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PETITION TO HALT MISLEADING	)	<b>Docket No.:</b>	
ADVERTISING BY ANNALS OF	)	Date:	<b>September 30, 2019</b>
INTERNAL MEDICINE	)		
	)		

# **Submitted to**

Federal Trade Commission
Bureau of Consumer Protection
600 Pennsylvania Ave., NW
Washington, DC 20580

Fax: (202) 326-3799

# **Submitted by**

Physicians Committee for Responsible Medicine 5100 Wisconsin Ave., NW, Ste. 400 Washington, DC 20016

## I. ACTION REQUESTED

The Physicians Committee for Responsible Medicine is a nonprofit public health advocacy organization supported by more than 175,000 members, including 12,000 physicians and many more health care professionals. The Physicians Committee requests that the Federal Trade Commission (FTC) bring an action pursuant to the Federal Trade Commission Act (FTCA) section 13, 15 U.S.C. § 53, to enjoin the *Annals of Internal Medicine* (AIM) from disseminating or causing the dissemination of any current or future misleading advertisements, as described in more detail below. The Physicians Committee also requests that FTC require AIM to issue a public retraction of and corrective statement regarding the advertisement issued on September 25, 2019.

#### II. LEGAL FRAMEWORK

FTC has broad authority to regulate advertising by corporations, trade associations, and food advertisers pursuant to FTCA sections 5, 12, and 15, which together prohibit "persons, partnerships, or corporations" from engaging in "unfair or deceptive acts or practices in or affecting commerce," 15 U.S.C. § 45(a), and from making "any false advertisement," 15 U.S.C. § 52, that is "misleading in a material respect," 15 U.S.C. § 55(a)(1). FTC pays "closest attention to . . . [a]ds that make claims about health or safety" or "that consumers would have trouble evaluating for themselves." FTC, *Advertising FAQ's: A Guide for Small Business* (2001), https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business.

The legal framework for FTC action and interpretation of the FTCA in the context of health claims is set forth in FTC's *Enforcement Policy Statement on Food Advertising* (1994), http://www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising, which relies on and works in conjunction with the *FTC Policy Regarding Advertising Substantiation* (1983), http://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation and the *FTC Policy Statement on Deception* (1983), https://www.ftc.gov/system/files/documents/public statements/410531/831014deceptionstmt.pdf.

An advertisement is deceptive if it contains a representation or omission that is likely to mislead consumers acting reasonably under the circumstances and the representation or omission is material. *Id.* at 2. A representation or omission is deceptive if it leaves consumers with a misimpression about a product. *Id.* at 3–4. A material representation or omission is one that is likely to affect a consumer's choice or use of a product. *Id.* at 5. The AIM advertisement described below meets all of these criteria.

## III. ARGUMENT

Beginning September 25, 2019, AIM promoted a supplement to its journal by widely disseminating an advertisement that contains the following misrepresentations (emphasis and formatting as shown in original as seen in Part V):

1. New guidelines: No need to reduce red or processed meat consumption for good health

A rigorous series of reviews of the evidence found little to no health benefits for reducing red or processed meat consumption

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Based on a series of 5 high-quality systematic reviews of the relationship between meat consumption and health, a panel of experts recommends that most people can continue to consume red meat and processed meat at their average current consumption levels.

. . .

most adults should continue to eat their current levels of red and processed meat intake

. . .

Among 12 randomized trials enrolling about 54,000 individuals, the researchers did not find statistically significant or an important association between meat consumption and the risk of heart disease, diabetes, or cancer. Amongst cohort studies following millions of participants, the researchers did find a very small reduction in risk amongst those who consumed three fewer servings of red or processed meat per week. However, the association was very uncertain.

. . .

The authors of an accompanying editorial from Indiana University School of Medicine say that while **the new recommendations are bound to be controversial, they are based on the most comprehensive reviews of the evidence to date.** Those that seek to dispute the NutriRECS findings will be hard-pressed finding appropriate evidence with which to build an argument.

These misrepresentations are directly at odds with abundant scientific evidence demonstrating the potential ill health effects of red and processed meat and the benefits of reducing consumption of red and processed meat. Additionally, contrary to the misrepresentations, the reviews referenced in the advertisement do not discount the benefits of avoiding red and processed meat; rather, they show only that weak evidence supports the conclusion that modest reductions in meat intake are accompanied by modest health benefits—a far cry from AIM's claim that there is "[n]o need to reduce red or processed meat consumption for good health."

The studies referred to in the advertisement were meta-analyses combining the results of prior studies. One of these meta-analyses<sup>1</sup> drew its analysis from the findings of the Women's Health Initiative, which was not designed to eliminate meat consumption. Participants in the Women's Health Initiative reduced meat intake only modestly, resulting in a modest reduction in mortality related to breast cancer. This finding in no way supports the notion that there is "No need to reduce red or processed meat consumption for good health." Rather, it shows that modest dietary changes yield modest benefits.

As an analogy, if studies showed that modest reductions in tobacco use yielded only modest health benefits, it would be inaccurate and dangerous to suggest that there is "No need to reduce tobacco use for good health."

Meta-analyses are designed to compile the results of prior studies that vary in quality, in the populations studied, and in the methods used. As such, they can often understate the effects that

are more clearly evident in well-conducted individual randomized trials. Well-designed observational studies and clinical trials clearly show benefits of avoiding meat.

Of the many pieces of evidence that bear on this issue, one comes from the Adventist Health Study-2, including nearly 61,000 participants. The body mass index of daily meat-eaters was 28.8 kg/m<sup>2</sup>—well over 25, which is the upper limit of the healthy range. For those eating meat less than once per week, BMI was a bit lower, at 27.3. But for those avoiding animal products altogether, the average BMI was 23.6. Similarly, diabetes prevalence was 7.6% in daily meat-eaters, 6.1% in those eating meat less than once per week, and only 2.9% in those avoiding animal products.<sup>2</sup> In other words, if modest dietary differences are associated with only modest health effects, this in no way discounts the fact that more substantial dietary differences are associated with much greater health effects.

The advertisement omits critical information about the underlying scientific evidence and the quality of the authors' methodology. For example, according to a 2012 study from the Harvard School of Public Health, eating red meat increases the risk of dying prematurely, including from heart disease or cancer. Among a group of 121,342 individuals followed for up to 28 years, each daily serving of red meat increased the risk of dying by 12 percent. For processed meat (e.g., hot dogs, ham, or bacon), each daily serving increased the risk of death by 20 percent. Conversely, those individuals avoiding these products had corresponding reductions in risk, compared with those eating them.

Two or more servings of red or processed meat a week can increase one's risk for colorectal cancer, according to a study presented in 2015 at the National Cancer Research Institute Cancer Conference. Researchers in that study examined dietary data from the UK Biobank, encompassing 500,000 men and women, for red meat consumption and bowel cancer incidence rates. Participants who ate red meat four or more times per week had a 42 percent increased risk for colorectal cancer, compared with those who ate it less than once per week. Those who consumed processed meat two or more times per week increased their risk for colorectal cancer by 18 percent, compared with those who consumed none. Again, avoiding these products was associated with reduced risk.

Similarly, the World Health Organization released a 2015 report based on an examination of more than 800 studies. The report classified consumption of red meat as "probably carcinogenic to humans" and consumption of processed meat as "carcinogenic to humans," the latter on the basis of sufficient evidence for colorectal cancer. The report also observed associations between red and processed meat consumption and stomach, pancreatic, and prostate cancers. Avoiding these products is associated with reduced risk.

A recent University of Oxford study concluded that eating just one slice of bacon a day is linked to higher risk of colorectal cancer. According to a study published online last year in the *International Journal of Cancer*, a diet high in red meat increases risk for colon cancer in women. The American Medical Association now calls on U.S. "hospitals to improve the health of patients, staff, and visitors by . . . eliminating processed meats from menus."

Well-executed randomized clinical trials have established the value of reducing red and processed meat consumption beyond reasonable doubt. This value is the result, in part, of avoiding meat *per se*, and, in part, of the fact that avoiding meat means replacing it with more healthful food choices. The Dietary Approaches to Stop Hypertension (DASH) study, based on the observation that people who avoid meat tend to have healthy blood pressures, rigorously tested a diet that reduced meat intake. The study reduced the number of red meat servings from 1.8 to 0.5, replacing meat with more healthful foods, finding significant reductions in blood pressure. 9

The DASH diet is now widely accepted as an effective intervention and is cited in the Dietary Guidelines for Americans. <sup>10</sup> The DASH diet had its greatest benefit for African Americans with hypertension. In eight weeks, their blood pressures dropped by 13.2 mm/Hg systolic and 6.1 mm/Hg diastolic. <sup>9</sup> This benefit is potentially lifesaving, yet AIM's false claim encourages individuals to discount these benefits, putting their lives at risk.

Similarly, a reduction in red and processed meat is a key part of the Mediterranean diet, which has been tested in large numbers of individuals, most notably in a randomized clinical trial including more than 7,000 individuals at risk for heart disease in the well-known PREDIMED (Prevención con Dieta Mediterránea) study. Results published in the *New England Journal of Medicine* in 2018 included a significant reduction in cardiovascular risk. <sup>11</sup> It is particularly noteworthy that, in the PREDIMED study, those who avoided meat the most and who most closely followed a vegetarian pattern had the greatest reductions in their risk of both all-cause mortality and cardiovascular mortality. <sup>12</sup>

An abundant body of evidence also shows that individuals who avoid meat altogether and replace it with more healthful foods reap benefits for heart health, body weight, and blood sugar control. Specifically, meta-analyses of randomized clinical trials have established that people avoiding meat have healthier cholesterol levels, <sup>13</sup> body weight, <sup>2</sup> blood pressure, <sup>14</sup> and blood sugar control. <sup>15</sup>

AIM's false claim would discourage individuals from avoiding meat and from replacing meat with more healthful food choices, putting them at risk for major health problems.

FTC evaluates misrepresentations and omissions such as these from the perspective of a consumer acting reasonably, or as an average consumer would, under the circumstances. FTC Policy Statement on Deception at 2. An advertisement that reasonably can be interpreted in a misleading way is deceptive even when other, non-misleading interpretations are equally possible. *Id.* at 3. "An interpretation will be presumed reasonable if it is the one the respondent intended to convey." *Id.* A representation or omission is material, and thereby causes injury, if the consumer would have chosen differently but for the deception. *Id.* at 5–6. Materiality is presumed when, as here, AIM "knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false." *Id.* at 5.

AIM misleadingly states that there is "[n]o need to reduce red or processed meat consumption for good health" because there are "little to no health benefits for reducing red or processed meat consumption." According to AIM, a "panel of experts" conducted the "most comprehensive

reviews of the evidence to date" and arrived at "recommendations . . . bound to be controversial" and available only in the journal sold by AIM.

AIM goes further, brazenly saying that "those who seek to dispute" its findings will be "hard-pressed finding appropriate evidence with which to build an argument." As a sophisticated national medical-specialty publication, AIM well knows the detriments of consuming red or processed meat. Yet AIM omits or misrepresents scientific evidence showing the ill effects of doing so, all in an apparent effort to convince consumers to change their behavior by consulting the journal or its website or by purchasing or subscribing to the journal. This is a deceptive practice that, to the extent it is influential, will contribute to substantial morbidity and mortality.

Many Americans currently suffer from health challenges. The majority of American adults are overweight, 30 percent have prediabetes or diabetes, and cardiovascular disease and cancer take an enormous toll, due, in part, to dietary choices that are influenced by advertisements, such as that promoted by AIM.

## IV. CONCLUSION

Abundant evidence links red and processed meat consumption to heart disease, colorectal cancer, and increased risk of premature death. Even eating just one slice of bacon a day is linked to higher risk of colorectal cancer. AIM's advertisement misrepresents or fails to mention such hazards and instead directs consumers to AIM's website and journal to obtain "[n]ew guidelines" and "new recommendations."

As a result, AIM's advertisement does far more than cause financial harm—it also promotes physical harm to those who follow its dangerous advice. The Physicians Committee therefore requests that FTC enjoin AIM from disseminating, or causing the dissemination of, the advertisement at issue and any similar misleading advertisements. The Physicians Committee also requests that FTC require AIM to issue a public retraction of and corrective statement regarding the advertisement issued on September 25, 2019.

#### V. EXHIBIT

# Annals of Internal Medicine®

Embargoed for release until 5:00 p.m. ET on Monday September 30 2019 Annals of Internal Medicine Tip Sheet

@Annalsofim

Below please find summaries of new articles that will be published in the next issue of *Annals of Internal Medicine*. The summaries are not intended to substitute for the full articles as a source of information.

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1. New guidelines: No need to reduce red or processed meat consumption for good health A rigorous series of reviews of the evidence found little to no health benefits for reducing red or processed meat consumption

Note: HD video soundbites of the authors discussing the paper are available to download at http://www.dssi.mon.com/MM/ACP-red-meat.

Recommendations: http://annals.org/aim/article/doi/10.7326/M19-1621

Editorial: http://annals.org/aim/article/doi/10.7326/M19-2620

URLs go live when the embargo lifts

Based on a series of 5 high-quality systematic reviews of the relationship between meat consumption and health, a panel of experts recommends that most people can continue to consume red meat and processed meat at their average current consumption levels.

Current estimates suggest that adults in North America and Europe consume red meat and processed meat about 3 to 4 times per week. The evidence reviews and recommendations are published in *Annals of Internal Medicine*.

Researchers from Dalhousie University and McMaster University in Canada, together with the Spanish (Iberoamerican) and Polish Cochrane Centers, performed four parallel systematic reviews that focused both on randomized controlled trials and observational studies addressing the possible impact of red meat and processed meat consumption on cardiometabolic and cancer outcomes.

A fifth systematic review addressed people's health-related values and preferences on meat consumption.

Based on those reviews, a panel comprised of fourteen members from seven countries voted on recommendations for red and processed meat consumption.

Their conclusion that most adults should continue to eat their current levels of red and processed meat intake, is contrary to almost all other guidelines that exist.

Among 12 randomized trials enrolling about 54,000 individuals, the researchers did not find statistically significant or an important association between meat consumption and the risk of heart disease, diabetes, or cancer. Amongst cohort studies following millions of participants, the researchers did find a very small reduction in risk amongst those who consumed three fewer servings of red or processed meat per week. However, the association was very uncertain.

In addition to studying health effects, the authors also looked at people's attitudes and health-related values surrounding eating red and processed meat. They found that people ate meat because they liked it or perceived it as healthy and would be reluctant to change their habits.

The authors say they did not consider ethical or environmental reasons for abstaining from meat in their recommendations, however, these are valid and important concerns, though concerns that do not bear on individual health.

The researchers used the Nutritional Recommendations (NutriRECS) guideline development process, which

includes rigorous systematic review methodology, and GRADE methods to rate the certainty of evidence for each outcome and to move from evidence to dietary recommendations to develop their guidelines.

According to the authors, this is important because dietary guideline recommendations require close consideration of the certainty in the evidence, the magnitude of the potential harms and benefits, and explicit consideration of people's values and preferences.

Most nutritional recommendations are based on unreliable observational studies.

However, the authors note that their recommendations are weak, based on low-certainty evidence. Of note, there may be reasons other than health concerns for reducing meat consumption.

The authors of an accompanying editorial from Indiana University School of Medicine say that while **the new recommendations** are **bound to be controversial**, **they are based on the most comprehensive reviews of the evidence to date**. Those that seek to dispute the NutriRECS findings will be hard-pressed finding appropriate evidence with which to build an argument.

**Notes and media contacts**: The meat recommendations include 5 reviews, a recommendation, and an editorial. For embargoed PDFs please contact Lauren Evans at <a href="mailto:laevans@acponline.org">laevans@acponline.org</a>. To speak with the lead author of the recommendations, Bradley Johnston, PhD, please contact him directly at <a href="mailto:BJohnston@dal.ca">BJohnston@dal.ca</a>. To reach Aaron Carroll, MD, MS, author of the accompanying editorial, please contact Christine Drury at <a href="mailto:cldrury@iu.edu">cldrury@iu.edu</a>.

#### VI. SCIENTIFIC REFERENCES

- 1 Zeraatkar D, Johnston BC, Bartoszko J, et al. Effect of lower versus higher red meat intake on cardiometabolic and cancer outcomes: a systematic review of randomized trials. *Ann Int Med.* 2019, in press.
- 2 Barnard ND, Levin SM, Yokoyama Y. A systematic review and meta-analysis of changes in body weight in clinical trials of vegetarian diets. *J Acad Nutr Diet*. 2015;115:954-969.
- 3 Pan A, Sun Q, Bernstein AM, et al. Red meat consumption and mortality: results from 2 prospective cohort studies. *Arch Intern Med*. 2012;172:555-563.
- 4 Bradbury K, Key T. The association of red and processed meat, and dietary fibre with colorectal cancer in UK Biobank. Poster presented at: National Cancer Research Institute Cancer Conference; November 3, 2015: Liverpool, UK. http://abstracts.ncri.org.uk/abstract/the-association-of-red-and-processed-meat-and-dietary-fibre-with-colorectal-cancer-in-uk-biobank/. Accessed September 27, 2019.
- 5 Bouvard V, Loomis D, Guyton KZ, et al. Carcinogenicity of consumption of red and processed meat. *Lancet Oncol.* 2015;16:1599-1600.
- 6 Bradbury KE, Murphy N, Key TJ. Diet and colorectal cancer in UK Biobank: a prospective study. *Int J Epidemiol*. Published online April 17, 2019.
- 7 Rada-Fernandez de Jauregui D, Evans CEL, Jones P, Greenwood DC, Hancock N, Cade JE. Common dietary patterns and risk of cancers of the colon and rectum: Analysis from the United Kingdom Women's Cohort Study (UKWCS). *Intl J Cancer*. 2018;143:773-781.
- 8 American Medical Association. Healthy Food Options in Hospitals H-150.949. 2018. https://policysearch.ama-assn.org/policyfinder/detail/Healthy%20Food%20Options %20in%20Hospitals%20H-150.949?uri=%2FAMADoc%2FHOD.xml-0-627.xml. Accessed September 27, 2019.
- 9 Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. *N Engl J Med*. 1997;336:1117-1124.
- 10 U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015. http://health.gov/dietaryguidelines/2015/guidelines/. Accessed September 27, 2019.
- 11 Martínez-González MA, Ros E, Estruch R. Primary Prevention of Cardiovascular Disease with a Mediterranean Diet Supplemented with Extra-Virgin Olive Oil or Nuts. *N Engl J Med*. 2018;379:1388-1389.
- 12 Martinez-Gonzalez MA, Sanchez-Tainta A, Corella D, et al. A provegetarian food pattern and reduction in total mortality in the Prevención con Dieta Mediterránea (PREDIMED) study. *Am J Clin Nutr.* 2014;100(suppl):320S-328S.
- 13 Wang F, Zheng J, Yang B, Jiang J, Fu Y, Li D. Effects of Vegetarian Diets on Blood Lipids: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *J Am Heart Assoc.* 2015;4:e002408.
- 14 Yokoyama Y, Nishimura K, Barnard ND, et al. Vegetarian diets and blood pressure: a meta-analysis. *JAMA Internal Medicine*. 2014;174:577-587.
- 15 Yokoyama Y, Barnard ND, Levin SM, Watanabe M. Vegetarian diets and glycemic control in diabetes: a systematic review and meta-analysis. *Cardiovasc Diagn Ther*. 2014;4:373-382.