is available on NHLBI's website.²² The 2007 version of the Handbook directs women to "Steer Clear of Fast Food."²³ "Fast food" or "quick service restaurants" make up a considerable portion of what is referred to as the beverage sales "fountain channel"—beverage sales dispensed from a soda fountain, as opposed to a can or a bottle. In 2007 it was reported that, "Coke controls 70% of the [fountain] channel and gets a third of its domestic sales and profit" from fountain sales.²⁴ One industry insider estimated that "McDonald's restaurants account for as much as 10% of Coke's North America profit."²⁵

In April of 2009, the Coca-Cola Company announced that, true to its 54-year relationship with McDonald's, it would be maintaining its presence as McDonald's fountain and bottled beverage provider and that Diet Coke would be part of its "core fountain line-up at McDonald's 14,000 U.S. restaurants."²⁶ Diet Coke has a clear interest in "fountain channel" sales. If women were to "Steer Clear of Fast Food," Diet Coke fountain sales would decline. The degree to which the NHLBI through its *The Heart Truth* campaign and other educational programs emphasizes and promotes its recommendation to "Steer Clear of Fast Food" substantially affects Diet Coke's interest in fountain channel beverage sales.

²¹ NHLBI, Mission Statement, <http://www.nhlbi.nih.gov/about/org/mission.htm>.

²² The Healthy Heart Handbook for Women, NIH Publication No. 07-2720 (2007) <http://www.nhlbi.nih.gov/educational/hearttruth/downloads/pdf/handbook-for-women.pdf>.

²³ Handbook at 86.

²⁴ Kate Macarthur, *Pepsi Gains Toehold in Coke Stronghold*, Advertising Age, March 12, 2007, http://adage.com/article?article_id=115485.

²⁵ *Id.*

²⁶ Coca-Cola Company, News Release, The Coca-Cola Company Announces Refreshing Line-Up of Fountain and Bottled Beverages for McDonald's U.S. Restaurants, April 27, 2009, http://www.thecocacolacompany.com/presscenter/nr_20090427_mcdonalds.html.

Diet Coke has interests that may be substantially affected by any future diet soft drink consumption recommendations made by the NHLBI

The existence of two prominent long-term observational heart study research findings showing a possible link between diet or artificially sweetened soft drink consumption and increased risk factors for heart disease should certainly be taken into consideration by NHLBI when making future dietary recommendations regarding soft drink consumption and heart health. The NHLBI is currently in the process of updating its *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. Any future dietary recommendations made by NHLBI would substantially affect Diet Coke's interest in maintaining product sales.

Co-sponsorship of *The Heart Truth* creates the appearance of partiality toward Diet Coke with respect to its interest in the 2010 US HHS and USDA revision of the *Dietary Guidelines for Americans*

The USDA and HHS are in the process of revising the nation's 2010 *Dietary Guidelines for Americans*. The American Beverage Association ("ABA") is currently advocating for the inclusion of two recommendations. Two Coca-Cola Company and Coca-Cola Bottler representatives are ABA Officers and six Coca-Cola Company and Coca-Cola Bottler representatives are members of the ABA Board of Directors. The ABA's participation in the 2010 *Dietary Guidelines for Americans* process included testimony at a January 29, 2010 committee hearing. NHLBI's co-sponsorship of the very high profile *The Heart Truth* campaign with Diet Coke creates an appearance of partiality towards the Coca-Cola Company and its trade association, the ABA, in the process of revising the *Dietary Guidelines for Americans*.

The Benefits of Co-Sponsorship with Diet Coke, a Prohibited Source, Are Not Outweighed by the Appearance of Product Endorsement and Partiality Conveyed by the Co-Sponsorship

Diet Coke has provided a wealth of dissemination and media attention to NHLBI's *The Heart Truth* campaign. The fact remains that the link between risk factors for heart disease and diet soft drink consumption remains an open question of scientific inquiry. In December of 2009, The Journal of the American Medical Association published a commentary entitled "Artificially Sweetened Beverages: Cause for Concern" urging further research of the issue.²⁷ There exists a real danger that diet soft drink consumption could be damaging the heart health of the very women who are the intended audience of *The Heart Truth* campaign. NHLBI's extensive co-sponsorship with Diet Coke including the provision of free Diet Coke samples at heart health screenings and promotion of the My Coke Rewards matching program, gives a very public appearance that NHLBI is taking sides in the debate over the role of diet soft-drinks and heart health.

²⁷ David S. Ludwig, *Artificially Sweetened Beverages: Cause for Concern*, 302 JAMA 2477-2478 (2009).

Conclusion

No benefits uniquely conveyed by Diet Coke's co-sponsorship can be outweighed by the strong appearance of product endorsement and partiality. We urge the National Institutes of Health Ethics Program to take immediate action to see to the termination of Diet Coke's co-sponsorship of NHLBI's *The Heart Truth* campaign.

Sincerely,

Cara L. Wilking
Staff Attorney
Public Health Advocacy Institute

Cc: Susan B. Shurin, M.D., Acting Director, NHLBI
Nancy O'Hanlon, Deputy Ethics Counselor, NHLBI

ATTACHMENT I
FREE SAMPLES PROVIDED AT HEART TRUTH ROAD SHOW EVENTS



“A woman gets her blood pressure taken at *The Heart Truth*[®] Road Show at Grand Central Terminal in New York, NY.”²⁸

²⁸Image and caption available at <http://www.nhlbi.nih.gov/educational/hearttruth/events/road-show-photos.htm>.



Tower of Diet Coke at 2008 Minneapolis Road Show event.²⁹

²⁹ From the album: "Heart Truth Road Show - Minneapolis, MN" by The Heart Truth Report, Added March 3, 2008 (available via *The Heart Truth's* Facebook page).



Another view of the tower of Diet Coke displayed at the 2008 Minneapolis Road Show event.³⁰ Diet soda appears to be flanked by NHLBI *The Heart Truth* educational brochures.

³⁰ From the album: "Heart Truth Road Show - Minneapolis, MN" by The Heart Truth Report, Added March 3, 2008 (available on *The Heart Truth's* Facebook page).