

# INTERNATIONAL JOURNAL OF HUMAN NUTRITION AND FUNCTIONAL MEDICINE

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Barceloneta sunset photo © 2019 by Dr Vasquez

**Critique • Post-Publication Review • Journal Editing • Research Methodology • Medical Education**

# Educational Errors in "Effect of Vitamin D and Omega-3 Fatty Acid Supplementation on Kidney Function in Patients with Type 2 Diabetes" published in JAMA 2019

Alex Vasquez DO ND DC FACN

## Context

Major medical journals publish bogus pro-drug and anti-nutrition research in order to 1) groom medical audiences for pharmaceutical purchases, 2) defend and please their pharmaceutical advertisers (who—in addition to spending hundreds of millions of dollars on advertising—commonly purchase article reprints for millions of dollars/\$, euros/€, pounds/£<sup>1</sup>), 3) maintain the financial and sociopolitical dominance of the medical profession, 4) deter the general public from seeking and using nonmedical treatments, and 5) misinform politicians and policymakers so that laws, public funds, policies, and research monies will be directed in favor of the medical profession, including medical schools (that produce consecutive generations of pharmaceutically indoctrinated and nutritionally illiterate clones) and drug researchers who use public funds to create privatized drugs that escalate profit of the pharmaceutical industry. While such has always been the inherent bias of the medical publishing industry, some of us noted a new wave of remarkable exacerbations of this bias including overt deceptions and ethical departures published in the biomedical research starting in 2018.<sup>2,3</sup> The cyclical-reciprocal feeding of misinformation from medical journals and drug companies to medical students, physicians, policymakers, the media (e.g., television, magazines, and newspapers—all of which receive millions of \$/€/£ in drug company advertising) creates the pro-pharma “echo chamber” which—when *repetition* becomes *consensus* becomes *practice* becomes *sales* becomes *profit for bribing politicians to write pro-*

*pharma laws forcing the population to receive mandatory drugs*<sup>4</sup>—becomes the pro-pharma “power vortex” with each aspect reinforcing the other, ultimately leading to medical profiteering, political dominance, censorship of information, blockade of criticism, and restriction of free speech, including banning of books, blockade of documentary films, censorship of individuals, and aggressive and structured attacks against medical professionals to “destroy, neutralize, discredit” them.<sup>5</sup>

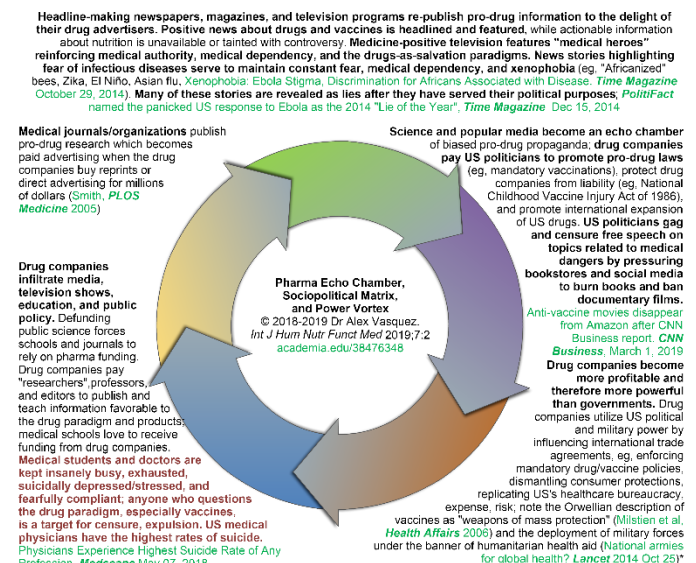


Illustration from: Pharma Echo Chamber, Sociopolitical Matrix, and Power Vortex. *IJHNF* 2019 [academia.edu/38476348](http://academia.edu/38476348) See also<sup>2,3</sup>

## Critique en breve

On November 8 of 2019, *JAMA—Journal of the American Medical Association* published “Effect of

Vitamin D and Omega-3 Fatty Acid Supplementation on Kidney Function in Patients With Type 2 Diabetes” (doi:10.1001/jama.2019.17380); this is yet another pathetic “nutrition study” which was so poorly designed and misrepresentative of the practice of clinical nutrition that it was sure to provide the desired “negative” results for *JAMA*’s medical audience and the resulting headlining news distributed to millions of professionals, policymakers, and patients. As a matter of course, the story was rapidly echoed by pro-pharma *Medscape* (and numerous other medial magazines) in the expected uniformed and adolescent commentary.<sup>6</sup> My initial critiques of this publication are as follows

1. **Authors and Editors failed integrate previous data:** In order for science to advance and avoid repeating the same errors and wasting misappropriated effort (i.e., repeatedly *recreating the wheel in the age of air and space travel*), research authors and journal editors have the responsibility to competently maintain awareness of the current *state of the art* so that research and publications reflect advancement in the field. Clearly in the case of this publication, neither the authors nor the editors represented the current state of the art in nutritional management the conditions discussed herein.<sup>7</sup> The numerous nutritional interventions previously shown to provide positive benefit for this condition were ignored in this publication to support what appears to have been the predetermined conclusion and goal.
2. **Nobody really thinks this would work:** This investigation was mostly a wild goose chase, a strawman fallacy. No Naturopathic or Clinical Nutrition student would intervene in such a complex condition as diabetes with pending renal insufficiency by *solely* using *underdosed* fish oil and *underdosed* vitamin D; as such this intervention represents clinical incompetence more so than the competent clinical practice of Nutrition and any of its related variants (e.g., Functional Medicine, Naturopathic Medicine, Functional Inflammology, etc).
3. **The investigators used inadequate doses of both nutrients in order to ensure failure of the intervention:** The authors used <50% of the proper dose of vitamin D for healthy patients<sup>8,9</sup>, let alone a proper dose for diabetic patients which is more commonly in the range of 10,000 IU per day.<sup>10,11</sup> The authors used 44% of the proper dose of EPA+DHA; obviously, under-dosing the treatments is expected to lead to lackluster results and *much ado about nothing*.
4. **The investigators intentionally hid the identity of the placebo so that readers would not know what really happened:** The authors failed to provide the identity of the “placebo” so that doctors and policymakers would not know that they used olive oil as the placebo in order to undercut the perception of

any clinical benefit; olive oil is one of the most potent antiinflammatory and cardioprotective oils known to biomedical science. Using olive oil as a “placebo” is inappropriate in an intervention testing the efficacy of a cardioprotective and renoprotective intervention.

5. **This study does not represent the modern practice of Clinical Nutrition:** Half-baked ideas presented as reasonable intervention are still half-baked ideas; this study is inappropriate in its design, implementation, and reporting. This study does nothing to inform the practice of Medicine, and—in fact by misrepresenting a flawed study as a legitimate study—this publication simply misleads healthcare professionals, policymakers, and the general public.
6. **As expected, this low-quality research was repeated throughout the pro-pharma echo chamber:** The inaccurate summary of this meaningless publication resounded via various pro-medical and pro-drug websites internationally. The commentary published by *Medscape* concluded, “This was a high quality trial that tells us that we don’t need to focus our energies here [on using vitamin D and fish oil]. Only a novice or ignoramus would consider this “a high quality [sic] trial” and describing it as such does more than mislead the reader about this particular topic but also by extension about the very nature of clinical research, ethics, and investigational study design.

**“A red herring is something that misleads or distracts from a relevant or important question. It may be either a logical fallacy or a literary device that leads readers or audiences toward a false conclusion.” from Wikipedia**

### Conclusion

This publication “Effect of Vitamin D and Omega-3 Fatty Acid Supplementation on Kidney Function in Patients with Type 2 Diabetes” published in *JAMA* 2019 is a disservice to physicians, policymakers, and patients and should be retracted from the biomedical record. This investigation intentionally underdosed both interventions, withheld the identity of the placebo, and attempted to apply these interventions in an inappropriate manner that was unlikely to benefit patients and was nearly ensured to produce negative results which would then be inappropriately generalized in news and other media outlets; as such this publication is a *red herring—a piece of information which is or is intended to be misleading or distracting*. Journal editors and trial authors should consult with legitimate nutrition experts prior to the design and publication of research outside their scope of training, knowledge, and experience. ☒

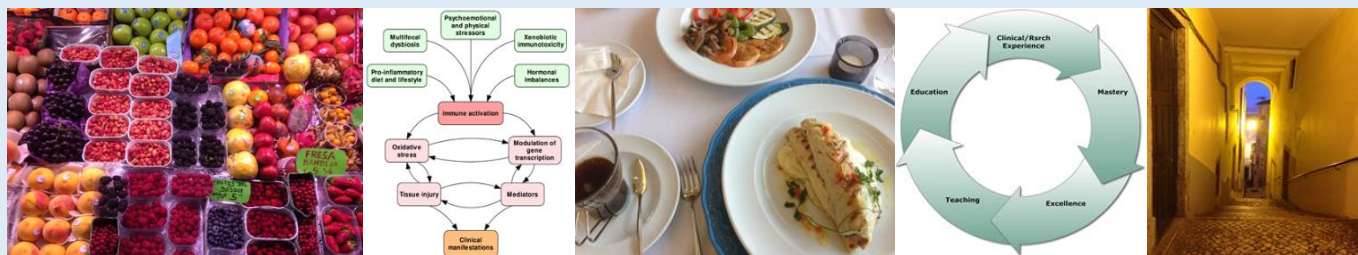


## Citations:

1. Smith R. Medical journals are an extension of the marketing arm of pharmaceutical companies. *PLoS Med* 2005 May;2(5):e138 <https://doi.org/10.1371/journal.pmed.0020138>
2. Vasquez A, Pizzorno J. Concerns About the Integrity of The Scientific Research Process-Focus on Recent Negative Publications Regarding Nutrition, Multivitamins, Fish Oil And Cardiovascular Disease. *Integr Med* (Encinitas). 2019 Feb;18(1):8-15 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6601430/> Archived by author (Vasquez) at <https://www.academia.edu/39907759>
3. Vasquez A. Vitamins Against Viruses: Implausible Pro-Vaccine Publications Contrasted Against Ignored Public Health Campaigns and Double-Blind Placebo-Controlled Clinical Trials. *Journal of Orthomolecular Medicine* 2019 <https://isom.ca/article/vitamins-against-viruses> Archived by author at <https://www.academia.edu/39406350>
4. "Critics of Senate Bill 277, which would eliminate the personal belief and religious exemptions for schoolchildren, accuse the measure's supporters in the Legislature of doing the bidding of donors who make vaccines and other pharmaceuticals. ... Receiving more than \$95,000, the top recipient of industry campaign cash is Sen. Richard Pan, a Sacramento Democrat and doctor who is carrying the vaccine bill. In addition, the industry donated more than \$500,000 to outside campaign spending groups that helped elect some current members last year. Leading pharmaceutical companies also spent nearly \$3 million more during the 2013-2014 legislative session lobbying the Legislature, the governor, the state pharmacists' board and other agencies, according to state filings." Miller J. Drug companies donated millions to California lawmakers before vaccine debate. *Sacramento Bee* 2015 Jun <https://www.sacbee.com/news/politics-government/capitol-alert/article24913978.html>
5. "Merck made a 'hit list' of doctors who criticized Vioxx, according to testimony in a Vioxx class action case in Australia. The list, emailed between Merck employees, contained doctors' names with the labels 'neutralise,' 'neutralised' or 'discredit' next to them. According to The Australian, Merck emails from 1999 showed company execs complaining about doctors who disliked using Vioxx. One email said: We may need to seek them out and destroy them where they live..." Edwards J. Merck Created Hit List to "Destroy," "Neutralize" or "Discredit" Dissenting Doctors. 2009 May <https://www.cbsnews.com/news/merck-created-hit-list-to-destroy-neutralize-or-discredit-dissenting-doctors>
6. Wilson FP. The Charlie Brown of Supplements Strikes Out Again. *medscape.com/viewarticle/920520* 2019 November 13
7. Vasquez A. *Textbook of Clinical Nutrition and Functional Medicine (Inflammation Mastery)*. International College of Human Nutrition and Functional Medicine. Barcelona, 2016 <https://www.inflammationmastery.com/book-nutrition-functional-medicine>
8. Vasquez A, Manso G, Cannell J. The clinical importance of vitamin D (cholecalciferol): a paradigm shift with implications for all healthcare providers. *Altern Ther Health Med*. 2004 Sep-Oct;10(5):28-36 <https://www.academia.edu/18078062>
9. Vasquez A, Cannell J. Calcium and vitamin D in preventing fractures: data are not sufficient to show inefficacy. *BMJ*. 2005 Jul 9;331(7508):108-9 <https://www.academia.edu/40429791>
10. Vasquez A. How to Understand, Refute, and Plan Studies Using Vitamin D. *Int J Hum Nutr Funct Med* 2017 <https://www.academia.edu/31412957>
11. Kimball SM, Mirhosseini N, Holick MF. Evaluation of vitamin D3 intakes up to 15,000 international units/day and serum 25-hydroxyvitamin D concentrations up to 300 nmol/L on calcium metabolism in a community setting. *Dermatoendocrinol* 2017 Apr 13;9(1):e1300213. doi: 10.1080/19381980.2017.1300213

**About the author and presenter: Alex Kennerly Vasquez DO ND DC (USA), Fellow of the American College of Nutrition (FACN), Overseas Fellow of the Royal Society of Medicine:** An award-winning clinician-scholar and founding Program Director of the world's first fully-accredited university-based graduate program in Human Nutrition and Functional Medicine, Dr Alex Vasquez is recognized internationally for his high intellectual and academic standards and for his expertise spanning and interconnecting many topics in medicine and nutrition. Dr Vasquez holds three doctoral degrees as a graduate of University of Western States (Doctor of Chiropractic, 1996), Bastyr University (Doctor of Naturopathic Medicine, 1999), and University of North Texas Health Science Center, Texas College of Osteopathic Medicine (Doctor of Osteopathic Medicine, 2010). Dr Vasquez has completed hundreds of hours of post-graduate and continuing education in subjects including Obstetrics, Pediatrics, Basic and Advanced Disaster Life Support, Nutrition and Functional Medicine; while in the final year of medical school, Dr Vasquez completed a Pre-Doctoral Research Fellowship in Complementary and Alternative Medicine Research hosted by the US National Institutes of Health (NIH). Dr Vasquez is the author of many textbooks, including *Integrative Orthopedics* (2004, 2007 2012), *Functional Medicine Rheumatology* (Third Edition, 2014), *Musculoskeletal Pain: Expanded Clinical Strategies* (commissioned and published by Institute for Functional Medicine, 2008), *Chiropractic and Naturopathic Mastery of Common Clinical Disorders* (2009), *Integrative Medicine and Functional Medicine for Chronic Hypertension* (2011), *Brain Inflammation in Migraine and Fibromyalgia* (2016), *Mitochondrial Nutrition and Endoplasmic Reticulum Stress in Primary Care, 2<sup>nd</sup> Edition* (2014), *Antiviral Strategies and Immune Nutrition* (2014), *Mastering mTOR* (2015), *Autism, Dysbiosis, and the Gut-Brain Axis* (2017) and the 1200-page *Inflammation Mastery 4<sup>th</sup> Edition* (2016) also published as a two-volume set titled *Textbook of Clinical Nutrition and Functional Medicine*. "DrV" has also written approximately 100 letters and articles for professional magazines and medical journals such as *TheLancet.com*, *British Medical Journal* (BMJ), *Annals of Pharmacotherapy*, *Nutritional Perspectives*, *Journal of Manipulative and Physiological Therapeutics* (JMPT), *Journal of the American Medical Association* (JAMA), *Original Internist*, *Integrative Medicine*, *Holistic Primary Care*, *Alternative Therapies in Health and Medicine*, *Journal of the American Osteopathic Association* (JAOA), *Dynamic Chiropractic*, *Journal of Clinical Endocrinology and Metabolism*, *Current Asthma and Allergy Reports*, *Complementary Therapies in Clinical Practice*, *Nature Reviews Rheumatology*, *Annals of the New York Academy of Sciences*, and *Arthritis & Rheumatism*, the Official Journal of the American College of Rheumatology. Dr Vasquez lectures internationally to healthcare professionals and has a consulting practice and service for doctors and patients. DrV has served as a consultant, product designer, writer and lecturer for Biotics Research Corporation since 2004. Having served on the Review Boards for *Journal of Pain Research*, *Autoimmune Diseases*, *PLOS One*, *Alternative Therapies in Health and Medicine*, *Neuropeptides*, *International Journal of Clinical Medicine*, *Journal of Inflammation Research*, *BMC Complementary and Alternative Medicine* (all PubMed/Medline indexed), *Integrated Blood Pressure Control*, *Journal of Biological Physics and Chemistry*, and *Journal of Naturopathic Medicine* and as the founding Editor of *Naturopathy Digest*, Dr Vasquez is currently the [Editor \(2013-\) of International Journal of Human Nutrition and Functional Medicine](#) and [Editor \(2018-present\) of Journal of Orthomolecular Medicine](#), published for more than 50 consecutive years by the International Society for Orthomolecular Medicine.





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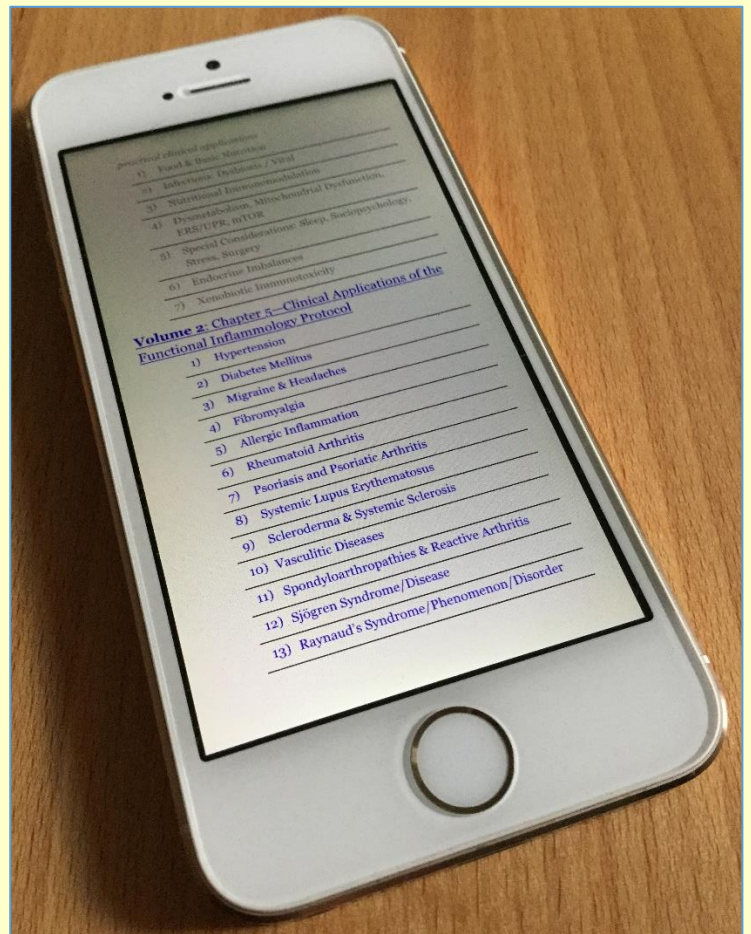
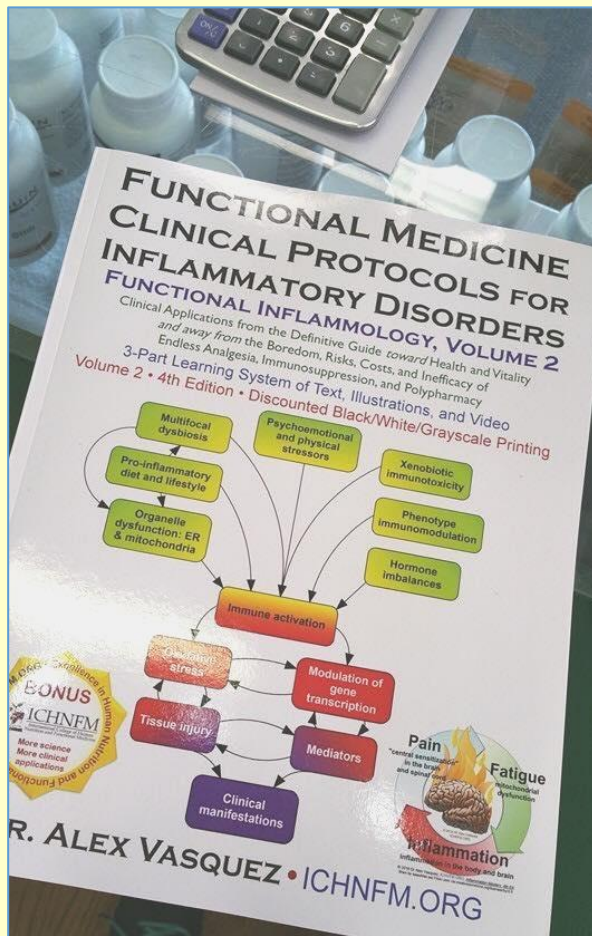
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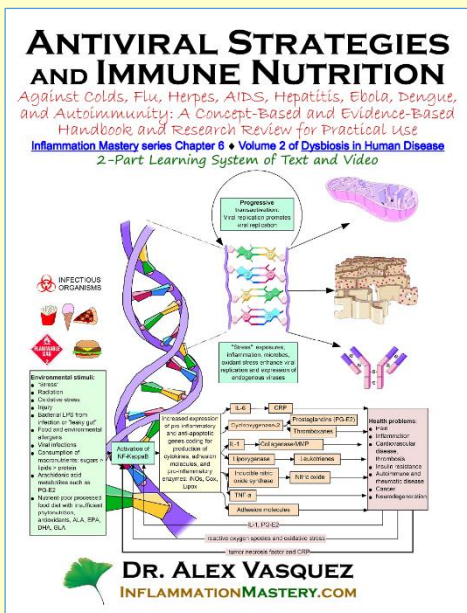
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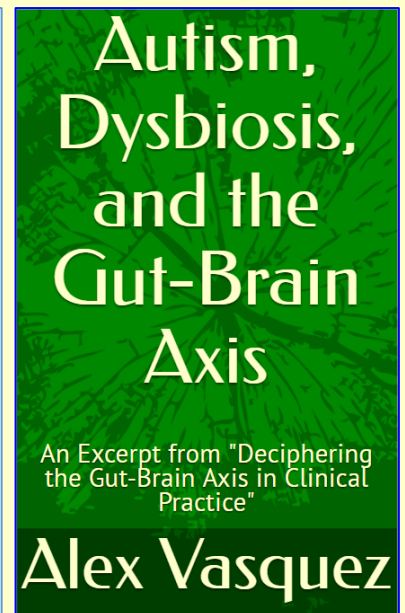
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"The purpose of life is to live it, to taste experience to the utmost, to reach out eagerly and without fear for newer and richer experience."

Eleanor Roosevelt (1884 - 1962)







Please review the Supplemental Files folder to review documents not compiled in the PDF.

**Letter re: ASCEND Study: N Engl J Med 2018 Aug 26  
doi:10.1056/NEJMoa1804989**

Journal:	<i>New England Journal of Medicine</i>
Manuscript ID	Draft
Article Type:	Letter about NEJM Article
Date Submitted by the Author:	n/a
Complete List of Authors:	Vasquez, Alex; ICHNFM
Abstract:	

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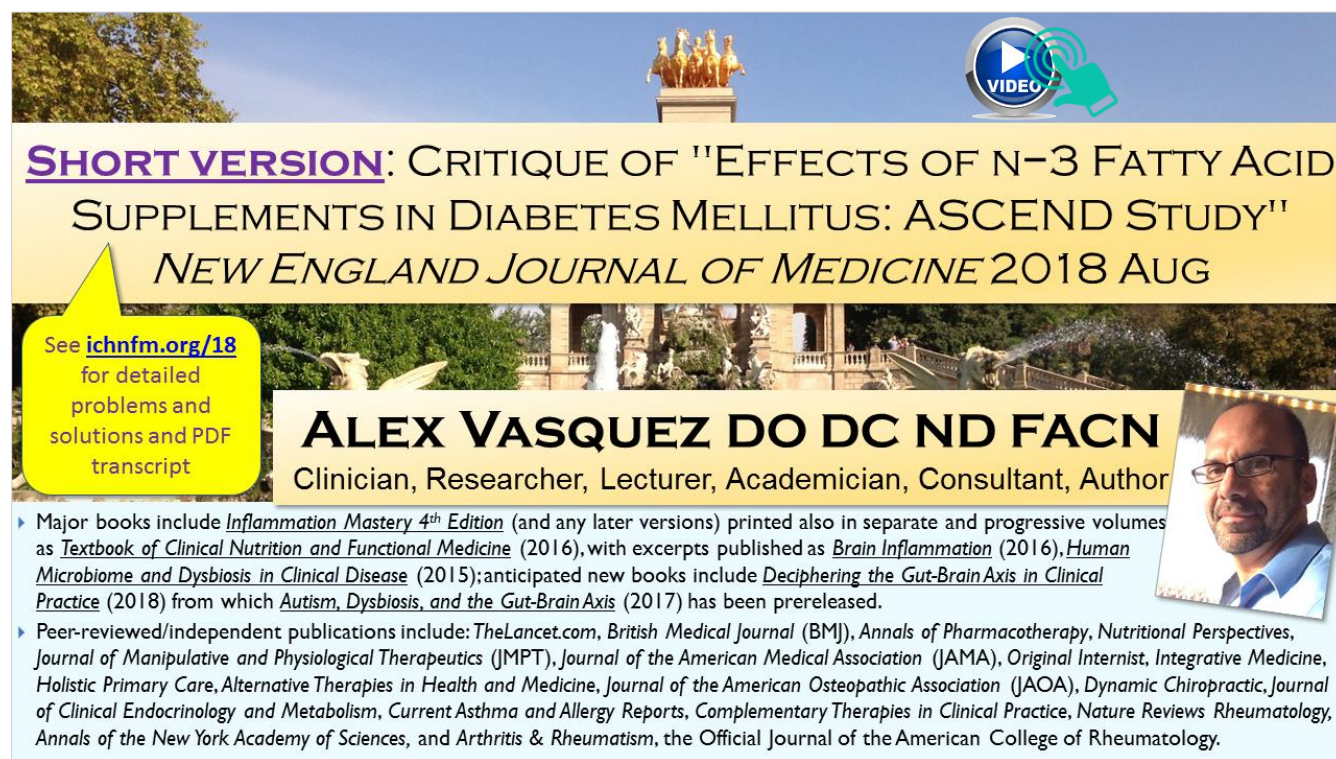
ASCEND showed no advantage of 1,000 mg/d marine n3 fatty acids against equally-dosed naturally occurring olive oil. Olive oil apparently reduces cardiovascular and total mortality<sup>1</sup>, while oleic acid shows direct vascular antiinflammatory, atheroprotective, and antidiabetic benefits.<sup>2</sup> A six-week trial among overweight subjects reported that olive oil 2 g/d was more effective than equidosed fish oil for reducing fasting glucose, HgA1c, hsCRP, and IL6.<sup>3</sup> A six-month trial among rheumatic patients showed that 6 g/d of olive oil provided analgesic and antiinflammatory benefits, leading the authors to conclude, “Olive oil can no longer confidently be used as a placebo control.”<sup>4</sup> Using olive oil as a comparator against other antiinflammatory treatments diminishes the therapeutic differential and apparent benefit for both substances; this results in a type-2 error and underappreciation of therapeutics’ effectiveness. 10% of ASCEND subjects were taking n3 supplementation at baseline, with corresponding omega-3 indexes of 6.6% and 7.1%, remarkably higher than the average 4% typical of Western societies.<sup>5</sup> Pre-treatment plus high baseline status would reduce the clinical response to intervention with n3 and olive oil supplementation.

[1] Hu FB. The Mediterranean diet and mortality—olive oil and beyond. *N Engl J Med.* 2003 Jun 26;348(26):2595-6  
[2] Palomer X, Pizarro-Delgado J, Barroso E, Vázquez-Carrera M. Palmitic and Oleic Acid: The Yin and Yang of Fatty Acids in Type 2 Diabetes Mellitus. *Trends Endocrinol Metab.* 2018 Mar;29(3):178-190. doi: 10.1016/j.tem.2017.11.009  
[3] Gammelmarm A, Madsen T, Varming K, et al. Low-dose fish oil supplementation increases serum adiponectin without affecting inflammatory markers in overweight subjects. *Nutr Res.* 2012 Jan;32(1):15-23. doi: 10.1016/j.nutres.2011.12.007  
[4] Brzeski M, Madhok R, Capell HA. Evening primrose oil in patients with rheumatoid arthritis and side-effects of non-steroidal anti-inflammatory drugs. *Br J Rheumatol.* 1991 Oct;30(5):370-2  
[5] Stark KD, Van Elsland ME, Higgins MR, Weatherford CA, Salem N Jr. Global survey of the omega-3 fatty acids, docosahexaenoic acid and eicosapentaenoic acid in the blood stream of healthy adults. *Prog Lipid Res.* 2016 Jul;63:132-52. doi: 10.1016/j.plipres.2016.05.001

On Mon, Dec 3, 2018 at 10:48 PM NEJM Letter wrote:  
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I am sorry that we will not be able to publish your recent letter to the editor regarding the Armitage article of 18-Oct-2018. The space available for correspondence is very limited, and we must use our judgment to present a representative selection of the material received. Many worthwhile communications must be declined for lack of space. Thank you for your interest in the Journal.  
  
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-- G. -- M.D.  
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Problems with your published article include the following:  
1. Under-dosed fish oil: described below  
2. Inappropriate placebo: The ASCEND study used an inappropriate placebo against underdosed fish oil, ultimately to pave the way for greater acceptance of the late-year launch of "purified prescription fish oil"...how convenient: AHA: Prescription Fish Oil Wins for CV Prevention, November 10, 2018  
<https://www.medpagetoday.com/meetingcoverage/aha/76252>  
3. Bad research in support of a new pharmaceutical drug launch: per above  
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6. Plenty of space: NEJM clearly has 250 words of space to publish these concerns, so only an imbecile would think that the journal "does not have space" to publish my critique. The original article had approximately 6,970 words (per computerized count) so that 250 words in a letter such as mine is less than 4% of the original article.  
  
To see an accurate review of your garbage research, please see my video review: <https://vimeo.com/287650812>  
  
Sincerely,  
Dr Alex (Kennerly) Vasquez  
  
Confidential: Destroy when review is complete.

# Brief Critique of "Effects of n3 Fatty Acid Supplements in Diabetes Mellitus: ASCEND Study"

## *New England Journal of Medicine* 2018 Aug



**SHORT VERSION: CRITIQUE OF "EFFECTS OF N-3 FATTY ACID SUPPLEMENTS IN DIABETES MELLITUS: ASCEND STUDY"**  
*NEW ENGLAND JOURNAL OF MEDICINE* 2018 AUG

See [ichnfm.org/18](http://ichnfm.org/18) for detailed problems and solutions and PDF transcript

**ALEX VASQUEZ DO DC ND FACN**  
 Clinician, Researcher, Lecturer, Academician, Consultant, Author

- Major books include *Inflammation Mastery 4th Edition* (and any later versions) printed also in separate and progressive volumes as *Textbook of Clinical Nutrition and Functional Medicine* (2016), with excerpts published as *Brain Inflammation* (2016), *Human Microbiome and Dysbiosis in Clinical Disease* (2015); anticipated new books include *Deciphering the Gut-Brain Axis in Clinical Practice* (2018) from which *Autism, Dysbiosis, and the Gut-Brain Axis* (2017) has been prereleased.
- Peer-reviewed/independent publications include: *The Lancet.com*, *British Medical Journal* (BMJ), *Annals of Pharmacotherapy*, *Nutritional Perspectives*, *Journal of Manipulative and Physiological Therapeutics* (JMPT), *Journal of the American Medical Association* (JAMA), *Original Internist*, *Integrative Medicine*, *Holistic Primary Care*, *Alternative Therapies in Health and Medicine*, *Journal of the American Osteopathic Association* (JAOA), *Dynamic Chiropractic*, *Journal of Clinical Endocrinology and Metabolism*, *Current Asthma and Allergy Reports*, *Complementary Therapies in Clinical Practice*, *Nature Reviews Rheumatology*, *Annals of the New York Academy of Sciences*, and *Arthritis & Rheumatism*, the Official Journal of the American College of Rheumatology.

The video of this presentation is archived at [ichnfm.org/18](http://ichnfm.org/18), and the transcript in PDF format—which is considered the final and citable version—is archived at [academia.edu/37326521](http://academia.edu/37326521); any corrections or updates will be made to the PDF file. The video contains citations which are not replicated in the PDF document; both the video and the PDF transcript should be reviewed for a complete representation of the information. This version was updated on **September 2, 2018**.


**Introduction:** Hello everyone. This is Dr. Alex Vasquez with the short version of my “Critique of the Effects of Omega 3 Fatty Acids Supplements in Diabetes” recently published as the Ascend Study in the *New England Journal of Medicine*, 2018 August. If you'd like to see the longer and more detailed version of this review, please see [ichnfm.org/18](http://ichnfm.org/18) for my videos from 2018.

**This was *not* a placebo-controlled study:** This is a randomized and *supposedly* “placebo-controlled” trial of 15,000 subjects. The intervention included either omega-3 fatty acids or olive oil—so this was *not a placebo-controlled study*. This was a *comparison* of relatively low-dose EPA and DHA against low-dose olive oil—so again, this is *not* a placebo-controlled study.

This study used *two* active interventions. One was fish oil and the other was olive oil, both of which are notably anti-inflammatory and cardioprotective. As such, the conclusion from this study that fish oil does not benefit diabetic patients is completely invalid. Furthermore, neither of the two active treatments were independently tested for their components and both of the treatments were provided by a drug company that has a financial interest in the failure of these treatments.

The drug company, Mylan, specifically paid 19 of the authors, oversaw the study design and supervised its paid consultants at key meetings, provided the treatment and the active comparator, neither of which again were independently tested, and also makes the main competing drug in this category of cardioprotection, in this case the statin drug, simvastatin.



<p>DR VASQUEZ'S RESEARCH REVIEW</p> <p><b>Today's main article being reviewed</b></p> <p><b>Problems with this publication</b></p> <p>Noting the pattern of bogus research</p> <p>What can be done</p> <p>What clinicians should do</p> <p>Critique of "Effects of n-3 Fatty Acid Supplements in Diabetes Mellitus: ASCEND Study" New England Journal of Medicine 2018 Aug</p>	<p><u><b>Olive oil is not a placebo but is clinically active in humans, starting with low doses: biological mechanisms</b></u></p> <p>▶ <b>Mechanisms of action and biological plausibility:</b> Squalene is also worthy of consideration</p> <p>▶ <b>Oleic acids:</b> May be described as a "conditionally essential nutrient"; component of cell membranes and thus modifies inflammatory mediator production and transmembrane signaling; directly cardiovascular-protective; "interferes directly with the inflammatory response that characterizes early atherogenesis... decreases the expression of several endothelial leukocyte adhesion molecules, among which vascular cell adhesion molecule-1, involved in the selective monocyte recruitment in the arterial intima. Oleic acid also determines a parallel reduction in messenger RNA for this molecule, interfering with the activation of the most important transcription factor controlling endothelial activation, nuclear factor-kappa B. ... oleic acid may contribute to the prevention of atherosclerosis also through a modulation of gene expression for endothelial leukocyte adhesion molecules" per Massaro et al, <i>Cardiologia</i> 1999 Jun</p> <p>▶ <b>Phytochemicals/polyphenols:</b> Ibuprofen-like antiinflammatory activity; notably potent antioxidant and antiinflammatory activity; "antidiabetic effect" per reduction of glycosylated proteins such as HgbA1c and normalization of fasting glucose even at low doses; inhibition of HER2 (erbB-2)-induced malignant transformation (breast cancer); neuroprotective; modulation of gut microbiota is notably relevant for T2DM.</p> <p>For additional context, clinical applications, and disease-specific as well as general protocols, see <b>Inflammation Mastery 4<sup>th</sup> Edition</b> <a href="http://ichnfm.org/im4">ichnfm.org/im4</a> and/or the two-volume set <b>Textbook of Human Nutrition and Functional Medicine</b> from <a href="http://amazon.com/author/alexvasquez">amazon.com/author/alexvasquez</a></p>	<p>ALEX VASQUEZ DO ND DC FACN</p>  <p>Doctor of Osteopathic Medicine (DO— UNTHSC, USA)</p> <p>Doctor of Naturopathic Medicine (ND—Bastyr University, USA)</p> <p>Doctor of Chiropractic (DC—Western States, USA)</p> <p>Overseas Fellow, Royal Society of Medicine</p> <p>Fellow, American College of Nutrition</p> <p>Author of Inflammation Mastery, <a href="http://ICHNFM.ORG/im4">ICHNFM.ORG/im4</a></p>
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This trial is invalidated by the use of an active treatment erroneously described as "placebo." It may be randomized, but it is **not** placebo-controlled.

They started this study in 2005 and at that time they already knew that olive oil was cardioprotective. In fact, that had been published in *The New England Journal of Medicine* in 2003, two years prior to the start of this study. Their claim that they used olive oil as a placebo is completely absurd because olive oil is well known to have anti-inflammatory and cardioprotective benefits, and more specifically, olive oil is known to be one of the most health-promoting and heart-protecting dietary components available.

The cardioprotective benefits of olive oil have been suggested in the research since the 1950s, were more established by 1986 in a key study, and have since been validated clinically and mechanistically.

In my more than 20 years of looking at biomedical research I have never seen a drug company so well entrenched within a study design including supervising key meetings and paying 19 of the authors. In the text of the article the authors describe themselves as "independent investigators" despite the fact that 19 of them received payment from various drug companies intimately involved with the study.

Furthermore, again, the drug company provided both the active treatment and its comparator. Authors were paid by the drug companies, but **these conflicts of interest were not published in the article**, products were not independently tested. The Omega-3 index was tested in 152 subjects; this is less than 1% of the study population, and I found that to be rather weak.

I also noted that their baseline Omega-3 index was abnormally high and their response to the Omega-3 supplementation was also abnormally high considering that they used only one-half of the typically effective dose.

Now let's take a quick look at some examples from the disclosure forms. Again, these were not printed in the article, but they are, of course, highly relevant considering that 19 of the authors were paid by drug companies including Bayer on four different occasions, also Solvay Pharmaceuticals, Abbott Pharmaceuticals and Mylan Pharmaceuticals.

You'll see that this pattern was recurrent among 19 of the authors of this study, and perhaps even more impressive is the fact that this was not published in the article. One has to go to *The New England Journal of Medicine* website to find this documentation.

What can be done about this is that we all have to become better critical thinkers and careful readers so that we can spot these gross errors in biomedical research publications.

What clinicians should do is to continue using fish oil supplements generally at a dose of 1900 milligrams per day if the goal is to optimize the Omega-3 Index to approximately 10%.

Thank you very much for looking at this brief presentation. If you'd like to see the full version, please go to [ichnfm.org/18](http://ichnfm.org/18). Those are the videos I've produced in 2018, and what you'll see there is the complete video as well as a pdf transcript. ☒

**Citation:** Vasquez A. Critique of "Effects of n3 Fatty Acid Supplements in Diabetes Mellitus: ASCEND Study" New England Journal of Medicine 2018 Aug: Video presentation ([ichnfm.org/18](http://ichnfm.org/18)) and official transcript ([academia.edu/37326521](http://academia.edu/37326521)) Date of this revision: September 2, 2018

**About the author:** Dr Vasquez holds three doctoral degrees and has completed hundreds of hours of post-graduate and continuing education in subjects including Obstetrics, Pediatrics, Basic and Advanced Disaster Life Support, Nutrition and Functional Medicine; while in the final year of medical school, Dr Vasquez completed a Pre-Doctoral Research Fellowship in Complementary and Alternative Medicine Research hosted by the US National Institutes of Health (NIH). Dr Vasquez is the author of many textbooks, including the 1200-page [\*Inflammation Mastery, 4th Edition\*](#). (2016) also published (by popular student request) as a two-volume set titled [\*Textbook of Clinical Nutrition and Functional Medicine\*](#). "DrV" has also written approximately 100 letters and articles for professional magazines and medical journals such as *TheLancet.com*, *British Medical Journal (BMJ)*, *Annals of Pharmacotherapy*, *Nutritional Perspectives*, *Journal of Manipulative and Physiological Therapeutics (JMPT)*, *Journal of the American Medical Association (JAMA)*, *Original Internist*, *Integrative Medicine*, *Holistic Primary Care*, *Alternative Therapies in Health and Medicine*, *Journal of the American Osteopathic Association (JAOA)*, *Dynamic Chiropractic*, *Journal of Clinical Endocrinology and Metabolism*, *Current Asthma and Allergy Reports*, *Complementary Therapies in Clinical Practice*, *Nature Reviews Rheumatology*, *Annals of the New York Academy of Sciences*, and *Arthritis & Rheumatism*, the Official Journal of the American College of Rheumatology. Dr Vasquez lectures internationally to healthcare professionals and has a consulting practice and service for doctors and patients. Having served on the Review Boards for *Journal of Pain Research*, *Autoimmune Diseases*, *PLOS One*, *Alternative Therapies in Health and Medicine*, *Neuropeptides*, *International Journal of Clinical Medicine*, *Journal of Inflammation Research* (all PubMed/Medline indexed), *Integrated Blood Pressure Control*, *Journal of Biological Physics and Chemistry*, and *Journal of Naturopathic Medicine* and as the founding Editor of *Naturopathy Digest*, Dr Vasquez is currently the Editor of *International Journal of Human Nutrition and Functional Medicine* and the Director for International Conference on Human Nutrition and Functional Medicine. Dr Vasquez has also served as a consultant researcher and lecturer for Biotics Research Corporation.

**Contextualizing resource**—same information in different formats and contexts:

- *Inflammation Mastery, 4th Edition* <https://www.amazon.com/dp/B01KMZZLAQ/> and
- *Textbook of Clinical Nutrition and Functional Medicine, vol. 1: Essential Knowledge for Safe Action and Effective Treatment* <https://www.amazon.com/dp/B01JDIOHR6/>



See video at <http://www.ichnfm.org/18>





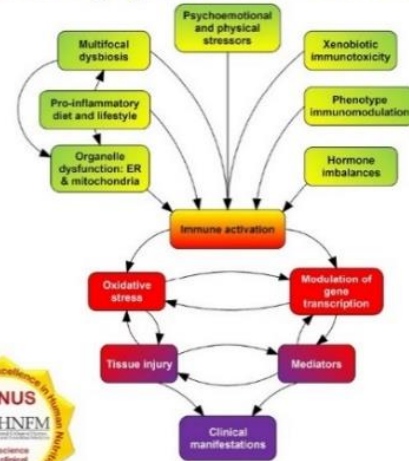
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### Introductory videos:

- Video introduction to books: <http://www.ichnfm.org/im4> and other videos: <http://www.ichnfm.org/18>
- Conference presentation—introducing the clinical protocol: <http://www.ichnfm.org/video-funct-inflam-1>

### Persistent inadequacies in nutrition education/training among physicians

**Introduction:** Despite the acknowledged importance of diet in the prevention of obesity, diabetes, hypertension and other components of cardiometabolic syndrome/disease, physicians are consistently and systematically untrained in nutrition. A few exemplary citations are summarized per the following:

- What do resident physicians know about nutrition? (J Am Coll Nutr 2008 Apr<sup>29</sup>): "OBJECTIVE: Despite the increased emphasis on obesity and diet-related diseases, nutrition education remains lacking in many internal medicine training programs. We evaluated the attitudes, self-perceived proficiency, and knowledge related to clinical nutrition among a cohort of internal medicine interns. METHODS: Nutrition attitudes and self-perceived proficiency were measured using previously validated questionnaires. Knowledge was assessed with a multiple-choice quiz. ... RESULTS: Of the 114 participants, 61 (54%) completed the survey. Although 77% agreed that nutrition assessment should be included in routine primary care visits, and 94% agreed that it was their obligation to discuss nutrition with patients, only 14% felt physicians were adequately trained to provide nutrition counseling. ... CONCLUSIONS: Internal medicine interns' perceive nutrition counseling as a priority, but lack the confidence and knowledge to effectively provide adequate nutrition education." These are impressive results showing that internal medicine doctors—specialists who commonly deal with diabetes, hypertension, obesity, and metabolic syndrome—do not have competence in nutrition, even by weak and basic standards.
- Relevance of clinical nutrition education and role models to the practice of medicine (Eur J Clin Nutr. 1999 May<sup>30</sup>): "Yet, despite the prevalence of nutritional disorders in clinical medicine and increasing scientific evidence on the significance of dietary modification to disease prevention, present day practitioners of medicine are typically untrained in the relationship of diet to health and disease."
- How much do gastroenterology fellows know about nutrition? (J Clin Gastroenterol. 2009 Jul<sup>31</sup>): "The mean total test score was 50.04%. ...CONCLUSIONS: Gastroenterology fellows think their knowledge of nutrition is suboptimal; objective evaluation of nutrition knowledge in this cohort confirmed this belief. A formal component of nutrition education could be developed in the context of GI fellowship education and continuing medical education as necessary."

**In sum:** The data consistently demonstrate that healthcare providers at the doctorate level are untrained in nutrition when assessed by rather simple standards; their knowledge of functional nutrition at the level of clinical intervention in the treatment of serious disease would reasonably be expected to be approximately zero. Thus, given that doctors are trained neither in musculoskeletal systems and that related disorders represent no less than 20% of general practice) nor nutrition (despite the fact that all patients eat food and that such dietary habits (and/or the use of nutritional interventions) impact nearly all known diseases in the known universe), one might wonder as to the cause and perpetuation of this *systematically imposed ignorance* on such topics of major importance. Consistent faults in medical education are not accidental.

#### Dumbing Us Down: The Hidden Curriculum of Educational Systems

"Look again at the seven lessons of school teaching: confusion, class position, indifference, emotional and intellectual dependency, conditional self-esteem, and surveillance. All of these lessons are prime training for permanent underclasses, people deprived forever of finding the center of their own special genius."

Such a curriculum produces physical, moral, and intellectual paralysis, and no curriculum of content will be sufficient to reverse its hideous effects. ... Schools teach exactly what they are intended to teach and they do it well."

Gatto JT. *Dumbing Us Down: The Hidden Curriculum of Compulsory Schooling*, p. 16

### Adverse effects of nonsteroidal anti-inflammatory drugs (NSAIDs), COX-2 inhibitors (coxibs)

**Introduction:** Nonsteroidal anti-inflammatory drugs (NSAIDs) have many common and serious adverse effects, including the promotion of joint destruction. Paradoxically, these drugs *cause* or *exacerbate* the very symptoms and disease they are supposed to treat: joint pain and destruction. In a tragic exemplification of Orwellian newspeak<sup>32</sup>,

<sup>29</sup> Vetter et al. What do resident physicians know about nutrition? An evaluation of attitudes, self-perceived proficiency and knowledge. *J Am Coll Nutr*. 2008 Apr;27(2):287-98

<sup>30</sup> Halsted CH. The relevance of clinical nutrition education and role models to the practice of medicine. *Eur J Clin Nutr*. 1999 May;53 Suppl 2:S29-34

<sup>31</sup> Raman M, Violato C, Coderre S. How much do gastroenterology fellows know about nutrition? *J Clin Gastroenterol*. 2009 Jul;43(6):559-64

<sup>32</sup> Orwell G. 1984. Harcourt Brace Jovanovich: 1949. "Newspeak" is defined by the Merriam-Webster Dictionary (m-w.com) as "propagandistic language marked by euphemism, circumlocution, and the inversion of customary meanings" and as "a language designed to diminish the range of thought," in the novel 1984 (1949) by George Orwell.



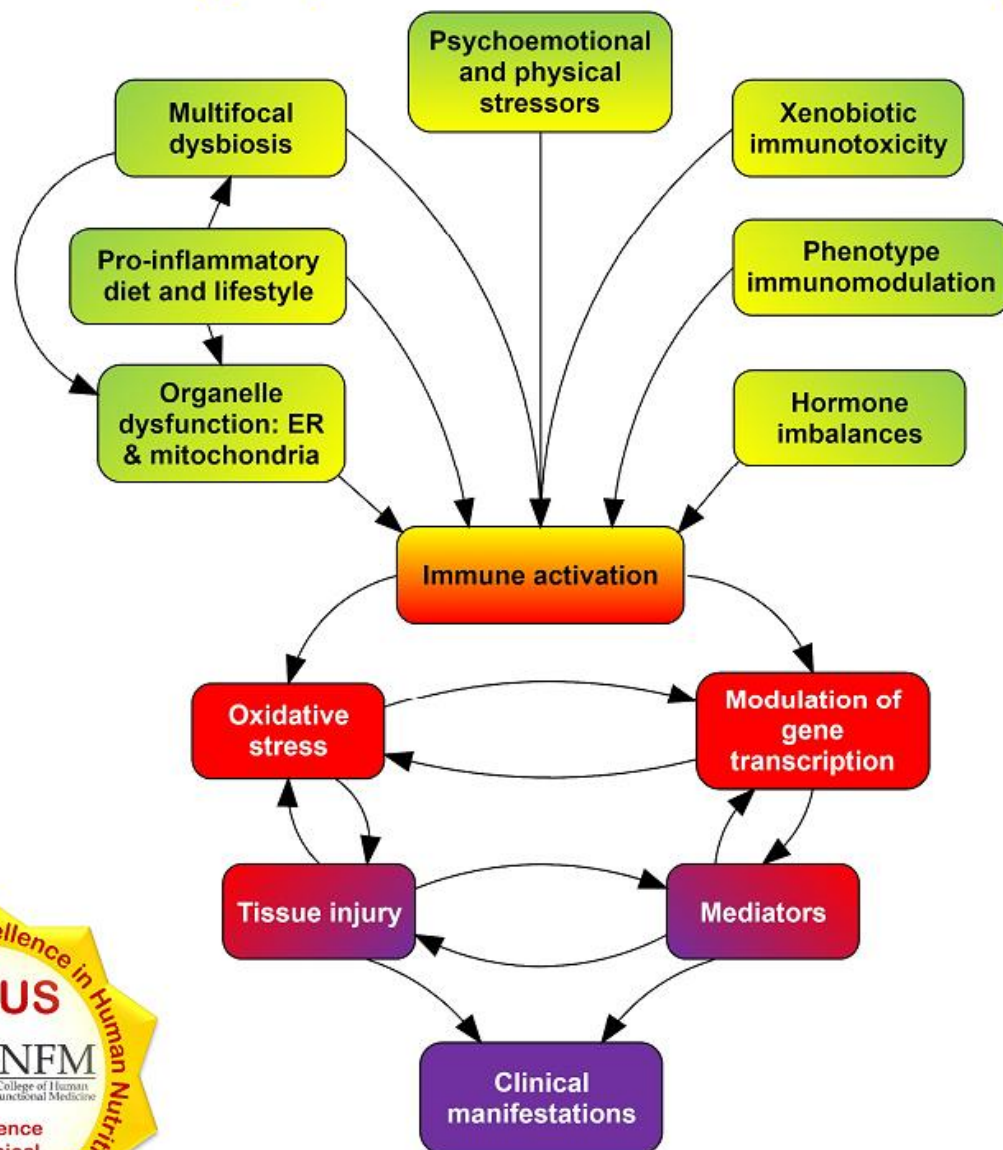
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As of 2019 and for the foreseeable future, the most current versions of all major patient management and clinical treatment protocols are published in *Inflammation Mastery, 4<sup>th</sup> Edition* as a single volume of 1,182 pages available in full-color print at discounted pricing directly from ICHNFM from <https://www.ichnfm.org/im4>, while the digital formats are available via several different platforms, including Amazon's Kindle (free) software, Barnes and Noble's Nook, Apple iBook, etc as hyperlinked below. Per popular request by students who were studying (as a required textbook) only one section at a time, "IM4" was also published in two easier-to-carry separate volumes under the name *Textbook of Clinical Nutrition and Functional Medicine*, which contain chapters 1-4 (pages 1-712+index) and 5 (713-1154+index), respectively. Video access is included with IM4 and TCNFM,1+2.

Availability in print and digital formats (examples):

- <https://www.ichnfm.org/im4>
- <https://www.amazon.com/Inflammation-Mastery-4th-Immunosuppression-Polypharmacy-ebook/dp/B01KMZZLAQ>
- <https://books.apple.com/us/author/alex-vasquez/id1139497284>
- <https://www.barnesandnoble.com/w/inflammation-mastery-4th-edition-alex-vasquez/1123259586?ean=9780990620464>

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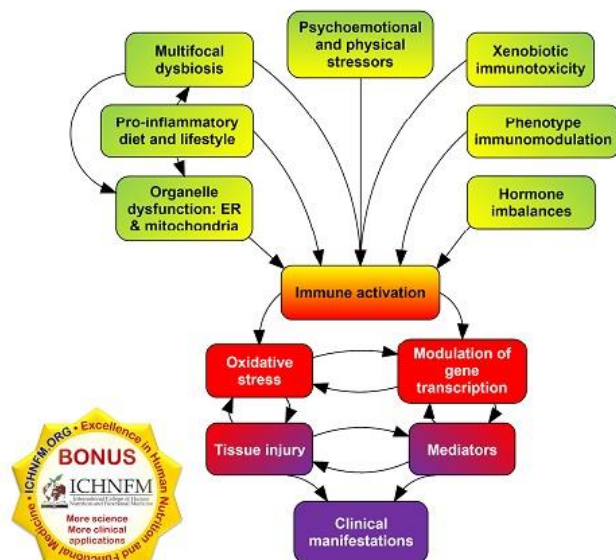
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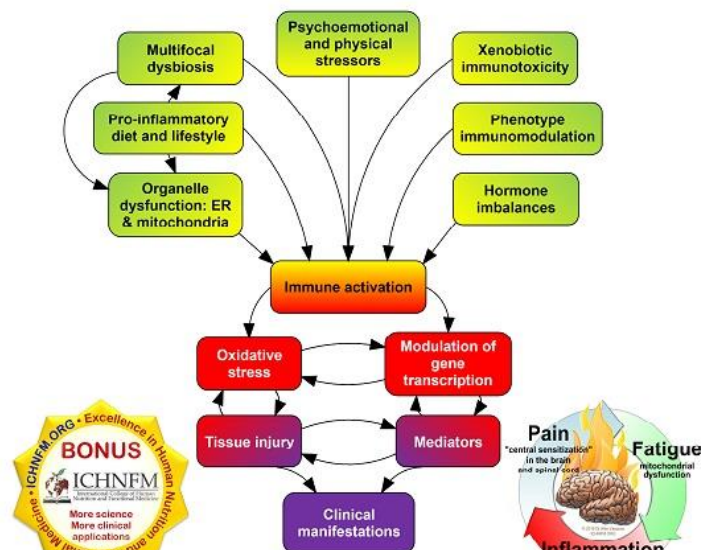
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1.	<b>Patient Assessments, Laboratory Interpretation, Clinical Concepts, Patient Management, Practice Management and Risk Reduction:</b> <i>This chapter introduces/reviews/updates patient assessments, laboratory interpretation, musculoskeletal emergencies, healthcare paradigms; the common and important conditions hemochromatosis and hypothyroidism are also included in this chapter since these need to be considered on a frequent basis in clinical practice</i>	1
2.	<b>Wellness Promotion &amp; Re-Establishing the Foundation for Health:</b> <i>Reviewed here are diet, lifestyle, psychosocial health, and—given the pervasiveness of persistent organic pollutants and their increasingly recognized clinical importance—an introduction to environmental medicine</i>	187
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practical clinical applications

- 1) Food & Basic Nutrition
- 2) Infections: Dysbiosis / Viral
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- 4) Dysmetabolism, Mitochondrial Dysfunction, ERS/UPR, mTOR
- 5) Special Considerations: Sleep, Sociopsychology, Stress, Surgery
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- 2) Diabetes Mellitus
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- 4) Fibromyalgia
- 5) Allergic Inflammation
- 6) Rheumatoid Arthritis
- 7) Psoriasis and Psoriatic Arthritis
- 8) Systemic Lupus Erythematosus
- 9) Scleroderma & Systemic Sclerosis
- 10) Vasculitic Diseases
- 11) Spondyloarthropathies & Reactive Arthritis
- 12) Sjögren Syndrome/Disease
- 13) Raynaud's Syndrome/Phenomenon/Disorder





# Concerns About The Integrity of The Scientific Research Process—Focus On Recent Negative Publications Regarding Nutrition, Multivitamins, Fish Oil And Cardiovascular Disease



Alex Vasquez, DC, ND, DO; Joseph Pizzorno, ND, Editor in Chief

## Abstract

The next step in reestablishing credibility seems to us honesty and recognizing we all share a common goal of the health and wellness of the human community and the planet. Everyone agrees that the current healthcare system, despite its many incredible successes, is also

showing its limitations and is no longer sustainable. We believe the solution starts with us the researchers and editors. A good first step might be formally recognizing the errors and showing how we can and *intend* to get better.

Evidence-based medicine—by definition—requires objective, reliable and accurate research and reviews from which to make the best decisions in patient care and public policy. The causes of inaccurate information, ranging from presumably innocent mistakes all the way to apparently intentional fraud, affect all scientific and biomedical disciplines.<sup>1</sup> While these accidental and intentional errors can derail our understanding of diseases and impact tens of thousands of affected patients, such inaccuracies in the field of nutrition are worldwide.<sup>2</sup> While a specific disease human population nutrition research particularly concerning nutrition research healthcare professions nutrition. Clinical vast majority of medical training programs are obviously in gastroenterology<sup>7</sup> training in clinical proclaims itself as including the entire territory of clinical nutrition.<sup>10</sup> A major and serious problem arises when unskilled and invalid research is published by authors (including nonphysician journalists<sup>11</sup>) in major journals which mischaracterizes the validity of nutrition interventions (e.g., essentially always concluding that nutritional interventions are inefficacious

or potentially hazardous) and then such research is used politically and in the media to disparage, restrict and regulate practitioners and nutrition supplement industry<sup>12</sup> to the detriment of human health.

Several factors disrupting the integrity of nutrition research are commonly found in studies published by “elite” universities in “top-tier” journals, which are then republished and distributed as “headlining news” in newspapers, magazines, and television via which they ent policy and ons of people. examples of ulations, lists sed solutions. pendent upon stigative and ts of clinical rovements are ignorance in

**PDF articles:** Full-text archives of the author’s articles are available per the following:

- <https://ichnfm.academia.edu/AlexVasquez>
- <https://www.ichnfm.org/public>
- VIDEO: BRIEF Critique of “Effects of n–3 Fatty Acid Supplements in Diabetes Mellitus: ASCEND Study” <https://vimeo.com/287650812>
- VIDEO: Bad Science in Medical Nutrition: Politics of Fish Oil <https://vimeo.com/314997927>

review recent examples of questionable or inaccurate publications related to nutrition. Perceived shortcomings are documented with both citations here and links to more detailed and authoritative reviews and video presentations. In some instances, speculations regarding the cause and consequences of identified errors are provided.

## Editorial

### Misrepresentations of Clinical Nutrition in Mainstream Medical Media: Growing Importance of Legitimate Expertise in Independent Peer-Reviewed Publications - Part 1

#### 2018 As a Milestone in the Post-Truth Era

Among the various topics that have either interested or fascinated me throughout my youth and well into my adult years, Nutrition has certainly reigned supreme. My personal routine has been to read as much as reasonably and practically possible on the topic, while not doing so to the exclusion of other topics in biomedicine, psychosociology and philosophy. Thus, with roughly 30 years of experience in reading books and primary research in the field of Nutrition, I could not help but notice the radical departures that occurred in 2018 from the previous norms to which I had grown accustomed.

Of course, 2018 was not the first year during which “bad research” was published in mainstream medical journals and then replicated throughout the echo chamber of mass media; one could observe this periodically occurring throughout the past 50 years, starting not at least with the demonization of dietary cholesterol and the glorification of processed foods, especially refined grains and so-called vegetable oils. But in 2018 what many of us observed was not simply poorly performed research but, in some cases, radical departures from any attempt to present descriptions that could be considered “reasonable” by previous standard.<sup>1</sup> Especially related to the topic of nutrition, mainstream medical journals and the media which parrots their conclusions have begun to present overt misrepresentations of Nutrition with regard for science, logic, biomedical history and

One has to be aware of a few key ironies that characterize mainstream medical discussions of nutrition: that 1) medical physicians receive essentially no training in clinical nutrition in their graduate school education and in their post-graduate residency training<sup>2</sup>, 2) medical physicians and organizations publish “research” and commentaries (both of which commonly conclude that nutritional interventions are inefficacious or unsafe), despite their lack of formal education on the topic, and then 3) main-

stream medical voices consistently call for “regulating the nutrition supplement industry” despite their lack of training on the topic and because of negative conclusions based on their own poorly conducted research and self-serving conclusions. As such, not only are the map-makers blind, but they mislead their blind followers, and then both groups promote themselves as expert cartographers and guides when advising the public on an area that none of them have studied or understood. We should have no surprise whatsoever when the “medical community” publishes poorly conducted and self-serving “research” on the topic of nutrition, to reach their desired conclusion that nutrition is unsafe and inefficacious, and that the profitable market needs to be managed of course by the selfsame “medical community” that is never received a decent 15 minutes on the topic of therapeutic nutrition. Pervasive and persistent ignorance on the topic of nutrition among medical physicians must be understood as intentional and strategic, because otherwise this problem would have been solved 30 years ago when it was first discussed during what was called at the time the “golden age of nutrition.”<sup>3</sup> The easiest way to manipulate people and to keep them in a perpetual state of confusion, ineffectiveness, and dependency is to

**PDF articles:** Full-text archives of the author’s articles are available per the following:

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when pondering the probable future of intellectual integrity and the products of education.



# Mitochondrial Medicine Arrives to Prime Time in Clinical Care: Nutritional Biochemistry and Mitochondrial Hyperpermeability (“Leaky Mitochondria”) Meet Disease Pathogenesis and Clinical Interventions

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## MITOCHONDRIAL MEDICINE ARRIVES TO GENERAL PRACTICE AND ROUTINE PATIENT CARE

Mitochondrial disorders were once relegated to “orphan” status as topics for small paragraphs in pathology textbooks and the hospital-based practices of subspecialists. With the increasing appreciation of the high frequency and ease of treatment of mitochondrial dysfunction, this common cause and consequence of many conditions seen in both primary and specialty care deserves the attention of all practicing clinicians.

We all know that mitochondria are the intracellular organelles responsible for the production of the currency of cellular energy in the form of the molecule adenosine triphosphate (ATP); by this time, contemporary clinicians should be developing an awareness of the other roles that mitochondria play in (patho)physiology and clinical practice. Beyond being simple organelles that make ATP, mitochondria

considered on a routine basis in clinical practice. *Mitochondrial medicine* is no longer an orphan topic, nor is it a superfluous consideration relegated to boutique practices. Mitochondrial medicine is ready for prime time—now—both in the general practice of primary care as well as in specialty and subspecialty medicine. What I describe here as the “new” mitochondrial medicine is the application of assessments and treatments to routine clinical practice primarily for the treatment of secondary/acquired forms of mitochondrial impairment that contribute to common conditions such as fatigue, depression, fibromyalgia, diabetes mellitus, hypertension, neuropsychiatric and neurodegenerative conditions, and other inflammatory and dysmetabolic conditions such as allergy and autoimmunity.

## BEYOND BIOCHEMISTRY

Structure and function are of course intimately related and must be appreciated before clinical implications can be understood and interventions thereafter applied with practical precision. The 4 main structures and spaces of the mitochondria are (1) intramitochondrial matrix—the innermost/interior aspect of the mitochondria containing various proteins, enzymes of the Krebs cycle, and mitochondrial DNA; (2) inner membrane—the largely impermeable lipid-rich convoluted/invaginated membrane that envelopes and defines the matrix and which is the structural home of many enzymes, transport systems, and important structures such as cardiolipin and the electron

play clinical inflammatory disease such as disorders such as stated during Nutrition and September 2014, mitochondrial

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mitochondrial dysfunction to clinical diseases must be

ce—contains kinase and comparatively (n) and—like h active and that need to to appreciate the highest importance; just as we have come to appreciate the

## Editorial

### Orthomolecular Medicine, Catalytic Creativity, and the Psychosocial Ecosystem

#### Transitioning From One Year to the Next

Various cultures since time immemorial have marked and celebrated the winter solstice with celebrations, meals with friends and family, and time away from work; transitioning from one calendar year to the next has given people pause and a moment to reflect on the events that happened in the past year and what might be anticipated in the next. Reflection with anticipation along with the realization that the future is somewhat malleable inclines people to imagine how the future might be shaped by the exertion of some modicum of creativity and effort. Any realistic conception of how we might improve the near future must segue from our recent past; we must have an awareness of what is going on around us as we look toward the future to visualize ourselves living within it and also acting upon it. What is going on in the world and how might I act upon that trend and flow in order to improve both its transition and its destination? What should each of us do on a personal level to (in the words of Mahatma Gandhi) be, embody, and materialize the change(s) that we want to see in the world?

#### Salutation and Introduction From the Journal's New Editor

Over the past few years I have reflected on several occasions how much I enjoy editing, and so I was correspondingly surprised and pleased when I was offered the opportunity to be the next Editor for the *Journal of Orthomolecular Medicine*. I began studying nutrition and orthomolecular concepts in my teen years and more diligently as I entered graduate school in the early 1990s. I read the "book that I read" *Your Nerves* (1975) by Jonathan V. Wright, MD, of whom would later be a professor at the University of California, San Diego. By the mid-1990s, Jeffrey Bland PhD had introduced me to orthomolecular medicine, which I practiced for personal<sup>3</sup> reasons. By this time my own personal library contained several hundred books, mostly dedicated to nutrition and health with another large section on philosophy and psychology. In 1994, I joined the Review Staff of the *Journal*

of *Naturopathic Medicine*, and I started publishing nutrition articles, perhaps most of which might be seen as practice in preparation of an important letter published in 1996 by the American College of Rheumatology in their journal *Arthritis and Rheumatism*. Since those early years and during the course of three doctorate degrees and teaching thousands of students/attendees internationally, I have reviewed for<sup>4</sup> and published in<sup>5</sup> a wide range of refereed journals in addition to publishing commissioned books, chapters, and independent publications and videos. Being an author and reviewer for many different publications—along with my experiences teaching internationally, treating patients in various settings, designing and directing academic programs, and producing educational videos—has given me a wide range of experiences and insights that I hope to bring to the benefit of the *Journal of Orthomolecular Medicine*.

#### We Must Work Together if We Are Going to Succeed

I have to start this conversation with a few hopes, assumptions, and beliefs, namely that you (the reader) and I (the author and new Editor) have a few things in common. On a professional level, by virtue of the fact that you are reading this essay, I will assume that you are interested or actively engaged in healthcare, medicine, nutrition, research and/or public health. I might also imagine that some smaller percentage of our new and established readers are perhaps less inclined toward the mechanisms and more drawn to the *Journal of Orthomolecular Medicine* for its potential humanistic insights and social contributions; we can reasonably assume that competent healthcare (and adequate nutrition) are basic human rights. I will admit a counterargument to my assertions, they are more to the point, my assertions are regardless of personal position, we share some common ground. The following:

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• We each want to receive and deliver the best healthcare possible: If we have a problem, then we each want the best possible solution. Efficiency of time or money is not the top priority when we are seeking solutions





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# CME

CONTINUING MEDICAL EDUCATION

## THE CLINICAL IMPORTANCE OF VITAMIN D (CHOLECALCIFEROL): A PARADIGM SHIFT WITH IMPLICATIONS FOR ALL HEALTHCARE PROVIDERS

Alex Vasquez, DC, ND, Gilbert Manso, MD, John Cannell, MD

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tice for more than 35 years, he is Board Certified in Family Practice and is Associate Professor of Family Medicine at University of Texas Medical School in Houston. **John Cannell, MD**, is a medical physician practicing in Atascadero, California, and is president of the Vitamin D Council (Cholecalciferol-Council.com), a non-profit, tax-exempt organization working to promote awareness of the manifold adverse effects of vitamin D deficiency.

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### OBJECTIVES

Upon completion of this article, participants should be able to do the following:

1. Appreciate and identify the manifold clinical presentations and consequences of vitamin D deficiency
2. Identify patient groups that are predisposed to vitamin D hypersensitivity
3. Know how to implement proper doses and with

While we are all familiar with the important role of vitamin D in calcium absorption and bone metabolism, many doctors and patients are not aware of the recent research on vitamin D and the widening range of therapeutic applications available for cholecalciferol, which can be classified as both a vitamin and a pro-hormone. Additionally, we also now realize that the Food and Nutrition Board's previously defined Upper Limit (UL) for safe intake at 2,000 IU/day was set far too low and that the physiologic requirement for vitamin D in adults may be as high as 5,000 IU/day, which is less than half of the >10,000 IU that can be produced endogenously with full-body sun exposure.<sup>1,2</sup> With the discovery of vitamin D receptors in tissues other than the gut and bone—especially the brain, breast, prostate and lymphocytes—and the recent research suggesting

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